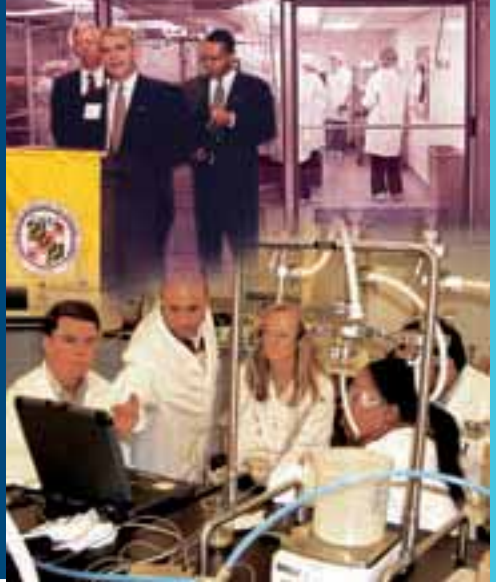
Science • Technology • Quality • Regulatory • Community

PDA Letter

Volume XLIII • Issue #5

www.pda.org/pdaletter

May 2007



In This Issue…

Happy 10th Anniversary TRI!

The PDA Training and Research Institute turns 10 this month, marking a decade of quality training and education.

And, PDA TRI will continue to provide hands-on, intensive, job-focused training in 2007!

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

TRI Celebrates 10th Anniversary

Gail Sherman, PDA

In this issue of the *PDA Letter,* we celebrate the 10th anniversary of the PDA Training and Research Institute (TRI), with articles focusing on TRI's original goals, what it has become and its future direction. You will hear from former TRI Directors and staff who were instrumental in its development more than 10 years ago. Selected faculty members reflect on their years of contributing to the growth of TRI's preeminent training programs for sterile processing. Current PDA staff members provide their perspectives of TRI lecture training and laboratory programs. We also thank our vendors and sponsors, without whom we could not offer these training programs.

As TRI moves into its 11th year, I believe it is true to say that TRI has achieved what the PDA Board of Directors thought it would when they made the very risky decision to invest in a unique educational facility and to create a hands-on training program that no one in the world had at the time. Certainly, even today, it is difficult to find comparable opportunities for learning. For example, even though aseptic processing training programs are now offered by several academic institutions, they are markedly different from TRI's flagship course. The Aseptic Processing Training course has the exclusive capability of simulating the manufacturing experience and providing students, already in the industry, with the base knowledge needed to understand and manage these processes.

In his final article as Director of TRI in the December 1999 issue of the *PDA Letter* (reprinted in this issue, page 30), **Mike Korczynski,** PhD, provided his perspective on the evolution of TRI. I find that our thoughts aren't so very far apart. For that matter, the Institute itself isn't all that different, especially now as we move into the next phase of educating our members and the industry at large. Mike wrote in 1997 about the "myriad of issues associated with the build out and how the facility must be ready to open on April 1 as there is a course scheduled that week." Today, I almost feel a sense of déjà vu as we build our new facility in Bethesda, Md. We plan to move in early July and intend to offer the first courses there in August. How little things really change over time!

There are always questions that one ponders upon looking at the success of a new product, and I'm sure there have been questions over the past 10 years about the value of PDA's initial investment in TRI. After some ups and downs, I believe we have tremendous opportunity to truly make this the premier training facility in the world in our areas of core competencies: sterile processing,

continued on page 18

2007

PDA/FDA Joint Regulatory Conference

Register early and save

Evolution of the Global Regulatory Environment: *A Practical Approach to Change*

September 24-28, 2007
Washington, D.C.

Conference	|	September 24-26
Exhibition	|	September 24-25
Training Courses	|	September 27-28

www.pda.org/pdafda2007

Are you looking for practical guidance on how to address evolving regulatory expectations using a scientific and risk-based approach in the global marketplace?

Get the information you need to meet these expectations at the 2007 PDA/FDA Joint Regulatory Conference!

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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Do you want to take control of your Environmental Monitoring operation while improving quality, increasing productivity, reducing costs, and ensuring regulatory compliance?

Moda's Environmental Monitoring solution, *Moda-EM*™, helps pharmaceutical Quality Control operations streamline the labor intensive and error-prone process of sampling, testing and monitoring the manufacturing environment.

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Table of Contents

Cover art: Ten years after Past PDA President Ed Fry celebrated TRI's inauguration, the Institute continues to be a leader in hands-on pharmaceutical education and training.

Coming Next Month
Hot Topics in Manufacturing

PDA Parenteral Drug Association

*Connecting People, Science and Regulation*SM

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

For more information, please contact:

Lu Castro, Senior Coordinator
Programs and Registration Services
Email: castro@pda.org
Tel: +1 (301) 656-5900 ext. 122

ATTENTION EXHIBITORS

PDA is seeking vendors who provide excellent products/services in support of this conference.
Space is limited and is available on a first come, first served basis.
To reserve your space, please contact Cindy Tabb at tabb@pda.org or +1 (301) 656-5900 ext. 222.

Editor's Message

It is exciting to be celebrating another anniversary. Last year was PDA's 60th, and this year we celebrate TRI's first decade!

This month's feature articles capture all you need to know about TRI—its past, its present and its very promising future. We hope you enjoy them all. To accommodate these articles, we had to hold the Interest Groups and Chapter Contacts pages.

I'm also extremely excited to introduce the Science & Technology Snapshot (pages 10–11). PDA Sr. VP **Rich Levy** devised the concept and writes an excellent introduction to what will become a regular feature in the Science & Technology section. We hope to receive feedback from readers on the Snapshot. We are considering adding a Quality & Regulatory Affairs Snapshot in the future.

After a three-issue hiatus, the SciTech Discussions—a reader favorite—reappear with a thought-provoking dialogue on global GMPs. Interested readers can link to the discussions at www.pda.org/pdaletter and keep the thread going. Next month's SciTech Discussions will capture several threads on steam sterilization.

I also want to highlight contributions from the new PDA membership team. **Hassana Howe, Ta-Méla Jeffries** and **Emily Alesantrino** supply articles that convey pertinent information to our members and chapters.

Letter to the Editor

I am writing to thank you for the excellent article about PIC/S in the March issue of the *PDA Letter* [vol. XLIII, issue #3, cover] and for acknowledging the importance of PIC/S. I was involved in the work of PIC/S over some ten years, and I think that Jim Lyda did capture the essence and atmosphere of the work carried out by the organizations.

The only thing I would expand on is around membership. As is mentioned in the article: *"Before a country's regulatory authority can become a member of the PIC/S, a detailed assessment is undertaken to determine whether the authority has the infrastructure and competence necessary to apply an inspection system comparable to that of current PIC/S members."* So most regulatory authorities will have to add, amend or correct their quality systems and/or legislation before being approved as a member of PIC/S. Only the regulatory authority concerned can decide on how fast these changes will be made. If changes to legislation are necessary, it may take considerable time before membership is approved. There are examples in the past, where major changes to the legislation have been made with impressive speed. One such example is Malaysia.

Regards,
Lilian Hamilton, AstraZeneca
Chair of PIC/S 2002-03

The PDA Letter is published 10 times per year, exclusively for PDA members. Subscriptions are not available. Articles in the PDA Letter may be reproduced with permission—contact the PDA Letter Editor for details.

***PDA Letter* Editor**
Walter Morris
+1 (301) 656-5900, ext. 148
morris@pda.org

Assistant Editor
Lindsay Donofrio
donofrio@pda.org

Advertising
Cindy Tabb, *Sales*
+1 (301) 656-5900, ext. 222
tabb@pda.org

PDA Global Headquarters
Bethesda Towers
4350 East West Hwy., Suite 200
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
Email: info@pda.org
www.pda.org

PDA Europe
Adalbertstr. 9
16548 Glienicke/ Berlin
Germany
Tel: +49 33056 43 6879
Fax: +49 33056 43 6884
Email: petzholdt@pda.org

PDA Training and Research Institute
c/o UMBC Technology Center
1450 S. Rolling Road
Baltimore, MD 21227 USA
Tel: +1 (410) 455-5800
Fax: +1 (410) 455-5802
Email: info-tri@pda.org

PDA Parenteral Drug Association

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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

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Tel: +1 (301) 656-5900 ext. 122

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Space is limited and is available on a first come, first served basis.
To reserve your space, please contact Cindy Tabb at tabb@pda.org or +1 (301) 656-5900 ext. 222.

Strengthening PDA Globally and Locally

Vincent Anicetti, Genentech, Inc.

CHAIR'S MESSAGE

Vincent Anicetti, Gementech, Inc.

It's a pleasure to tell you of the progress PDA has made on two of the key goals that the Board of Directors outlined a year ago. While PDA's purpose is science and education, it is also important that we are a successful, nonprofit business. Managing our finances to maintain a sustainable nonprofit business is a necessary foundation for our ability to advance pharmaceutical science.

One of the goals we established a year ago was to increase our operating reserves as an organization. PDA does not exist to make money; we are a nonprofit organization. However, it is good sense to operate in the black most of the time and to have a safety net for the times you don't. Operating reserves are that safety net, and most nonprofits are advised to carry six to nine months of reserves for a rainy day. I am very pleased to let you know we have achieved this and developed a solid business plan to maintain it. I'd like to thank the hard work of PDA President **Bob Myers** and the entire PDA staff in achieving this goal. It's extremely important to the organization for two reasons. First, if you are constantly thinking about the bottom line, you will not look very far into the future. Second, it allows us to take some risks with programs that have great scientific content but may not draw a large audience. I want PDA to be able to pursue its activities based on science and need, not simply the bottom line.

A second goal we set forth in 2006 was the establishment of strong European organization and scientific strategy. Thanks to the efforts of PDA Sr. VP **Georg Roessling**, PhD, his staff and the European chapters, we have made tremendous progress in the past year. PDA cosponsored its first meeting with the EMEA last year, and we expect to host more than 20 scientific meetings in 2007, with at least one in each of our European chapters. Why the emphasis on Europe? Pharmaceutical development and manufacture is increasingly subject to regional regulatory requirements and inspectorates. To be effective in providing science-based education and guidance to both industry and regulators, PDA must address policy and practice on a global basis. I hope to use the PDA Europe model for establishing stronger PDA programs and presence in other parts of the globe.

In my final year as chairman of PDA, I have asked the Board of Directors to focus on one additional goal. It is to strengthen our chapter system. As a PDA member who started in the West Coast Chapter and who served as its president, I strongly believe our chapter system is an incredible resource to PDA and its members. While our chapter system is certainly not broken, I believe we can increase our support activities for chapters and fully realize their potential to help our many members who are on limited travel budgets and seeking local networks.

Through the hard work and dedication of many volunteers and staff, PDA has led the advancement of parenteral drugs for more than sixty years. I am sure you are all as proud as I of the contributions PDA has made to patient safety and educating the professionals who help ensure it. Hopefully the progress we have made in building our organization the past two years will help in part to ensure that PDA remains a leader in the advancement of parenteral science for the next sixty years.

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!

2008 Annual Meeting

April 14-18, 2008 | THE BROADMOOR - Colorado Springs, Colorado

CALL FOR PAPERS

Dear Friends and Colleagues:

Have you or someone you know in the pharmaceutical and biopharmaceutical community done something special in the past year, something that would be of particular interest to the rest of the world? Such as:

- Solved an unusually difficult technical problem
- Validated a difficult process or an unusual dosage form
- Expanded upon ideas about what "risk-based" means and how it can be implemented
- Developed a new sterilization process or method

We encourage you to submit a scientific abstract for presentation at the PDA 2008 Annual Meeting, which will be held April 14-18, 2008 at The Broadmoor in Colorado Springs, Colorado. Abstracts must be noncommercial in nature, describe new developments or work and significantly contribute to the body of knowledge relating to pharmaceutical manufacturing, quality management and technology. Industry case studies demonstrating advanced technologies, manufacturing efficiencies or solutions to regulatory compliance issues are preferable and will receive the highest consideration. All abstracts will be reviewed by the Program Planning Committee for inclusion in the meeting or in poster sessions.

Please include the following information along with your abstracts 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

SUBMIT YOUR ABSTRACT TODAY

http://convention2.allacademic.com/one/pda/annual08/

PDA is seeking presentations 30 minutes in length, that present major challenges and practical approaches to resolution in the following areas:

Biotechnology Sciences

- Implication of ICH Q8, Q9, Q10
- Cell culture/line development
- Cold Chain Management
- Disposables for biopharmceutical manufacturing
- Innovative manufacturing
- Downstream processing
- Technology transfer
- Viral clearance/inactivation
- Contamination control
- Advances in aseptic filling
- Sterilization technologies

Quality Sciences

- Application of ICH Q8, Q9, Q10
- Cleaning and multi-product manufacturing
- Compliance case studies
- Environmental monitoring
- Harmonization of quality issues
- Microbiological methods and trends
- Process Analytical Technologies (PAT)
- Quality management systems
- Risk management and risk-based GMP
- Raw material and product impact
- Supplier quality management
- Validation of pharmaceutical and biopharmaceutical processes

Manufacturing Sciences

- Aseptic processing - new technologies
- Barrier/isolators/RABs
- Advances in dosage form deliveries
- Blend uniformity and solid dose processing
- Blow-Fill-Seal
- CIP/SIP trends and innovation
- Contract manufacturing
- Design/management of multi-product facilities
- Production strategies in the global market environment
- Industry manufacturing and product trends
- Parenteral primary packaging
- Pre-filled syringes and injectors

ABSTRACTS MUST BE RECEIVED BY JUNE 30, 2007 FOR CONSIDERATION

For more information, please contact Lu Castro, Senior Coordinator, Programs and Registration Services, PDA at +1 (301) 656-5900 ext. 122 or castro@pda.org.

