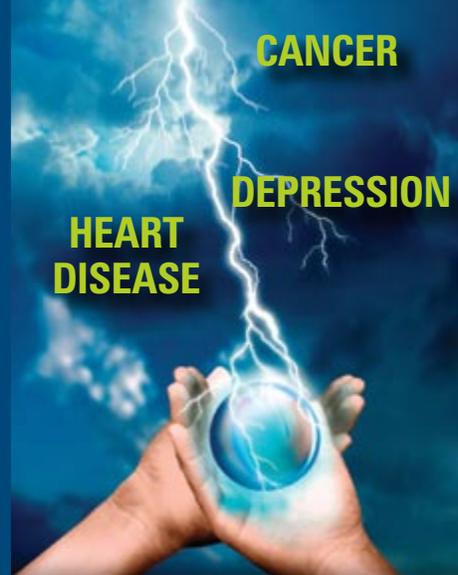


# PDA Letter

Volume XLV • Issue #6

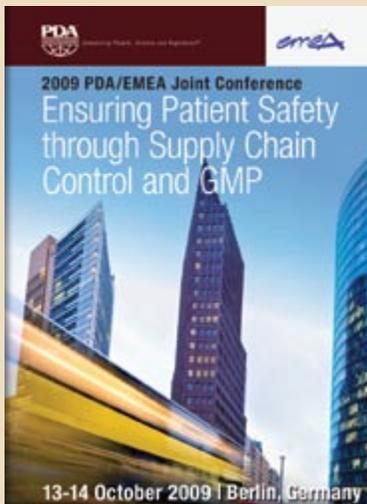
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June 2009

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## Annual Meeting Offers Predictions of Industry Future

Walt Morris, PDA

Las Vegas provided the perfect backdrop to the 2009 PDA Annual Meeting as opening and closing session speakers speculated on the future of health care and where the industry needs to be and presented the risks of noncompliance with GMPs.

The impact of the microchip on pharmaceutical manufacturing was the theme of the conference, and many of the talks touched on it in a variety of ways. Several of the plenary session presentations, however, took a different tack, looking instead into the crystal ball and divining where the industry will be in the coming years with respect to technology.

### U.S. Health Care Faces Tsunami of Chronic Care

Keynote speaker **Ian Morrison**, a consultant and futurist, went beyond the isolated ring of pharmaceutical manufacturing and control and outlined his vision of the broader health care tent. Morrison has broad experience working with health care and pharmaceutical firms. His large client list includes large pharma companies, major health care insurers, and large hospital systems.

Focusing exclusively on the United States, Morrison noted a number of eye-opening statistics about the world's largest market for health care services and products. First was the sheer size of the market itself, with 16% of the U.S. GDP going to health care costs, twice as much as the OECD countries. Despite the large amount of resources spent, the United States has an alarmingly high barrier to access, with 47 million people uninsured and a growing number of people not adequately insured. Americans most vulnerable to "medical oblivion," according to Morrison, are those aged 50-65. In sum, he asserted, the overall value of U.S. healthcare is not very high, comparatively speaking, because the United States is "spending way more and getting less."

Some of the hard data presented by Morrison was even more eye opening. For instance, he reported OECD data on per capita health care spending (2004) for nine industrialized countries, and the United States outpaced the field by nearly 100%. The \$6,102 per head spent in the United States nearly doubled that spent in Canada (\$3,165) France (\$3,159), and Australia (\$3,120), and was more than double that spent in Germany (\$3,043) and the other four countries listed (United Kingdom, Japan, New Zealand and Spain). The median per capita health care expense for the 30-nation OECD for 2004 was \$2,552.

*continued on page 19*

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**Cover art:**  
*Futurist Ian Morrison predicts a tsunami of chronic care involving cancer, heart disease and depression could overwhelm health care systems worldwide.*

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## Editor's Message

### Uncertain Present Drives Views of the Future

We chose to focus on the predictions of the future in covering the 2009 Annual Meeting. As the economy continues to sour, many of us wonder what the future holds. Consultant and futurist **Ian Morrison's** talk definitely caught the attention of meeting delegates. His focus on health care delivery in general was not misplaced at a conference for pharmaceutical manufacturing and control professionals. As Conference Chair **Ian Elvins** put it, "This is obviously a topic of crucial importance to not only the industry in deciding where we go and what the industry needs, but also to everyone of us individually. This clearly is an area which is not the easiest one for us." Elvins knows, being a senior vice president of global biologics quality and regulatory affairs for Lonza Biologics.