Science & Technology *Snapshot*

Introducing the Science & Technology Snapshot

Rich Levy, PDA

Dear Member:

When I joined the PDA staff in October 2005 as Senior Vice President of Scientific and Regulatory Affairs, I focused my science team's efforts on the PDA Strategic Plan's Goal No. 1, which focuses on Science, Technology and Innovation. We have been making great strides in driving PDA scientific activities and deliverables. It is only natural that we provide you with periodic and timely overviews of what is going on in Science and Technology.

To do so, we have created this "Science & Technology Snapshot" page in the *PDA Letter,* which will appear in every issue. Each "Snapshot" will highlight selected strategic and tactical activities of PDA in the science and technology area. In this month's edition, the Snapshot will provide briefings on pending technical reports (see below), a summary of volunteer opportunities, a preview of the content of the next PDA Journal, a look at a scientific topic of interest and an update on the Mycoplasma Task Force. In the future, Snapshots will feature other activities, including those of our Interest Groups and Advisory Boards.

I am very excited to bring you the Snapshot. I know as a longtime PDA member and volunteer how important it is for the Association to clearly communicate its activities. I am confident this Snapshot will be a valuable resource in this effort.

I hope you enjoy our first Science & Technology Snapshot. If you have any other topics you think we should include or any other feedback, please email us at snapshot@pda.org.

Technical Report *Watch*

In Global Review

Drafts of the following technical reports are undergoing review by the global PDA membership.

TR-26 (2007 Revision) *Sterilizing Filtration of Liquids:* Global review for this TR is open May 11-June 22. The TR-26 Revision Task Force met at the 2007 PDA Annual Meeting to review a completed first draft.

In Edit

Once global review is closed, revisions are considered by the task force based on the comments received. The document then undergoes a final technical edit.

Biological Indicators for Sporicidal Gassing Processes: Specification, Manufacture, Control and Use: The task force is currently reviewing and considering all comments received during global review. Next, the document will undergo a final technical edit.

Filtration of Liquids Using Cellulose-Based Depth Filters: This TR is now undergoing final editing.

In Ballot

Following technical editing, PDA's advisory boards (SAB, BioAB) are responsible for reviewing the document and voting for or against publishing the document as presented. If approved by the Advisory Board, the PDA Board of Directors votes on the document. If approved by the Board, the TR is published.

TR-1 (2007 Revision) *Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control:* This TR has been submitted to the SAB for vote.

TR-43 *Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing:* This TR has been approved by the SAB and is in preparation to be sent to the Board of Directors for approval.

Journal *Preview*

The following manuscripts will be published in the May/June 2007 edition of the PDA Journal. Of note is the research submitted by PQRI on the FDA Team Biologics program. Another noteworthy manuscript is that on microbial ingress through breaches in aseptic manufacturing systems.

Some Observations on Airborne Particles in Blow-Fill-Seal Filling Rooms, **Stefan Sundström, Bengt Ljungqvist** and **Berit Reinmüller**

Microbial Ingress through Breaches in Aseptic Manufacturing Systems: Experimental Investigation of Pressure-driven Leaks of Liquids, **Rizwan Sharnez, Robert Stianchi, Mark Stannard** and **P. K. Yegneswaran**

Freeze-drying Process Monitoring Using A Cold Plasma Ionization Device, **Y. Mayeresse, R. Veillon, Ph. Sibille** and **C. Nomine**

Preparation and Properties of Valdecoxib-Hydroxypropyl beta-cyclodextrin Inclusion Complex, **S. Baboota, P. Gowrishankar and M. Ali**

continued on page 32

Task Force *Corner*

Mycoplasma TF Report

At the 2007 PDA Annual Meeting in Las Vegas, Nev., 30 members of the Mycoplasma Task Force met to further develop a 20-question survey on the topic and to identify what PDA technical reports would result from the task force's efforts. The ultimate goal for the survey is to produce a PDA publication that would be helpful to a variety of stakeholders, including drug companies, filter companies and raw material suppliers.

The group formed in 2005 and met for the first time in 2006. At that time, the task force divided into four subgroups covering the following topics: standardization of Mycoplasma filters, inactivation of Mycoplasma from plant peptones and complex media, emerging Mycoplasma issues from plants and insects and Mycoplasma Testing

Each subgroup is preparing a plan for a PDA technical report on the four topics.

continued on page 14

Leadership *Opportunities*

Call for Authors

The leaders of the task force of revision for TR-30 *Parametric Release with Moist Heat* (1999) met at the 2007 PDA Annual Meeting, where they created a "call for authors" and brainstormed on the scope of the revision. If interested in participating in the development of this TR, please send an email to **Genevieve Lovitt** at gilovitt@mindspring.com.

Help Steer PDA's Biopharmaceutical Strategy

The Biotechnology Advisory Board (BioAB) is looking for volunteers to address the following topics of interest to the PDA community:

1. Cell line characterization phase 1 to license application
2. Analytical validation: toxicology to license application
3. GMPs from phase 1 to licensure

If you are interested, please contact **Iris Rice,** Executive Coordinator, Scientific and Regulatory Affairs, PDA, electronically at rice@pda.org or call +1-301-656-5900, ext. 129.

Sci-Tech *Trends*

PDA Survey Sheds Light on Current Practices in Setting Residue Limits

Destin LeBlanc, Cleaning Validation Technologies

PDA conducted an online survey on the topic "Residue Limits for Cleaning Validation in Finished Dosage Form Manufacturers" during the fall 2006. The survey was designed by the following team: **Destin LeBlanc,** Consultant, Cleaning Validation Technologies; **Michelle Stephenson,** Compliance Officer, GMP and Safety, Pfizer; **Jennifer Carlson,** Technical Manager, Genentech; and **Paul Pluta,** PhD, Validation Manager, Abbott Laboratories. The results of the survey are summarized below. In some cases, the responses total more than 100% because multiple responses were allowed per participant. Note that while there were 67 total participants, not all responded to every question. Unless otherwise specified, the percentages are percentages of those who responded to that specific question.

Survey Participation

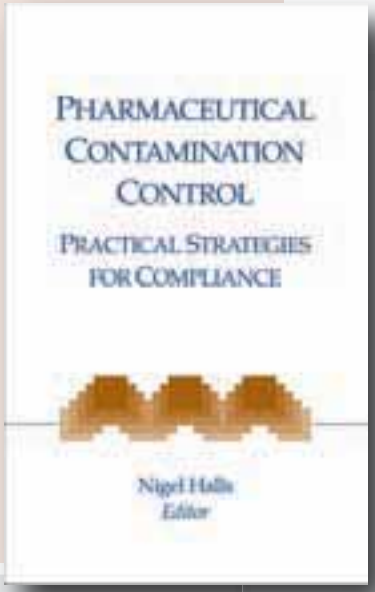
There were a total of 67 respondents, with 80% from North America, 16% from Europe and 4% from other

continued on page 13

April Top 10 Bestsellers

From the PDA Publications Store:

Pharmaceutical Contamination Control:
Practical Strategies for Compliance

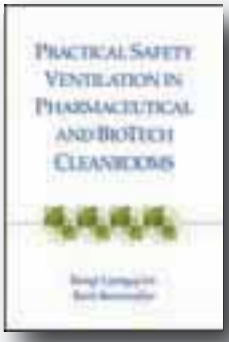


Edited by Nigel Halls, PhD

An invaluable guide and desk reference for readers in need of guidance in the assessment and management of contamination risk. Published 2007. 289 pages.

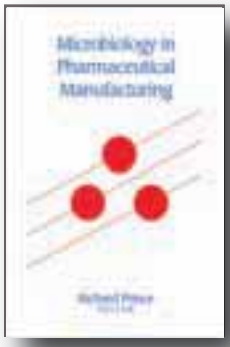
Item No. 17246 PDA Member $255 Nonmember $315

Featured Titles:

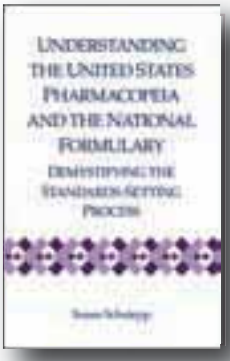


Practical Safety Ventilation in Pharmaceutical and Biotech Cleanrooms
Item: No.17233
PDA Member:$250
Nonmember:$309

Featured Titles:



Microbiology in Pharmaceutical Manufacturing
Item: No.17185
PDA Member:$285
Nonmember:$359



Understanding the United States Pharmacopeia and National Formulary
Item: No.17250
PDA Member:$240
Nonmember:$299

Risk-Based Software Validation
Item: No.17256
PDA Member:$200
Nonmember:$249

www.pda.org/bookstore

Tel:+1 (301) 656-5900 | Fax:+1 (301) 986-1361

Top Ten Bestsellers:

1. Pharmaceutical Contamination Control: Practical Strategies for Compliance
   Edited by Nigel Halls, PhD
   Item No. 17246, PDA Member $255, Nonmember $315
2. Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing
   By Destin A. LeBlanc
   Item No. 17253, PDA Member $240, Nonmember $299
3. Systems-Based Inspection for Pharmaceutical Manufacturers
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17243, PDA Member $255, Nonmember $319
4. Environmental Monitoring: A Comprehensive Handbook, Volume I, II, and Protocol CD
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17239, PDA Member $530, Nonmember $659
5. Chinese Drug GMP: An Unofficial Translation Including Related Sections of the Taiwanese, U.S., and ICH-API GMP
   Edited by Steven S. Kuwahara and Simon Xiuwei Li
   Item No. 17263, PDA Member $240, Nonmember $299
6. Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
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7. The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance
   By Siegfried Schmitt, PhD
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8. Confronting Variability: A Framework for Risk Assessment
   Edited by Richard Prince
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9. Encyclopedia of Rapid Microbiological Methods, Volume I, II, III
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10. Pharmaceutical Filtration: The Management of Organism Removal
    By theodore H. Meltzer, PhD and Maik W. Jornitz
    Item No. 17253, PDA Member $225, Nonmember $279

PDA Survey Sheds Light on Current Practices in Setting Residue Limits, continued from page 11

locations. Participation by department was as follows: 46% from validation, 24% from quality assurance, 15% from technical service, 10% from quality control, 3% from regulatory, 2% from production/manufacturing and 15% from other departments. By facility type, 73% were part of a multinational company, 11% were part of a regional company, 16% were the sole manufacturing location for their company and 5% were contract manufacturers.

Product Types

By type of product, 94% made drug products, 10% made combination drug/device products, 5% made diagnostics and 10% made other products. The physical form or type of products made included:

- 67% solid oral dosage forms
- 42% sterile injectables
- 32% liquid oral dosage forms
- 25% topicals (dermatologicals)
- 20% hard gel capsules
- 17% soft gel capsules
- 8% ophthalmic
- 7% inhalant spray
- 7% inhalant aerosol
- 12% other (including transdermals, stents, suppositories, vaginal creams and aseptic injectables)

Acceptance Criteria (General)

A large majority of respondents established cleaning validation acceptance criteria for the API (91%) and the cleaning agent (91%), and those 91% also required that the equipment be visually clean. A significant majority (64%) set acceptance criteria for bioburden. One-third (32%) set acceptance criteria for endotoxin, which is consistent with the percentage who manufacture sterile injectables. 30% set limits for API degradation products, which was rather surprising for finished drug manufacture. 15% included other criteria, such as particles, TOC and conductivity.

Limits for the API

The intent of the survey was to distinguish whether limits for active were established only on a carryover calculation, or whether criteria such as a default value and visually clean were also included. Almost half the respondents (49%) established the limit for the API was based *only* on the typical dose-based carryover calculation. 45% set the limit based on the *most stringent* of a typical dose-based calculation, a default value and visually clean. Another 22% set the limit based on the *most stringent* of a typical dose-based calculation and a default value. 10% set limits based on process capability, 6% set them based on the analytical method limit of detection and 4% set them based on a standard default value. 16% set limits on a variety of other criteria. The percentages here add to more than 100% because of the option of selecting more than one response. The authors believe the data for this question should be evaluated with care since people responded with more than one response.

For these respondents that used a dose-based calculation (71% of the total survey participants), the most common "safety factor" applied to the API dose was 0.001 (85%). A less stringent factor (0.01) was utilized by 13% of the respondents. 2% use a more stringent factor of 0.0005 and 6% use an even more stringent factor of 0.0001

For respondents that used a default value for the API (53% of the total survey participants), the most comment default value was 10 ppm (89%). 6% used a default value of 1 ppm and 6% used a default value of greater than 15 ppm. Only 3% used a default value of less than 1 ppm.

For respondents that set a limit for API degradation products (32% of the total survey participants), 42% established the limit based *only* on a toxicity (such as LD_{50}) carryover calculation, 8% established it based on the *most stringent* of a toxicity carryover calculation and a standard value and 19% based it on the *most stringent* of a toxicity carryover calculation, a standard value and visually clean. 15% based it only on a standard default value, and 15% based it on the limit of detection of the analytical method. 8% based it on process capability. 18% had other responses, mainly referring to measuring the degradation products by a non-specific method such as TOC. Care should be used in interpreting the data for this question, since only 16 respondents indicated that they set limits for API degradation products, but a total of 22 provided valid responses to this question.

Cleaning Agent Limits

For respondents that set limits for the cleaning agent, 45% established the limit based *only* on a toxicity (such as LD_{50}) carryover calculation, 17% established it based on the *most stringent* of a toxicity carryover calculation and a standard value and 34% based it on the *most stringent* of a toxicity carryover calculation, a standard value and visually clean. 11% based the limit on a return to pharmacopeial water specifications. 9% based it only on a standard default value and 9% based it on the limit of detection of the analytical method. 11% based it on process capability. 17% had other responses, such as organoleptically clean.

For those respondents who only cleaned with commodity chemicals (hydroxides and/or acids), 66% set limits for those commodity chemicals on typical toxicity-based carryover calculations. 17% set limits based on a return to pharmacopeial water specifications. 17% set limits based on pH and conductivity specifications, while 6% set limits only on conductivity specifications and 6% set limits based only on a pH specification. 14% set limits on other criteria, such as TOC.

For those respondents who used two different cleaning agents in sequence (49% of the total survey participants), 58% set limits for and analyzed *both* cleaning agents. 24% set limits for and analyzed *only* the second cleaning agent. 21% had other responses, including analyzing for the worst-case cleaning agent.

Toxicity-Based Calculations

For those respondents who used toxicity-based calculations (either for cleaning agents or degradation products), 61% use one factor to convert an LD_{50} value to a NOEL value, and then apply a safety factor to convert the NOEL to an ADI. 24% use only one factor to covert the LD_{50} directly to the ADI. 18% use neither of the two previous methods.

For those respondents who use toxicity-based calculations (either for cleaning agents or degradation products), the most common total or combined factor used was 0.001 (48%). 16% use a factor of 0.0005, 20% use a factor of 0.0001, 8% use a factor of 0.00005 and 8% use a factor of 0.00001. 4% use a factor more stringent then 0.000001. Care should be used in interpreting these responses. Perhaps more clarity was needed in phrasing the question, because a *combined or total factor* to convert an LD_{50} to an ADI should ordinarily not be as low as 0.001.

For respondents that used a default value for the cleaning agent (48% of the total survey participants), the most common default value was 10 ppm cleaning agent (69%). 16% used a default value of 1 ppm and 9% used a default value of greater than 15 ppm. 6% used a default value of less than 1 ppm.

"Visibly Clean" as *Sole* Acceptance Criterion

29% of the respondents had ever used visibly clean as the sole acceptance criterion. 73% had not used that criterion.

For those who had used "visibly clean" as the sole acceptance criterion, all (100%) had performed spiking studies to determine levels at which the residue is visible or not visible on representative surfaces.

For those who had used "visibly clean" as the sole acceptance criterion, 64% specified in the protocol locations to be examined *and also* expected a general observation of all surfaces. 27% did *not* specify in the protocol locations to be examined, while 9% *only* expected observation of those locations specified in the protocol.

Bioburden Limits

For those respondents who set limits or bioburden, 59% used a standard default value, while 28% set limits based on pharmacopeial water specifications. 13% set limits based on a carryover calculation. 9% set the limit based on the limit of detection of the bioburden method and 9% set limits based on the manufacturing process segment. 3% set limits based on process capability. Other responses, such as product specifications, totaled 13%.

For those respondents who set bioburden limits, 38% always did some level of identification of recovered organisms. 38% only identified organisms if they exceeded the acceptance limit. 28% did not perform any identification of organisms.

For those who did attempt to identify organisms, 52% identified to the *species* level and 30% identified organisms only to the *genus* level. 44% may investigate colonies which were not typical isolates from their facility. 11% did other types of identification, such as Gram staining.

Endotoxin Limits

For those respondents who set limits on endotoxin, 75% set limits based on pharmacopeial water specifications (assumed to be WFI specifications of 0.25 EU/mL). 15% set limits based on a carryover calculation. 15% set limits based on the limit of detection of the endotoxin method and 25% set limits based on the manufacturing process segment. 10% set limits based on process capability. Other responses (30%) included release specifications or a standard value.

Limits for Excipients

20% had set a specific analytical limit for a formulation excipient and then measured it in a protocol, while 80% had not.

For those who did set specific analytical limits for excipients, 40% based it on process capability. 30% based it on a default value (such as 10 ppm) in the next product. 30% set it based on toxicity calculations. 20% set it based on a visually clean criterion. 20% gave other responses.

While this survey is not scientific in its selection of respondents, it does provide some basic information on current practices in setting residue limits in finished drug manufacturing.

Task Force Corner, continued from page 11

At the latest meeting, the subgroups submitted their questions, and the task force is now working on a first draft of the survey. The purpose of the survey is to flesh out the state for mycoplasma in the 21st century, from testing to filtration to raw material preparation to prevalence of different isolates.

The group intends to meet at the 2007 PDA/FDA conference in September. After a draft of the survey and the proposed PDA technical reports are complete, the BioAB will review the proposals and decide if the survey can be distributed to the industry and if the proposed PDA TR can be sponsored.

If you are interested in contributing in any way, please contact **Iris Rice,** Executive Coordinator, Scientific and Regulatory Affairs, PDA, electronically at rice@pda.org or call +1-301-656-5900, ext. 129.

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Recent Sci-Tech Discussions: Worldwide GMPs?

The following unedited remarks are taken from PDA's Pharmaceutical Sci-Tech Discussion Group, an online forum for exchanging practical, and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. The responses in the Sci-Tech Discussions do not represent the official views of PDA, PDA's Board of Directors or PDA members. Join at www.pharmweb.net/pwmirror/pwq/pharmwebq2.html.

I am working in a manufacturing laboratory located in the European region, so EMEA GMP's must be followed. Nothing strange at this point for all of you. But then I started to look in other agencies, organizations [etc.] for other GMP rules, and I found, ICH, WHO, FDA, PICS, Etc.

And I asked myself…Is there too much legislation about drug manufacturing or is this something that can not be harmonized in the three regions? Why [does] WHO have its own rules? Why [does] PIC have them, too? Have you ever tried searching for legislation, guidances [etc.] about "Pharmaceutical Drug Distribution and Transportation"? You will find Irish guidances, USP Chapters, Canada Guidelines, etc. I think that we are creating too much legislation instead of trying to sum up and harmonize. Otherwise what does "harmonization" mean? I am expecting all your contributions and valuable opinions.

Respondent 1: I am in the same boat with you! We are contract manufacturers of APIs for clinical trials, and even though there is a "harmonized" world guidance, it is incredible the myriad of "observations" we get from clients based on local, state, country, region, their own "home-made," etc., that are not covered by ICH Q7A.

In some instances ICH clearly has a section regarding a particular issue, and the client's observation is not listed as a requirement in Q7A, the FDA or any other regulatory agency. I am seeing requests from clients, for example, to apply requirements for Class 100 rooms to Class 100,000 rooms for no reason whatsoever, other than they are doing it in their own plants!

I was talking to a GMP consultant friend of mine, and we got to the conclusion that industry itself, not the regulatory agencies, is tightening the regulations (perhaps in fear of misinterpreting regulations) to the point that one day, regulatory agencies will not need to issue new or update regulations because industry will have updated ones in place, and they will all become "industry standard practices," therefore enforceable throughout the industry. Our own industry has become our worst enemy in terms of regulatory issues. We are letting fear conquer good science!

Respondent 2: All of us who provide health care products for more than one market or region or customer are in the same boat, and rather than being harmonized and smoother, the water constantly gets choppier. (Have you seen the Canadian GMP draft?) Although most of the various regulatory bodies have similar approaches, there are enough differences in the wording, and even more in the interpretations by inspectors, consultants and other experts to create a huge matrix of possibilities that can't all be met. Our approach is to review all relevant agency rules and guidance and typically would look for the most encompassing and follow it. Of course that isn't always possible either. In those cases, good science and validation is what should get you through.

In the end, we are at times still at the mercy of investigators and regulators that simply have a slightly unique point of view. You have to decide if you will comply or not. Our industry does not have a strong record of challenging regulators even when good science, logic and evidence is seemingly on our side. And that's the basis for your comment about the industry being our own worst enemies. That might be a bit too generalized, but most of us have seen sufficient evidence of this. I particularly enjoy the concept of "guidance." The regulators specify that the guidance is not mandatory, but in case you take the "not mandatory" too seriously, there are a host of references to the mandatory sections of official rules and requirements (GMPs) to remind you of the contrary. Good luck.

Respondent 3: You have very neatly put your finger on a key GMP issue. There is an urgent need for a single, worldwide, harmonized set of GMPs with equal enforcement by all national inspectorates. The leaders in the efforts to have a harmonized GMP and common training for inspectors are the Pharmaceutical Inspection Cooperation/Scheme. With over 25 countries now members, and with several key countries at the observer stage (including FDA), there is promise that the PIC/S system could go really global, and perhaps be adopted by ICH. For details of PIC/S check their website at http://www.picscheme.org/index.php.

Respondent 4: [Respondent 3], I agree 100% with your sentiments. Getting a harmonized set of GMP standards is the easy part, if all parties are willing, I estimate 5-10 years. Getting harmonized enforcement standards is close to impossible. Like you, I work in many countries and we both know that, even in Europe, there are different standards. Expanding this across a wider industry. An EMEA inspectorate, instead of national inspectorates, would be a major step in the right direction, but almost certainly a political nonstarter.

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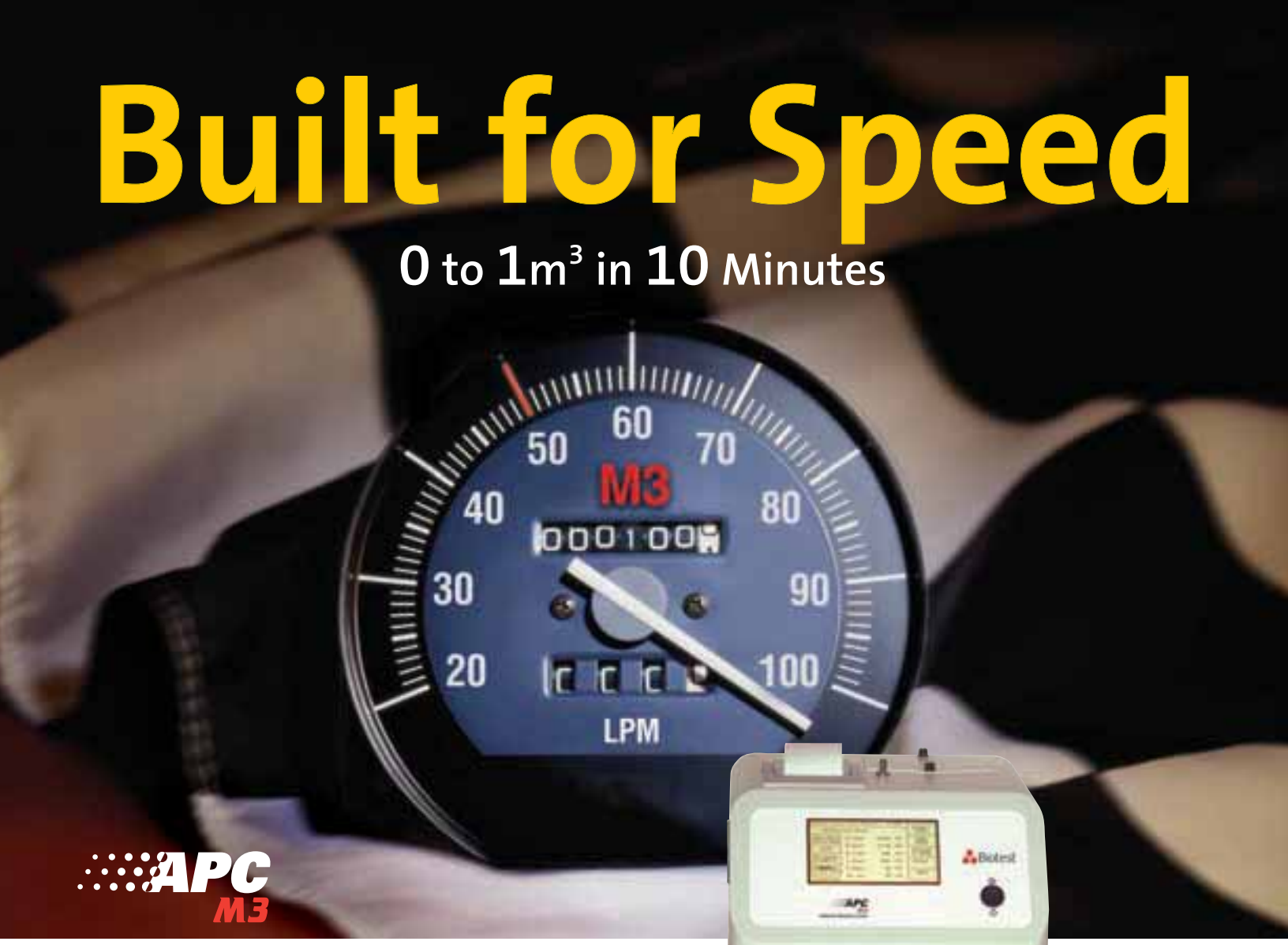

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TRI Celebrates 10th Anniversary, continued from cover

microbiology and biotechnology.

Here are the questions I ask myself every day and certainly in every planning cycle:

- Why is TRI successful and how do we maintain that success?
- Who is our audience and how do we broaden that audience to meet the needs of our industry?
- Where are we headed over the next 10 years, and, more importantly, how are we going to get there?

PDA President Bob Myers works with Vectech Pharmaceutical Consultants to finalize plans for the Bethesda facility.

Why is TRI successful and how do we maintain that success?

We have accomplished our mission by providing a unique learning experience for the students who walk through our doors, both on-site and off-site. We maintain a student to instructor ratio that allows for extensive interaction in the teaching environment and prepares our students to walk away with the skills and knowledge they need to succeed in this industry. We provide hands-on training that is not available in many settings, which enables our students to experience true-to-life manufacturing and laboratory environments. When our students smell the media and watch the mold grow, they are truly in a working environment! And our instructors are dedicated to teaching, not lecturing. They want to be part of TRI and engage the students by sharing their knowledge and experience in their classrooms. We maintain our success because we listen to our audience and to our instructors. When they tell us it's time to put an old course to bed, we add a more relevant and timely one to the curriculum. The only limitation we face is that we can not offer everything all the time, but that will change to a degree with the new facility.

Who is our audience and how do we broaden that audience to meet the needs of our industry?

This is probably the toughest question I face every time I make a decision to hold or cancel a course. Our audience is the pharmaceutical and biopharmaceutical manufacturing industry. In the old days, we were probably able to say we trained staff only from big pharma in the United States. But no longer: Today, our training reaches large and small firms, academics and regulators worldwide. Most recently, TRI was chosen by the Ministry of Health of the Republic of Kazakhstan to train nearly 100 of its regulators in GMPs, medical devices and laboratory practices, including gowning. We also have provided six weeks of training for the Italian Inspectorate and have trained the U.S. FDA. We hope our new Bethesda, Md., location, which is closer to the FDA's office, will facilitate more partnership opportunities on training issues relevant to our industry and the FDA.

TRI has begun to spread its wings a bit in Europe as well, engaging members of the European industry and regulatory authorities. Traditionally, TRI has successfully run courses in conjunction with PDA's major international conferences. After our success at the PDA/EMEA meeting last autumn, we have further grounded ourselves in Europe and have earned positive name recognition. This year we will offer stand-alone course series—patterned after our U.S. programs–in Berlin and Dublin, and we anticipate adding more in the coming years.

We are also participating in more local efforts, which could translate into more training opportunities in our own backyard. I am currently involved with industry and government organizations serving the pharmaceutical and biopharmaceutical industries here in Maryland to help identify the skills desired by the industry to increase the pool of skilled workers in our area. We are also communicating with academic institutions both locally and abroad about accreditation opportunities. For more on these initiatives, stay tuned to future Letters for updates.

Where are we headed over the next 10 years, and, more importantly, how are we going to get there?

The last part of this question is the easiest to answer. We will meet our goals for the next 10 years because of our members. We will engage them in our decision making, listen to their comments and implement programs that will help them succeed in their chosen professions. Without our members, we are just another training organization, and that is not what we want to be.

Where are we headed over the next 10 years? TRI is expanding its laboratory training programs to concentrate on more than the traditional sterile

processing competency that helped us get to where we are today. Our intent is to focus on new technologies, and our many donors and sponsors make that possible by providing supplies and equipment for our new facility, including bioreactors, chromatography equipment and syringe filling machines. Their support enables us to begin the process of developing more bioscience/biotechnology training programs and to engage a whole other part of the industry that we have only minimally focused on over the past 10 years.

While we will continue to offer our traditional lecture course series, we will focus on those held in conjunction with our major meetings, and we will increase our focus on our in-company training or product/discipline driven training at one location (see related article, page 44). TRI will engage its new Advisory Committee and instructors to develop a curriculum that concentrates on PDA's core competencies.

Before I close, I would be remiss if I did not thank all of those people who have supported TRI over the years as instructors, donors, sponsors and participants in our many programs (see related article, page 46). We are also grateful for the faith and confidence of the PDA Board of Directors, which has believed this project would succeed when others may have closed its doors. Finally, I must not forget the dedication of the staff who keeps these programs moving forward.

And so we move forward through the next decade. I hope that whoever is sitting in this chair in 2017 will look back on this article and say, "Things aren't that much different than they were 10 years ago."

Happy Anniversary TRI!

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TRI's Aseptic Processing is an Industry Standout

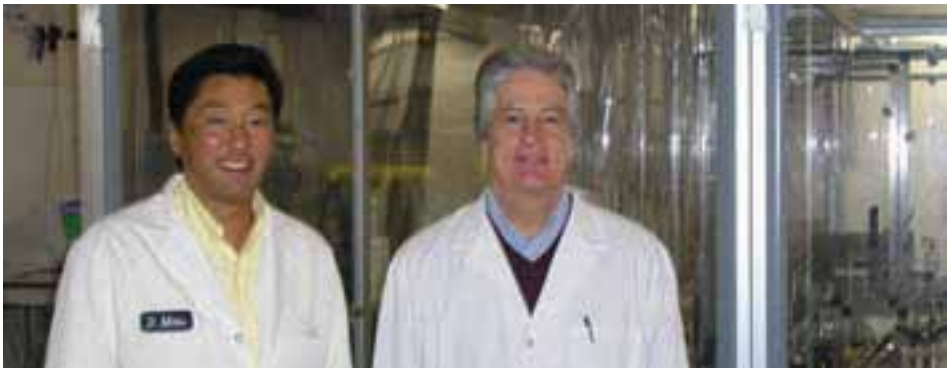
Lindsay Donofrio, PDA

Since its inception, the "Aseptic Processing Training Program" has been the student favorite at PDA's Training and Research Institute (TRI)…and for good reason. The program represents a rare educational experience that combines hands-on laboratory and lecture training and is conducted by industry-leading faculty in a simulated industrial environment. The success of this course warranted increasing its availability from once to four times per year and has contributed to the long-term strength of TRI.

While the course changes with the industry, the original curriculum was set nearly a decade ago by former TRI Director **Mike Korczynski**, PhD. Since 1999, **John Lindsay**, Aseptic Solutions, and **Dave Matsuhiro**, Cleanroom Compliance, have served as lead instructors of the Aseptic Processing course. At the time, Lindsay had been active with PDA for a number of years and welcomed the opportunity to get more involved with the Association. For Matsuhiro, the Aseptic Processing course was his first affiliation with PDA.

Over time the course has evolved a great deal, mirroring changes in the industry and the regulatory environment. When the U.S. FDA updated the aseptic processing guidance in 2004, the course was altered to adopt these changes. The same was true when the EMEA amended its GMPs to include Annex 1, Manufacture of Sterile Medicinal Products. The Standard Operating Procedures (SOPs), which are in the students' class binders, are also maintained to reflect regulation changes.

Lindsay commented on the course's evolution: "In fact, it changes every time we do the course based on what the students' needs are. In a way, the course is a lot like real manufacturing in that it's constantly evolving and changing and hopefully improving." While it's not typical for students to take the class a second time, "if they did," observed Matsuhiro, "they would find a completely different class."



Dave Matsuhiro, Cleanroom Compliance, and John Lindsay, Aseptic Solutions

However, Lindsay continued, "with respect to the types of students who attend, I don't think they've changed that much." The course's students span a large range of experience levels, including entry-level employees and technicians to chief operating officers. Human relations people have even attended the course. "I thought that was kind of interesting," said Matsuhiro. "They were doing the hiring for their company, so they wanted to have a little bit of information about what these people do."

A number of companies repeatedly choose to send students to the course, which testifies to the program's effectiveness and practical value. "Companies who have sent students to the course continue to send new people because they feel it is an enhancement to their career and understanding of the aseptic process," reported Matsuhiro. "We get the same companies coming over and over." Lindsay added that "there are even certain departments in some companies that require employees to take the course."

Students from these types of companies are not the only ones interested in the course. Other participants include professionals who have never done aseptic processing before. They attend on behalf of companies who are building a process for a facility. "In order to make it work, they have to understand it," said Lindsay. These people have come from all over the world—Australia, Canada, China, India, Japan, South Africa, Taiwan and Europe.

Course Serves Various Levels of Expertise

The variation in student experience presents a challenge for Lindsay and Matsuhiro along with the rest of the course faculty. "It's difficult to have a class that everybody is going to be interested in all at once, but we have to lay down the basics to make sure everybody is on the same page in order to go forward," stated Lindsay. "Some people might be microbiologists but not know aseptic processing. So they may be very familiar with some areas and then have no idea about others…. Since they're coming in at different levels, that's the reality."

In order to accommodate all participants, the faculty continues to make minor modifications. They keep the interest of the more experienced students by encouraging them to help other students. "Experienced students can really help the class go quicker because now you have two instructors opposed to just one person focusing on 12 people," explained Matsuhiro.

The experienced participants can be just as challenging to teach as the inexperienced students. Often, these students have already established habits, making change more difficult. The training experience, however, usually opens their eyes to a different perspective along with new methods and techniques.

Over the years, Lindsay and Matsuhiro have formed a basic core of instructors, but because of the course's large time commitment, they also call on other faculty to serve as substitutes when conflicts exist. They have found that former students actually make the best faculty. Because these individuals have gone through the entire course, they add continuity to the training program. "If you go back to the early days, the challenges we had were that [Dave and I] may have known how everything should fit together, but the other faculty members did not," commented Lindsay. "We are the common thread and make sure the course always comes back to the items that are most important," added Matsuhiro.

In a laboratory-focused training program, much of the curriculum greatly depends on the set-up of the facility. For example, while the current facility does not meet GMP standards, it makes for an excellent learning environment. Matsuhiro elaborated: "If you really look at the historical data for our media fills, they've been pristine. The facility is so basic, almost unacceptable for a real-life facility, and we're still able to get clean media fills off. So, if the students go back to reasonably modern-day technology, they shouldn't have any problems in their fill rooms."

Upgraded Facility Coming Soon

This summer the training program will move from its current Baltimore location to the new facility in Bethesda. The new site will offer students a facility which more accurately represents the industry standard. Along with modern equipment, making the new facility realistic for the students will include writing new SOPs. "That will be a huge challenge," stated Matsuhiro. The instructors also look forward to the opportunities that will arise from a new environment. "I think once we get into the new facility and start playing with it, light bulbs will start going off," noted Lindsay. "It's easy for us now because we've been doing what we're doing for a couple of years. I mean it's good to still see the students learn what they are learning, but I think the new facility will restimulate us to make the course a little different."

Lindsay and Matsuhiro would also like to see more regulatory officials attend the training program and believe the new location will facilitate larger attendance from FDA. "It adds credibility to the class when we have regulatory people working alongside the other students," said the latter instructor. "They're just here to learn, and I think that says a lot for the class that people from the regulatory agencies are coming here to learn about aseptic processing too." Lindsay added, "All of the titles go away, and they work together and go through the same experiences together."

Beyond the theoretical and pragmatic experience received by the students, "we really try to put the students in other people's shoes," said Matsuhiro. People know their individual areas, including validation, regulatory and environmental monitoring, but may not understand the challenges experienced by their coworkers in other fields. "During the course, students learn to appreciate other departments and other operators a lot more. It gives them a better understanding of the whole process."

Vendor and Faculty Contributions Key

The success of the Aseptic Processing Training Program is due in part to the generous contributions of its vendors. "Realistically, without these donations, this class would be so cost prohibitive it would be almost impossible to run," explained Matsuhiro. "The commodities are just astronomical. We've been very fortunate to have such big supporters of the course."

Not only is supporting the training program a challenge, but the instructors devote a great deal of time and effort. "It's a lot of work," said Matsuhiro. "We come in the week before. We work on the weekends and have to come in early and stay late. But I think the gratifying part is when we see the students understand what we're trying to show them." The instructors regularly receive telephone calls and emails from former students with questions. "The questions mean they understand enough to ask opposed to not asking anything," commented Matsuhiro.

While the Aseptic Processing course requires a great commitment, Lindsay's PDA participation extends beyond his contributions to this course. He has written chapters in PDA/DHI technical books, and as a result of his association with the training program, he served on the Product Quality Research Institute Aseptic Processing Working Group in 2003. Matsuhiro's PDA involvement includes teaching a number of other microbiology-focused courses for TRI.

If you would like to learn more about TRI's Aseptic Processing Training Program, please contact PDA's **James Wamsley** at +1-410-455-5800 by email at wamsley@pda.org. More information can also be found on PDA's website under Training and Education. TRI is now accepting registrants for the October/November Aseptic Processing session, which will be held at TRI's new Bethesda, Md. training facility.

Intergenerational Wonder Team Filters Knowledge for TRI Students

Lindsay Donofrio and Walt Morris, PDA

Ted Meltzer, Capitola Consulting, and Maik Jornitz, Sartorius

Like Socrates and Aristotle, Moses and Joshua, Master Po and Caine, Obi Wan and Luke, and even Miyagi and Daniel[1], PDA has its own intergenerational wonder team, which is highly educated in the science of industrial filtration. When it comes to filters, no book or article is too thick and no TRI course too long for this pedagogical pair.

Who is this dynamic duo? None other than PDA's very own **Ted Meltzer**, PhD, Capitola Consulting, and **Maik Jornitz**, Sartorius.

And what brought these two filter experts together? It all began fifteen years ago in London where Ted was presenting on filters at the Center for Professional Advancement. At this meeting, he was impressed by a young man named Maik Jorntiz who came to the aid of a defenseless competitor whose filters were the subject of an unprovoked and unwarranted attack from another audience member. Maik rose and declared: "We all know the filter has been successfully used in the industry for years, so we should stop this and come back to the point to learn about filtration!" With that, Ted knew, at long last, he had found a protégé—someone who shared the same goal of learning and teaching about filters and filtration, no matter what brand. "It was about integrity," Ted says.

Because Ted and Maik have written extensively together on filtration (many of their books are published through PDA/DHI), they were invited to teach the basic and advanced "Pharmaceutical Filtrations and Filters" courses at TRI. This was a unique opportunity for the filtration team.

"When you look into the filtration field, there is no university out there which studies filtration," Maik says. "Everybody learns hands on about filtration when they actually go to their jobs." Certain manufacturers do offer training courses, but these programs are mainly focused only on the companies' products and staff. "These courses don't offer fundamental training for the industry."

As someone who just celebrated his 91st birthday in March, Ted sees himself as a missionary to the younger generation, or what he sarcastically refers to as the "de-generation." Since 1993, Ted and Maik have collaborated on a number of projects in efforts to educate future scientists and engineers. "Ted has a lot of theoretical know how as a chemist, and I'm the practical part as an engineer," explains Maik. The synergy between them has made them successful partners. "There is no question about it," says Ted. "You know, Maik is with it, he's current, he knows the plant scene. He's got the practical skills, and I envy him."

Jokingly, Maik replies, "So the question is, who's more valuable: the theoretical guy or the practical guy?" Clearly, the sum is greater than the parts: "When we write books or publications, it's very important that we have both parts," states Maik. "We need both parts—the theoretical and the practical."

Challenging Collaboration

Ted and Maik are constantly challenging each other. While they often have conflicting opinions, through discussion they reach similar conclusions and determine which areas of filtration need more focus. "The other thing we do is ask each other questions," continues Maik. "Then a new idea pops up, a new project pops up—training, books, anything."

Their greatest challenge is to continuously create new ideas and innovative information for the industry. "Because what we don't like is constantly asking questions," notes Maik. "You can write a publication that only asks questions but gives no answers. We want to give answers." To date, Ted and Maik have collaborated on over 70 publications, and they continue to publish for PDA.

Ted, who has been a PDA member since 1968, and Maik, also a longtime member, stay with PDA because it is

continued on page 26

PDA Calendar of Events for North America

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

Conferences

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

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

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 15-16, 2007
2007 PDA Visual Inspections Workshop
Bethesda, Maryland

October 29-November 2, 2007
PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
(Conference, Courses and Exhibition)
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 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
Bethesda, Maryland

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

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

October 17-18, 2007
Visual Inspection Training Course
Bethesda, Maryland

October 23-24, 2007
Fundamentals of D, F and z Value Analysis
Bethesda, Maryland

October 25-26, 2007
Validating a Steam Sterilizer
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

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

October 15-17, 2007
Philadelphia Training Course Series
Philadelphia, Pennsylvania

Chapters

May 15, 2007
PDA Metro Chapter
Ion Mobility Spectrometry (IMS) for Cleaning Validation
Somerset, New Jersey

June 13, 2007
PDA New England Chapter
Sterilizing Filtration
Burlington, Massachusetts

Europe/Asia-Pacific

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

Europe

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

December 4-7, 2007
Practical Aspects of Aseptic Processing
Basel, Switzerland

December 12-14, 2007
Dublin Training Course Series
Dublin, Ireland

Asia

July 5, 2007
PDA Japan Chapter
J-Pharmaceutical Affaires Law Update
Tokyo, Japan

September 23, 2007
PDA Japan Chapter
Conference with US Task Force before PDA/FDA Joint Conference
Washington, D.C.

November 13-14, 2007
PDA Japan Chapter
Annual PDA Japan Chapter Meeting
Tokyo, Japan

Intergenerational Wonder Team Filters Knowledge for TRI Students, continued from page 23

a science platform. "That's the beauty. That's the reason we choose TRI because it's PDA TRI," says Maik. "We could have chosen this training course with other organizations. But you see, PDA TRI was always the pioneer. PDA stands for science and integrity. And it was the first hands-on facility where students could do hands-on training."

An Ideal Vehicle

TRI is an ideal vehicle for Ted and Maik because it offers them a forum to share their expertise. "Not only can we train theoretically at TRI, but we can also offer the more advanced hands-on training," explains Maik. "The fundamentals course is a three-day face-to-face session with a lot of questions." In the second half of the year, Ted and Maik teach the advanced program. "The students have the opportunity to make mistakes on purpose and learn to troubleshoot, so when they are back in their office, they can say, 'I've seen that before.'" Many of the attendees who participate in the basic training return for the more advanced course.

It is not unusual for Ted and Maik to remain in touch with former students. In fact, they encourage the students to call or email them with questions and comments. "We take a community approach," says Ted. "It's an obligation on our part to make the technology known to others." In the future, Ted and Maik would like to establish an online forum where they can stay in contact with every student they train worldwide. "We want a place where former students can post questions, develop conversations and receive answers," states Maik. "We don't want to keep all of this information in our heads; we want to share it. That's our responsibility. Somebody taught us, and now it's out turn." Ted and Maik would also like to see TRI continue to move into Asia and Europe.

When asked about the value of his friendship with Maik, Ted quips, "I could answer precisely, but you'd be writing a lot of four-letter words." Laughing, Maik adds, "We have a very deep friendship. We both support each other. Not only in the professional field of filtration but also in private. We are always there for each other"

Ted and Maik joined the faculty at TRI to give back to both PDA and industry. "We've accumulated a certain amount of experience in the filtration field," notes Maik. "A lot of people think it is easy. It's not. So having the experience, we have to bring our knowledge and experience forward. This is our passion."

Note

1. Socrates and Aristotle are perhaps the most well-known teacher-student philosophy pairing worldwide. Biblical figure Joshua fulfilled the mission of his master Moses by leading the Israelites into Canaan. In the 1970's U.S. television series *Kung Fu,* martial arts master Caine avenged Master Po's death by bringing justice to the American wild, wild West. In the movie trilogy *Star Wars,* Luke Skywalker avenged his master Obi Wan Kenobi by defeating the Empire. In the 1980's movie *Karate Kid*, awkward teen Daniel "waxed on" and "waxed off" for Mr. Miyagi—oh, and he won the martial arts competition *and* got the girl in the end!

For more Information

Please contact PDA's Jessica Petree at +1-410-455-5800 or by email at petree@pda.org to register for the basic or advanced Pharmaceutical Filtrations and Filters course. More information on TRI can also be found on PDA's website under Training and Education.

Kazakhstan Training at TRI

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– FDA Guidance For Pharmaceutical cGMPs, September 2004

Applied Biosystems

Going Out on a Limb: PDA Launches TRI to Educate Industry

Walter Morris, PDA

In the mid-1990s, the PDA staff and a group of forward-thinking PDA Board of Directors, led by Mike Korczynski, PhD, identified an opportunity for PDA to fill a training void in the areas of aseptic processing and sterile product manufacturing. This group successfully built a consensus among the PDA Board and by 1997 the facility for the Training and Research Institute (TRI) was completed at the University of Maryland, Baltimore County. Launching the Institute continued PDA's tradition of generating innovative training tools for the membership and the industry at large.

The inaugural lecture courses, offered on May 12, 1997, were right on target: "Auditing Pharmaceutical Microbiology Laboratories" and "Viable Environmental Monitoring." Two days later, the Institute presented "Automated Identification and Quantification of Microorganisms" and "Pharmaceutical Water Systems." June courses included "Clean Room Design Problems and Clean Room Construction Protocols," "Design and Validation of Terminal Sterilization Processes" and "Leakage and Parenteral Packaging Seal Integrity."

The Institute also offered courses on the technological cutting edge, with lectures like "Electron Beam Sterilization" (June 1997), "Identification of Particulate Matter by Light Microscopy" (August 1997) and "Fundamentals of Lyophilization" (October 1997).

From the start, the Institute's ability to take learning on the road was evident. In its first year, course series were held in Ireland, Japan, Sweden and Canada. Its commitment to serving the burgeoning biotech industry was displayed as well, with the following courses: "QC for Biopharmaceuticals," "Parenteral Biopharmaceuticals" and "CBER Regulations for Biotechnology."

Road to Sustainability

Despite these and other high quality scientific offerings, TRI suffered in its first year from the growing pains that most new ventures experience. As the professional staff and faculty searched for the right blend of lecture and laboratory courses to best serve the industry, the Institute struggled financially. Several board members, including current PDA President Bob Myers, were named to an oversight committee for TRI, which was formed to examine the situation.

Myers sat down with the PDA Letter and discussed this tenuous period for TRI and how the Institute has flourished since. "Initially," he explained, "TRI was an investment for PDA, and it wasn't at all clear that it was going to be a viable endeavor from a financial point of view. It was a big risk. It consumed a significant amount of our

continued on page 30

PDA Training and Research Institute—The Beginning

Russell E. Madsen, The Williamsburg Group, LLC

Plans for a PDA training facility with hands-on laboratory capability began in the mid-1990s. The project grew out of discussions between the PDA Board of Directors and PDA staff members **Edmund M. Fry, Suzanne Stone** and **Russell Madsen**. Stone and Madsen developed the initial business plan, the final version of which was submitted to the Board for action in June 1996.

The business plan envisioned the objectives of what is now known as TRI to be "to provide a setting in which PDA's educational programs and research efforts can be expanded" and "to enable PDA to offer full-range training in pharmaceutical manufacturing processes."

Location of the facility was determined to be important. The Board believed that TRI should be near its intended users, near a major airport and have adequate hotel accommodations nearby to accommodate students, faculty and researchers. Also considered an important factor was association with a major university. A final consideration was the need for proximity to the PDA offices in Bethesda, Md. The UMBC Technology Enterprise Center in Baltimore, Md., met those criteria and was selected as the site for TRI.

Now the design work commenced. Design Collective, Inc. (DCI) in Baltimore was selected to do the design work. Madsen and Stone coordinated the development of the site plan with DCI, which ultimately consisted of 11,000 square feet consisting of four offices, three classrooms, three laboratories, a conference room, reception/registration area, storage space and a kitchen/vending area.

When the design work was completed, bids for the construction of the facility were collected. Bids closed on October 15, 1996, and The Whiting-Turner Contracting Company of Baltimore was selected as the general contractor. Construction was completed in 1997. **Michael S. Korczynski,** Ph.D., Abbott Laboratories, was selected as the first Vice President of Training/Director TRI (see related article page 30). The rest is history.

PDA *Training and Research Institute*

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13-15 November 2007 / Berlin, Germany / *www.pdatraining.org*

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

13 November 2007

Learn how to control contamination within your classified environments with a successful cleaning and disinfection program. You will learn how to choose and apply cleaners and disinfectants properly depending on the surface, environment and product, which will reduce labor costs and commodity usage. Key Topics include proper sanitization of a pharmaceutical cleanroom, equipment cleaning/disinfection procedures and validation of disinfectant performance and application. In the end, you will be able to develop validation protocols and a proper cleaning and disinfection program to suit the needs of your company.

Instructor: Peter Koger, *Veltek Associates, Inc.*

Risk Based Approach and Risk Management in Pharmaceutical Manufacturing Processes

13 November 2007

The FDA is keen to encourage companies to adopt risk management techniques in their manufacturing operations. The recent initiative GMP in the 21st Century A Risk-Based Approach advocates the use of these techniques. This course will provide participants with a regulatory and historical background to pharmaceutical risk assessment and the use of risk assessment and risk management tools. It will comprise of a combination of formal presentations, group exercises and group discussion sessions. Group exercises will allow attendees to learn about risk assessment tools by using them to solve hypothetical problems, based on real life experiences of the course tutor. Following the risk assessment exercise, each group will be asked to develop a control philosophy to manage the risks identified.

Instructor: Trevor Deeks, *Emergent BioSolutions*

Fundamentals of Pharmaceutical Filtrations and Filters

13-15 November 2007

Filtration is used to separate unwanted particles, both viable and non-viable, from drug preparations. This highly-interactive training course is intended to provide a fundamental understanding of pharmaceutical filtrations and filters. The course will enable the participants to concentrate on the use of filters for the most demanding and critical operations for the manufacture of aseptic products.

Instructor: Maik W. Jornitz, *Sartorius*

Instructor: Theodore H. Meltzer, PhD, *Capitola Consulting*

Quality System Strategies for Investigational Drugs - Getting it Right the First Time

14-15 November 2007

This course will address the FDA Draft Guidance for the manufacture of drugs for Phase I trials and compare its recommendations with Annex 13 of the EU GMPs. The course is designed to be highly interactive with the opportunity for the audience to ask questions and to exchange views with other participants struggling with similar conundrums. Students will participate in an exercise to provide solutions to specific quality problems observed in the day-to-day quality operations in their companies.

Instructor: Karen Ginsbury, *Pharmaceutical Consulting Israel, Ltd.*

Development of Qualification and Validation Protocols - A Risk Management Approach

15 November 2007

The objective of this course is to provide instruction for the development and writing of qualification and validation protocols and summary reports utilizing up-to-date risk management and objective-based approaches. The course is designed to be in lecture format, encouraging group participation, questions, and answers throughout. It will be an interactive workshop, designed to develop the test methodology and acceptance criteria for a process/system validation protocol and program.

Instructor: Hal Baseman, *ValSource, LLC*

Check ***www.pdatraining.org*** for new courses being added to the European Training Course Series in Berlin!

PRACTICAL ASPECTS OF ASEPTIC PROCESSING

4-7 December 2007 / Basel, Switzerland

www.pdatraining.org/paap

For those looking for a comprehensive overview of current aseptic processing practices, this course is it. You will learn what is necessary to build an effective aseptic process, including: facility design, velocity testing and airflow studies, HEPA certification, microbiological issues and how to manage environmental control systems. Hands-on experience with proper gowning procedure and sanitization is also included.

Instructor: John Lindsay, *Aseptic Solutions Inc.*

Instructor: Peter Koger, *Veltek Associates, Inc.*

DUBLIN TRAINING COURSE SERIES

12-14 December 2007 / Dublin, Ireland

Check ***www.pdatraining.org*** for new courses being added to the Dublin Training Course Series!

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time and reserves in the first couple of years."

In 1998, "we were down to six months in making the decision to continue TRI or not," he said. "At the time, we were offering the Aseptic Processing Training course only once a year, and it had sold out each time. Our membership was speaking to us about what they wanted us to present. There were several other courses that sold out each offering as well, so we decided to present these courses more often. Those hands-on courses are our core competency and are world class even now." For example, the Aseptic Processing Training (see related article, page 21) course has been offered four to five times a year and always sells out. "Once we did that," Myers said, "TRI became not just a viable asset but one that sets PDA apart as a global leader in sterile technology."

For sure, he added, the aseptic processing training "has turned out to be the unique program that has made TRI special." TRI's future was further secured with the creation of a number of courses spun off of the aseptic training (see related article, page 45). Myers pointed out that many of these microbiology and filtration courses are "unique" in the industry.

A Place for Research…Too

PDA members might not know that TRI is available for research as well as training. In the new facility in Bethesda, Md., he added, "we'll probably do our own technical report research where required. For example, there was research on sterilizers required in completing Technical Report No. 1 that we did at Hospira, but we could do it in house from now on with our new state-of-the-art Fedegari autoclave."

Myers knows firsthand what can be gained by using the facility for research: "I had the experience of conducting qualification of a new technology in the Baltimore, Md., facility in 2003. The Medical-Instill INTACT™ filling technology, its new presterilized vials with unique penetrating needles for filling and disposable filling filters and lines were all qualified at TRI." Myers served as COO for Medical-Instill at the time.

Medical-Instill sold the technology and it is now becoming commercial through Aseptic Technologies in Belgium, which is developing an "upgraded system" based on the Medical-Instill system.

Michael Korczynski's Final Message to PDA as TRI Director

This article first appeared in the December 1999 PDA Letter. *Dr. Korczynski passed away in 2006.*

As I near the end of my third and final year as Director of PDA's Training & Research Institute, I feel it's important to share my thoughts about what I believe has represented a tremendous opportunity for the Association in particular and the industry at large. I still marvel at the unique opportunity I've been fortunate enough to lead. To turn an idea into a fully functional Institute that not only serves the industry with in-process training of its personnel, but also provides a venue for practical applied research that might be used by industry, is an achievement that I'm proud to have been involved in. The Institute should be used by industry as a resource for conducting unbiased applied studies that can be of value to not only the sponsoring company, but perhaps influence and/or modify, where needed, current regulatory and/or compendial requirements.

My concern, of course, is that many PDA members and the industry at large may not recognize the true worth and potential of PDA TRI. It is built, it is here and industry representatives will need to both use it and support it. This is the challenge that lies ahead.

During my tenure as Vice President of Education and Director of the Institute, I have encountered and worked with many of our marvelous faculty. Indeed, we have a faculty that is second to none relative to training in the pharmaceutical industry. They are the true strength of our worldwide educational programs and must consistently meet high expectations imposed by both our educational requirements and students' expectations.

It must also be said that the people who most appreciate and recognize the total potential of PDA TRI are our equipment and laboratory suppliers. They have been extremely supportive in supplying the Institute with equipment and supplies for many of the laboratory sessions. Our steadfast and supportive suppliers were of paramount help in helping me initiate the laboratories at the Institute, and their contributions are still valued today.

Also, I cannot say enough about my competent staff. They have played a major role in the expansion of our worldwide educational programs and greatly assisted me in the development of the PDA Training and Research Institute. I owe them many thanks.

During the last three years, I have basically lived this job. I have done what I intended to do and have fulfilled my three-year commitment. I am confident that PDA will not only continue, but expand, its pharmaceutical educational initiatives in the future, and I look forward to watching it happen as a member.

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TRI: Needed More Than Ever

Bob Mello, PhD, U.S. FDA

Prior to 1997, PDA offered training programs through its exceptional lecture-based series as part of various PDA conferences or in other training-only venues. During the conceptual period for the Training and Research Institute (TRI), it was recognized that classroom instruction, reinforced with focused, practical, "hands-on" laboratory work, could provide pharmaceutical professionals with a unique industry training experience. Starting with the first course in May 1997, and continuing through the years, highly respected subject-matter experts in the pharmaceutical sciences have shared their knowledge with course participants representing a wide range of technical abilities. With limited class sizes, student-faculty interactions were maximized and generated a dialogue that benefitted both parties. This training venue always fostered new collaborations and friendships. Looking back, TRI was what our industry needed at that point in time. Looking ahead, it is needed now more than ever, as technologies, and the need to be properly trained in them, continue to evolve. Therefore, as a former Director of TRI, I want to add my congratulations to PDA on the 10th anniversary of the establishment of the Training and Research Institute. Best wishes for continued success.

"Many people consider this system to be one of the truly great innovations of the last 20 years."

TRI welcomes other projects and new technologies, Myers explained, particularly in areas of sterile manufacturing and quality control and freeze drying. "It is a place where new technologies can be tested and verified without risk to product, plant or a company's reputation."

A Facility for the Future

Moving ahead, Myers believes TRI will perform even better in its new Bethesda location.

"And right now," he said, "we have new opportunities with this consolidation. We are not going to give up anything that was a strength at the Baltimore campus, but we have improved the facility to the point where we can give multiple courses at the same time. And we have received donations that will allow us to modernize our curriculum. Already we have a prefilled syringe course tentatively scheduled for late 2007 based on a donation by Groninger. We anticipate establishing biotech process and purification courses with vessels already donated to make this a viable course.

"In addition, we will have a renewed or upgraded and redesigned system and circuit which will give hands-on experience with clean-in-place design, engineering and validation. These and aseptic—which will continue to be a valuable course—and our other microbiology courses are continuing to be improved with new rapid micro techniques.

"Our facility will be more popular here in Bethesda, which is a great town, and more accessible by most people as well as the regulatory groups in the area. When I say more accessible, I mean by the three airports in the region, and it is on the Washington Metro system. It also has close proximity to the U.S. FDA, and we anticipate that their participation could increase—both as faculty and students."

In conclusion, Myers captured how unique TRI has been and will continue to be in the industry: "We are fortunate at this point to be able to consolidate, modernize and upgrade TRI. We are installing a modern sterile filling area with the most modern support filling equipment available. For all intents and purposes, it is capable of manufacturing sterile products at the highest level. We will provide an area that our students will get to experience hands-on sterile processing without the risk of contaminating the valuable products being made by our membership in their plants."

Journal Preview, continued from page 11

Development of Parallel Line Analysis Criteria for Recombinant Adenovirus Potency Assay and Definition of a Unit of Potency, **Dr. Y. Ogawa, Farah Fawaz, Candice Reyes, Julie Lai** and **Erno Pungor, Jr.**

Development of a Process Control Scheme for Reduction in Weight Variation of Capsules, **Prasun Das**

Comparative Sterilization Effectiveness of Plasma in O2-H2O2 Mixtures and Ethylene Oxide Treatment, **J.M.F. Silva, A.J. Moreira, D.C. Oliveira, C.B. Bonato, R.D. Mansano** and **T.J.A. Pinto**

Results of a Survey of Biological Drug and Device Industries Inspected by FDA under the Team Biologics Program, **V. Gangi**

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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

Amended Organ Transplant Rules Effective April 11, 2007: U.S. FDA and the U.S. Health Resources and Services Administration (HRSA) are amending their regulations to include as part of an organ those blood vessels recovered with the organ that are intended for use in organ transplantation (HRSA regulation) and to exclude such blood vessels from the definition of human cells, tissues or cellular or tissue-based products (HCT/Ps) (FDA regulation). The purpose of this final rule is to amend the regulations so that blood vessels recovered with organs and intended for use in organ transplantation, and labeled as such, are governed by the regulations pertaining to organs. The regulation of other recovered blood vessels remains unchanged. We (HRSA and FDA) believe that this change will eliminate the burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction).

E-Case Reports Pilot: Apply by September 10, 2007: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are seeking sponsors interested in participating in a pilot project to test the submission of case report form (CRF) data provided electronically in extensible markup language (XML) based on the Operational Data Model (ODM) developed by the Clinical Data Interchange Standards Consortium (CDISC). This pilot will test the ability of a new data format to support all review activity, which our current submission format is incapable of doing. Data supplied in ODM format by sponsors during the pilot project will not replace any regulatory requirements for submitting CRFs. We anticipate that a successful pilot will allow CDER and CBER to routinely accept CRFs from studies employing electronic data capture (EDC) in ODM format in marketing applications provided in electronic format.

Submit written or electronic requests to participate in the pilot project by September 10, 2007. General comments on the pilot project are welcome at any time.

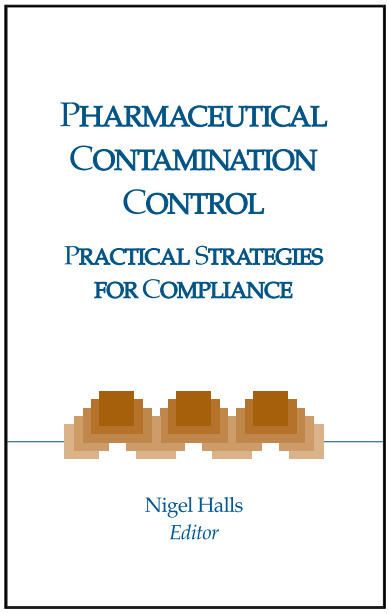
Recommended Reading

From the PDA Bookstore

Pharmaceutical Contamination Control: Practical Strategies for Compliance

Edited by Nigel Halls, PhD

Jeanne Moldenhauer, PhD, Excellent Pharma Consulting, reviews this recommended resource for understanding the risk of contamination in pharmaceutical environments:



Item no. 17246
PDA member: $255
Nonmember: $315

In order to manage and communicate risks associated with microbiology, it is necessary to understand the risks of contamination present in a pharmaceutical facility.

A new publication published by PDA/DHI, Pharmaceutical Contamination Control: Practical Strategies for Compliance, provides a great description of areas to consider in your contamination control program. Nigel Halls, editor of this book, has compiled a wealth of useful information.

Some of the topics covered in this book include:

- Water Systems and the Risks of Microbiological Contamination from Water
- Isolator Technology
- Caveats of Bacterial Endotoxin Testing
- Role of the QC Laboratory in the Control of Contamination
- Risk Management: Practicalities and Problems in Pharmaceutical Manufacture
- Bacterial Retentive Filtration
- Cleaning and Preparation

This book is very practical and useful regardless of your technical discipline. The authors of the various chapters are worldwide experts in the subject matter. Reading this book is like benefiting from tens of thousands of dollars of consulting at your site.

The only problem with the various books released by PDA/DHI this year, is finding enough time and money to buy and read them all!

www.pda.org/bookstore

Tel: +1 (301) 656-5900
Fax: +1 (301) 986-1093

Local PDA Chapters & TRI: Making a Difference Together

Ta-Méla Jeffries, PDA

TRI is responsible for the overall education and training component of PDA. This responsibility includes education and training courses offered at TRI's facility in Baltimore, Md., as well as at other off-site locations. TRI holds several popular training classes, including "Aseptic Processing Training Program," "Environmental Mycology Identification Workshop" and "Advanced Pharmaceutical Filtrations and Filters."

While a large number of PDA members take advantage of these training classes, TRI is limited to the places where training classes are offered…or so most members think. Did you know that PDA Chapters can request to offer TRI Lecture Courses in your area? Well, it's true!

The Chapter leaders can simply contact TRI to request a TRI course as part of their next meeting or as a stand-alone event. The Chapters provide input on course topics and faculty, and TRI does the rest. TRI will then develop the course programming, content, marketing and communication materials, and, upon the chapter event's conclusion, TRI will provide a summary of the attendees' feedback.

If a Chapter would like to be more involved with the success of their program, they can instead choose to cosponsor the event with TRI. In this case, the Chapters work closely with the TRI staff to promote, plan and coordinate the event. Cosponsoring offers the Chapters the chance to receive association-wide recognition for their event.

If you have ever looked longingly at an advertised TRI event but haven't had the opportunity to travel to the training location, then contact your local PDA Chapter and have the class brought to you!

Advance Your Career at PDA's Career Fairs

Ta-Méla Jeffries, PDA

Third Annual PDA Career Fair: Largest to Date

As part of the 2007 Annual Meeting, PDA hosted its 3rd Annual Career Fair. All 1,100 attendees at the meeting had access to the Career Fair. Following two successful fairs, the 2007 Annual Career Fair was the largest yet, with 11 employers eagerly waiting to interview (and hire) some of PDA's finest members.

Companies participating in this year's Career Fair were Schering-Plough (diamond sponsor), Amylin, Boston Scientific, Vertex, Teva Pharmaceuticals, Celltrion, Bayer Healthcare, Allergan, Genentech, Charles River Laboratories and Merck & Co. These employers were on hand to take resumes, interview candidates and hire. If you missed it this time, please make sure you attend next year!

Schering-Plough was one of 11 employers at the 2007 Career Fair

PDA Membership in Action: Free Virtual Event

PDA will be hosting a Virtual Career Fair and Exhibition, May 30-31.

Don't have time to take off to attend a Career Fair? Then the Virtual Career Fair is exactly what you need! There will be employers on hand to chat, accept resumes and set up interviews.

Won't be at your computer May 30-31? Good news! The Virtual Career Fair and Exhibition will be available "On-Demand" for an additional 90 days after the event is over. While you won't able to chat or interview with employers, you will be able to view company information and view the latest career opportunities.

Connect Remotely at PDA's Virtual Career Fair

Not looking for a job? There is something at the Virtual Career Fair and Exhibition for you, too. Vendors will be available to give presentations and demonstrate the latest in pharmaceutical and biopharmaceutical technology. These free live seminars make this event both engaging and educational.

Registration opens May 1. Space is still available for employers and exhibitors. Contact Ta-Méla Jeffries at jeffries@pda.org.

PDA
Parenteral Drug Association

2007 PDA Extractables/Leachables Forum

November 6-8, 2007 | Bethesda, Maryland

Call for Papers/Posters and Exhibitors

Dear Friends and Colleagues,

The 2007 PDA Extractables/Leachables Forum Program Planning Committee invites you to submit scientific abstracts regarding high-level, comprehensive and insightful information on the materials, chemistry, quality, regulatory and toxicological aspects of extractables/leachables studies for podium and poster presentation at the 2007 PDA Extractables/Leachables Forum. The theme of this year's forum is *Confronting Leachables and Extractables Issues in an Evolving Regulatory Environment.* An extensive schedule of presentations are planned on relevant subjects such as:

- Packaging and Processing Materials
- Principles of Conducting Extractables and Leachables Studies
- Key Analytical Techniques for Performing an Extractables/Leachables Study
- Extractables/Leachables from Processing Equipment
- Correlating Extractables and Leachables
- Risk Assessment and Acceptance Criteria
- Quality by Design
- Critical Path Initiatives
- Managing the Entire Supply Chain

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

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

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

Case studies are particularly desired. Commercial abstracts featuring promotion of products and services will not be considered. After June 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
- 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:

Mya Fountain
Email: fountain@pda.org
Tel: +1 (301) 656-5900, ext. 146

ATTENTION EXHIBITORS

PDA is seeking vendors who provide excellent products/services in support of this conference.
Space is limited and is on a first come, first served basis.
To reserve your space, please contact Cindy Tabb at tabb@pda.org or +1 (301) 656-5900, ext. 222.

Authors Wanted: Publish Your Research or Article with PDA

Hassana Howe, PDA

As a member of PDA, you are able to submit articles for publication in the *PDA Journal of Pharmaceutical Science and Technology* and the *PDA Letter*. This is a great opportunity to share your ideas with the PDA community of over 10,000 members.

The Journal is considered to be one of the most relevant and highly cited vehicles for peer-reviewed scientific and technical papers in the pharmaceutical and biopharmaceutical industries. The Journal will publish original research reports on applications and technology, as well as reviews and commentary. The Journal is distributed to PDA members and over 250 institutional subscribers bimonthly.

The *PDA Letter* is another forum for members to communicate their thoughts and expertise. The Letter is distributed 10 times per year to members. PDA accepts submissions at any time for the various departments: Science & Technology, Quality & Regulatory Affairs, Membership Resources, Programs & Meetings and Education. Original feature articles relevant to the PDA community will also be considered for publication.

For more information on how to submit to the *PDA Journal of Pharmaceutical Science and Technology* please visit: **www.pda.org/journalauthors**. For more information on how to submit to the *PDA Letter*, please visit: **www.pda.org/letterauthors**.

PDA is looking for feature article authors for the following *PDA Letter* issues in 2007:

Issue	Topic	Submission Due
July/August	Aseptic Processing/Sterile Products	May 27, 2007
September	Computer Validation	June 23, 2007
October	Pharmacopeial Harmonization	July 28, 2007

2007 Annual Meeting New Member Breakfast

Emily Alesantrino, PDA

The 2007 New Member Breakfast was a huge success with over 90 new members in attendance. With one of our biggest turnouts in years, this networking event was a great opportunity to learn more about PDA and to meet fellow members.

We can attribute the success of this meeting to the board members and staff involved. Board Members, **John Shabushnig,** PhD, Pfizer, and **Maik Jornitz**, Sartorius, gave insightful presentations on their PDA membership experiences and how PDA has contributed to their career-long learning. Also in attendance was 35-year PDA veteran **Ted Meltzer,** PhD, Capitola Consulting, who shared his PDA stories and successes with fellow members.

If you are a new PDA member and were unable to attend the 2007 Annual Meeting, PDA will be hosting its next New Member Breakfast at the PDA/FDA meeting in September. If you would like more information on the upcoming PDA/FDA New Member Breakfast, please visit www.pda.org/pdafda2007 or contact the Membership department at info@pda.org.

We thank all the new members who made this event successful and memorable, and we look forward to making the 2008 Annual Meeting New Member Breakfast just as successful at The Broadmoor in Colorado Springs!

Maik Jornitz, Sartorius, welcomes new members

PDA
Parenteral Drug Association

Virtual Career Fair and Web Exhibition

World Wide Possibilities

www.pda.org/vcf

May 30 – 31, 2007 • 9 a.m. – 5 p.m. EST

No Registration Fee Required

PDA's Virtual Career Fair brings the experience of an interactive career fair to the convenience of the internet.

- Explore career opportunities and advancements
- Achieve national and global exposure
- Feel secure in a 100% confidential environment
- Chat live with employers, interview and receive job offers

Web Exhibition

- Visit with industry leading experts as they present the latest in innovative technology
- Experience interactive web casts, product demonstrations and educational seminars for free!
- Connect and network with industry leading experts by communicating in a real-time environment

24 hour access to Virtual Career Fair and Web Exhibition information

PDA Welcomes New Members

Damon Asher, Millipore

Heather Attra, Cardinal Health

Shea Barber, Genentech

Angela Barefoot, Alcon Laboratories

Ryan Bass, Centocor

Lori Beer, Potomac Photonics

Robert Berry, Johnson & Johnson

Joelle Blakaitis, Medimmune

Adebayo Boboye, 3A Engineering & Validation

Robert Brokamp, Jacobs Engineering

David Brown, sanofi pasteur

Damaris Brown, sanofi pasteur

Jennifer Buckman, Eli Lilly

Aaron Burke, Millipore

Benjamin Burton, Bausch & Lomb

Tara Byerly, Artes Medical

Robert Capen, Merck

Warren Chin, Amgen

Sophie Chong, GlaxoSmithKline Biologicals

Gladys Collazo-Pollock, Valtec Consulting

John Collins, UMBI Shady Grove

Daniel Comstock, Acambis

Vincent Corvari, Eli Lilly

Luis Dasta, U.S. FDA

Nicole David, Tyco Healthcare

Andrea Desonglo, Biogen Idec

Stephen Earhart, Tyco Healthcare/ Kendall

Marcus Eber, Merck

Pat Eves, Canadian Blood Services

Mara Faustino, i3

Thomas Fink, Wyeth

Steve Folio, Cardinal Health

Kari Frantzen, MDS Nordion

Michael Frid, Wolfe Laboratories

Thomas Gill, Amgen

John Groat, Biolog

Katherine Grousnick, Centocor

Cedric Hall, Alcon Laboratories

Cynthia Harris, Cardinal Health

Michael Hoffmann, Genentech

Shane Holmes, Consultant

Douglas Holste, Wyeth

Michael Hortiatis, Bausch & Lomb

David Humpherys, Baxter Healthcare

Michael Huss, Amgen

David Jackson, Solstice Neurosciences

Becky Jones, Genentech

Brian Jordan, ValSource

James Karkow, Commissioning Agents

Kelly Kaufman, Array BioPharma

Anne Kelly, King & Spalding

Zinma Khaw, GTC BioTherapeutics

Anis Khimani, Millipore

Bob Kibler, ChemImage

Young Hwoan Kim, Good-Will

Young Kim, TDS Pharm

Andrew Kinney, Emergent BioSolutions

Ivar Kljavin, Genentech

Petko Kondov, Sopharma

Jean Kuan, Allergan

Karl Kussow, FedEx Custom Critical

Dave Lee, Amgen

Rick Lehman, Baxter Healthcare

Joanne Lewis, Ipsen Biopharm

Evan Lewis, Proteolix

Kevin Liegel Novo, Nordisk Pharmaceuticals Industries

Charles Listigovers, sanofi pasteur

Scott Liu, Amgen

Stephen LoCastro, GlaxoSmithKline

James Lynch, SAIC-Frederick

Debra MacPherson, sanofi pasteur

Nicola Magriotis, Arcotronics Technologies

Kathryn McCourt, Vertex Pharmaceuticals

Kevin McCracken, Acambis

Brian Morgan, Particle Measuring Systems

John Moser, ECVS

Takushi Nakamura, Agilent Technologies

Brian Nisbet, Brian Nisbet Associates

Patrick O'Laughlin, Merck

Christian Ofslager, Wyeth

Hirohiko Okada, Kongo Chemical

Domenika Pashankova, Sopharma

Leeanne Pearson, Genzyme

Erin Perkins, Dyax

Iain Pickersgill Daiichi, Sankyo Pharma Development

Florian Pobitschka, WAK-Chemie Medical

Udaykumar Rakibe, Ranbaxy Laboratories

Michele Rasamoelisolo, Viventia Biotech

Annabelle Rebultan, Genentech

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

PDA[SM]
Parenteral Drug Association

Global PAT Conference

Unlocking the Knowledge in Your Process

May 22-23, 2007 | Bethesda, Maryland

www.pda.org/pat

Featured FDA Speakers

Keynote: **Moheb Nasr, PhD,** Director, Office of New Drug Quality Assessment, CDER
Joseph C. Famulare, Deputy Director, Office of Compliance, CDER

Quality by Design for Biopharmaceuticals: Concepts and Implementation

May 21-22, 2007
Bethesda, Maryland

www.pda.org/qbd

Featured FDA Speakers

Barry Cherney, PhD, Deputy Director, Division of Therapeutic Proteins, CDER
Richard Friedman, Director, Division of Manufacturing and Product Quality, CDER
Chris Joneckis, Senior Advisor for Chemistry, Manufacturing and Control (CMC) Issues,CBER
Patrick Swann, PhD, Deputy Director, Division of Monoclonal Antibodies, CDER
Janet Woodcock, MD, Deputy Commissioner and Chief Medical Officer

2007 PDA/FDA Conference: Program Chair's Message

Washington, D.C. · September 24-28, 2007

Susan Schniepp, Hospira

Every day we are faced in our industry with deciphering the meaning of new terms and phrases. Sometimes the definition of these expressions is clear and other times it is ambiguous. Today's new "buzz" words include such phrases and expressions as quality by design (QbD), risk-based approach to quality systems and design space, to name a few. In addition to understanding today's terms, we also need to interpret new guidances and assess new compliance approaches to be savvy in understanding GMPs for the 21st century. If you find yourself struggling to understand today's regulatory focus and environment, you should attend the 2007 PDA/FDA Joint Regulatory Conference. This conference promises to be one of the most exciting and informative events held by any organization this year. The theme of the conference is *Evolution of the Global Regulatory Environment: A Practical Approach to Change.* The concept is to challenge the attendees to rethink, reinterpret, redesign and reapply industry processes and practices using a scientific and risk-based approach in a global market. With the adoption of ICH Q8, Q9 and the emergence of Q10, industry and regulatory authorities need to review the regulations and come to consensus on their application in light of the new paradigm of quality by design, risk-based approach to quality systems and design space. The reinterpretation of the regulations needs to consider the impact on manufacturing, quality and regulatory functions during product life cycle.

Conference sessions will take on a new look this year, offering more pharmaceutical industry case studies covering operations from the laboratory to global change control process. Quality and regulatory disciplines will continue to interact and discourse on risk-based decisions that do not compromise regulatory approval. The case studies, in most instances, will be followed by an expanded panel discussion with FDA participation. Representatives from almost all sectors of the FDA will be on hand for the discussions. Six sigma case studies from the pharmaceutical industry will be the topic of a track session where attendees can listen to how pharmaceutical manufacturers are employing six sigma as a part of their daily processes. Laboratory operations will also be predominantly featured because many of the new directives impact this area.

I hope you will consider joining the PDA and FDA at the conference this year to learn more about the new emerging regulatory initiatives and their practical applications as they relate to your company.

2007 PDA Cold Chain Conference: Program Chair's Message

Bethesda, Md. · June 13-14, 2007

Rafik Bishara, PhD, PCCDG Chair

On behalf of the Program Planning Committee, I would like to extend a warm invitation to the 2007 PDA Pharmaceutical Cold Chain Management Conference, *Transportation and Storage of Temperature-Sensitive Pharmaceuticals in a Risk-Based Regulatory Environment: A 21st Century Initiative.*

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 that the quality and integrity of the temperature-sensitive medicines are not compromised in the distribution channels.

This year's event will offer the opportunity to join colleagues and experts from around the world to learn how the current risk-based regulatory environment is affecting what pharmaceutical professionals need to do to ensure product and patient safety when dealing with temperature-sensitive pharmaceuticals. Members of the PDA Pharmaceutical Cold Chain Discussion Group (PCCDG) will examine PDA TR No. 39 – 2007 Revision, on cold chain management. This will include harmonization with our European colleagues from the Cold Chain Committee (C3) and the Pharma Logistic Forum (PLF).

We have planned a well-rounded program to provide attendees with a wealth of information, a variety of learning opportunities and an environment that stimulates discussion. Attendees will also learn how they can get involved with the PCCDG and the formation of the Temperature-Controlled Pharmaceuticals Group , which includes the PCCDG, C3 and PLF.

We look forward to seeing you in June at the 2007 PDA Pharmaceutical Cold Chain Management Conference.

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

Connecting People, Science and Regulation℠

TRI Your Hand at One of Our Training Courses

Jessica Petree, PDA

Let's face it. We are not all experts at everything we do. We need training to do many of our everyday tasks. You may work wonders in the cleanroom, but did you nail gowning the first time you attempted it? You probably had to practice.

Even a minimal amount of training is needed for anyone to be successful. You go to school, study and get hands-on practice time. Finally, after all of this hard work, you get hired. In order to perform the job to the standards of your company, you get trained. Over time, you become comfortable with your position in the company and gain confidence in your performance of the tasks associated with your job.

Eventually, however, you learn that the workplace is dynamic. Your boss might tell you that your duties are going to change a *little*, and then a little develops into *a lot*. Or perhaps you have been working in a cleanroom and are reassigned to the microbiology laboratory, but your skills are a bit rusty. Or the U.S. FDA throws a new guidance on your plate, and you look at it in amazement as if you cannot believe anything more could possibly be added to your job.

Now you need training—information on how to meet these new expectations. To help professionals like you meet your goals, PDA created TRI! TRI employs leading experts in the pharmaceutical and biopharmaceutical industry and offers a catalog of courses from which to choose. Hundreds of TRI's programs can be brought in-house and even more can be developed for you and your company (see below). TRI offers training that can specifically meet individual needs. Whether you need to learn how to control operational costs in your cleanroom, develop a training program for your employees or need help preparing for an FDA or EMEA inspection—TRI has a course suited for you.

For more information, please go to www.pdatraining.org for a current list of courses, or contact me personally for help finding the course most beneficial for you and your employees. I can be reached at petree@pda.org or by phone at +1-410-455-5800.

"By Request" Courses

Should you be interested in having a course developed specifically for you, please contact Jessica Petree at petree@pda.org and provide the following information:

- Focus of the course—what you want to be taught, including what specific information you would like participants to gain from this training
- How many people will be trained
- How long training will take place
- Where training will take place

We will be in touch with information regarding your request as soon as possible.

Annual Call for Courses

PDA Training and Research Institute (TRI) is seeking new courses for the 2008 schedule. These courses will be used in course series located around the United States and Europe and in conjunction with major PDA conferences. Attendees will include professionals from a variety of backgrounds in the pharmaceutical and biopharmaceutical industry.

Submission Deadline: June 30, 2007

TRI is looking for new courses in the following areas:

- Compliance
- Manufacturing
- Quality
- Biotechnology
- Sterilization
- Microbiology
- Lecture
- Training

Don't see the subject area for which you have an idea? If you feel that your course will address a hot topic in the industry, please feel free to submit it!

For a course proposal template, please log on to www.pdatraining.org and click "Support TRI" in the right-hand menu. Submit your proposals along with a brief bio or résumé to Jessica Petree at petree@pda.org. If you have any questions, please feel free to contact Jessica via the email address provided or by phone at +1-410-455-5800.

Upon review by TRI, submitters of proposals will be advised of the status of their course proposals by July 31, 2007.

Why, Yes! TRI Does Offer a Laboratory Course For You

James Wamsley, PDA

Whether or not you have ever attended a laboratory course at PDA's Training and Research Institute (TRI), you have probably heard a lot about the "Aseptic Processing Training Program"—and for good reason. Over the years, the two-week course has developed a strong reputation. It always sells out very quickly. The faculty is extremely knowledgeable and dedicated. The hours are long, but, because it touches on almost every subject area needed to produce a sterile product through aseptic processing, it makes the time investment worthwhile. All of the above are good reasons for its popularity.

I am sure that everyone who has attended has their own reason for why it was important to take two weeks to participate in this training. And if you have not attended the course, there are probably just as many reasons. Maybe it is not in the budget this year, you cannot take two weeks away from your job or maybe your job does not require you to know how to gown up properly or perform a sterility test. It is for these reasons that PDA has developed training based on the individual segments of the Aseptic Processing course.

I am a firm believer that the total is only as good as the sum of its parts. This idea holds true for TRI's Aseptic Processing program. What makes the course so great is how each part fits into the scheme and goal of the training. By taking these parts and expanding upon them to create a whole course, PDA has been able to tailor to the training needs of specific job functions and titles. And these courses are developed and taught by the same instructors delivering the training during the course. Therefore, PDA is able to provide the training *you* need.

The first of these courses, "Developing and Validating Cleaning and Disinfection Programs for Controlled Environments," was developed based on the principles taught in a two-hour session in the Aseptic Processing course. This two-day course is taught by **Art Vellutato,** Veltek Associates, and is designed to teach attendees how to control contamination within their classified environments with a successful cleaning and disinfection program. Whether you are a manager in manufacturing, a quality assurance supervisor or a microbiologist, this course provides the information necessary for you to perform your duties related to cleaning and disinfection in areas such as: anti-microbial effectiveness testing, validation documentation, protocol development, etc. Spin-offs are not always successful and occasionally run into some road blocks or hit a few speed bumps along the way. But, since its first session in 2004, this course has been very popular both among students who wanted more after hearing Vellutato's two-hour presentation and students who are only focused on this topic.

PDA has been able to tailor to the training needs of specific job functions and titles.

Jeanne Moldenhauer, PhD, Vectech Pharmaceutical Consultants, who has been a mainstay on PDA's faculty since TRI opened in 1997 developed a spin-off of her own in 2005. "Rapid Microbiological Methods" was developed to highlight new technologies being used in the industry to help speed up the release of product. While rapid micro methods are only touched on in her presentation during the "Aseptic Processing Training Program," there was enough interest from students to warrant developing a full-week course with lectures from the U.S. FDA and USP, as well as demonstrations and training sessions on several rapid detection and identification systems that are now being used in industry. What is so unique about this course is that a company interested in purchasing such a system can send a student to this course who can begin evaluating several systems for use at their company all at one time and in one place rather than waiting for a demo unit to make its rounds throughout the country. The added benefit of this type of training is that the student can pick the brain of the FDA speakers regarding rapid micro methods. Being able to do this all in one place, within a week provides multiple benefits that cannot be had anywhere else.

The first session of the Aseptic Training Program that students attend is Basic Microbiology, taught by **David Matsuhiro,** Cleanroom Compliance. This segment serves as the basis for much of what the students learn during the remainder of the course. First offered in January 2005, "Pharmaceutical and Biopharmaceutical Microbiology 101" has proved to be a popular addition to the PDA curriculum. Despite several other advanced microbiology techniques and subjects offered elsewhere, there seemed to be a need in the industry for a hands-on offering of a course that introduced the student to basic principles of microbiology and how different aspects of manufacturing incorporate microbiology. Understanding the principles of microbiology and how they relate to personnel monitoring, cleaning and disinfection, environmental monitoring and other processes can help companies save time and money.

Segments of the Aseptic Processing program emphasize and teach students how to collect data, implement

continued on page 46

Ten Great Years—Thanks to Our Sponsors!

James Wamsley, PDA

As we celebrate our 10th anniversary, it is only fitting that we here at PDA's Training and Research Institute (TRI) get away from talking about what we do and try to show how much we truly appreciate all the work that other people and companies do that allows us to do our jobs.

Everyone who works in this industry understands the costs associated with manufacturing, training and education. There are several individuals and corporations that make it possible for us to operate, and they deserve recognition because without them we would likely not exist.

At TRI we receive donations throughout each year from several vendors, including equipment calibration and preventative maintenance services, agar plates, microbes, equipment and laboratory instrumentation, cleaning supplies, cleanroom gowns and software. Anyone who is involved in the purchasing of supplies or equipment and software for their companies understands how quickly the cost of these supplies can add up. By providing services and supplies such as those listed, we are able to offer laboratory and lecture courses at prices that are still affordable for most companies. Not only do vendors supply commodities and equipment, but a few donate their employees' valuable time to provide training as instructors.

We have been very fortunate as well, throughout this build-out process and move to Bethesda, Md. to receive an unprecedented amount of support from several companies in the form of services (design and engineering), new equipment, building materials, labor and sponsorships. Companies that have provided donations and other support to TRI during this process will be recognized at the new facility in a very visible manner. We wanted to take this opportunity to thank all of our sponsors and donors over the past 10 years, and also those who will surely come forward in the next 10. If you would like information on ways you can support TRI or sponsor the new facility, please feel free to contact us. Below is a list of our most recent sponsors and donors.

TRI Supporters

Alcan Packaging
Alcon Laboratories
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Becton Dickinson
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Cardinal Health
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Hach Ultra
ITW Texwipe
Kimberly-Clark
Lyophilization Technology
Millipore
Novatek
Pall
Perfex
Prudential Cleanroom Services
Raven Biological Laboratories
Remel
Sartorius
Steris
Steritool
Synbiosis
Vectech Pharmaceutical Consultants
Veltek Associates
West Pharmaceutical Services

Why, Yes! TRI Does Offer a Laboratory Course For You, continued from page 45

processes and interpret the information collected. The Environmental Monitoring Trending section has grown into a three-day course focused on the collection, maintenance and interpretation of environmental monitoring data. "Environmental Monitoring Database and Trending Technologies" introduces students to the regulations, technology and software that can be used to capture all the data collected and makes decisions based on what would otherwise be overwhelming amounts of data. The systems demonstrated and used by the students during the course are all 21 CFR, Part 11 compliant, which is of increasing concern in this digital age.

I have highlighted these courses to spotlight the ever-improving and expanding TRI curriculum. We continually update and improve our courses to meet our members' needs. Many of these courses arose in part from suggestions by attendees to our courses. We offer several other courses throughout the year that cover a variety of subjects. If you do not see something in the catalog that interests you, please do not hesitate to contact us at TRI, +1-410-455-5800, with your suggestions or needs, and be sure to keep an eye on our website for new courses as they become available.

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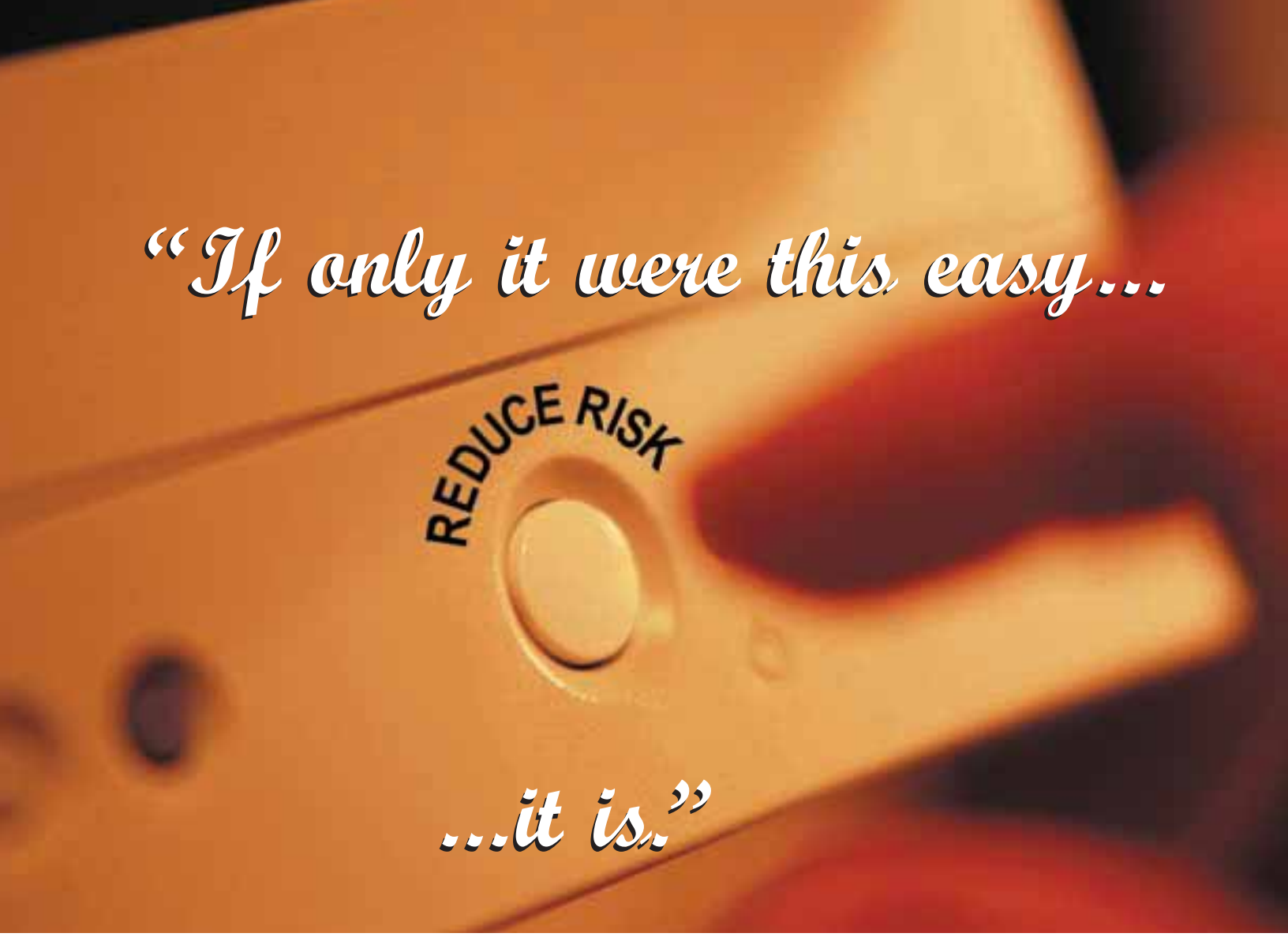

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