Indeed, the recession affects us all, including associations like PDA. Elvins wasn't the only one experiencing "a few sleepless nights" prior to the meeting "wondering with the economic crisis just how many" people would attend the annual meeting. Fortunately, attendance was near target. We hope for the same with the upcoming PDA/FDA and PDA/EMEA conferences.

Certainly, the Annual Meeting covered much more than we could ever hope to report on in one issue of the *PDA Letter*, but besides the plenary session, this issue captures some of the other interesting happenings at the meeting:

- Interest Group Briefings from the meeting (pp. 11 and 23)
- The New Member Breakfast and the Volunteer Luncheon (p. 24); the latter event was MC'ed by the editor of this publication.
- We further honor PDA's 2008 Honor Award winners in a photo spread on pages 6-7.
- We have included a number of photos from the Annual Meeting in the Faces and Places, pp. 38-40.
- PDA's Training and Research Institute reports on its exhibit at which faculty members demonstrated the Institute's capabilities, p. 42.

If you notice a drop in the quality of this year's photos, that's because your fearless editor reprised his role as amateur meeting pictorial chronicler... thanks to the recession (we cut the professional photographer out of this year's budget).

So as you read this issue and think about your future, I hope you also think about brighter days that are sure to come both for our industry and for PDA!

# PDA Letter

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# Annual Meeting Banquet Honors PDA's Hard-Working Members

At its 2009 Annual Meeting in Las Vegas, Nev., PDA recognized hard-working contributors that have shaped the Association in recent years. PDA's 2008 Honor Award winners were recognized at the traditional banquet the night before the meeting commenced.

PDA congratulates each winner and thanks them for their service to the Association.

*\*Those with an asterisk following their name were not present for the banquet.*

## James P. Agalloco Award

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

**Harold Baseman**, ValSource



Harold Baseman

## Frederick J. Carleton Award

Presented as a tribute to lifetime contributor Fred Carleton, this award is designated for a past or present Board member whose services on the Board are determined by his/her peers as worthy of such recognition. This year's recipient is:

**Lisa Skeens**, PhD, Baxter Healthcare



Lisa Skeens

## Distinguished Service Award

This award is given in recognition of special acts, contributions or service that has contributed to the success and strength of PDA. This year's recipients are:

**Myron Dittmer**,\* MFD & Associates

**Masashi Imamura**,\* Toyama-Chemical

**Zena Kaufman**,\* Abbott Labs

**Daikichiro Murakami**, Taikisha

**Mathias J. Romacker**,\* Amgen

**Thomas Schoenknecht**, PhD, Amgen

**Louis Zaczkiewicz**, GxP Quality Consulting



Daikichiro Murakami



Thomas Schoenknecht



Louis Zaczkiewicz

## Distinguished Editor/Author Award

This award is presented annually for the best editor/author of PDA-DHI co-published books as selected by PDA members. This year's recipients are:

**Anne F. Booth**, Booth Scientific

**Siegfried Schmitt**, PhD, Parexel Consulting



Anne F. Booth



Siegfried Schmitt

## Special Recognition Award

This is the very first PDA Special Recognition Award and it is awarded to **Rich Levy**, PhD, PDA, for his outstanding contributions to the advancements of pharmaceutical science for PDA.



Rich Levy

## Service Appreciation Award



John Ferreira



Sara Hendricks



Art Vellutato, Jr.

This award is given in recognition of special services performed on behalf of PDA. This year's recipients are: **Patrick Bronsard**,\* SNC-Lavalin Pharma, **John Ferreira**, Bänziger Systems, **Frank Hallinan**,\* Wyeth, **Sara Hendricks**, Commissioning Agents, **Nate Manco**,\* ECO Animal Health and **Art Vellutato, Jr.**, Veltek Associates

## Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is given in recognition of very long service, of a very significant nature, to PDA. This year's recipient is:

### Julius Knapp,

Research & Development Associates



Julius Knapp

## Gordon Personeus Award

Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member for his or her long-term acts or contributions that are of noteworthy or special importance to PDA. This year's recipient is:

### Karen Ginsbury,

PCI Pharmaceutical Consulting



Karen Ginsbury

## President's Award

This award recognizes a PDA staff member, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year. This year's recipients are: **Jason Brown**, PDA, **Leslie Edmonds**, PDA and **Hassana Howe**, PDA

## Frederick D. Simon Award

Presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology*, this award is named in honor of the late Frederick D. Simon, a previous PDA Director of Scientific Affairs. The winning article is "Qualification of High-Recovery, Flocked Swabs as Compared to Traditional Rayon Swabs for Microbiological Environmental Monitoring of Surfaces," *PDA Journal of Pharmaceutical Science and Technology*, May/June 2008, page 191–199.

**Manuela Bini**,\* GlaxoSmithKline

**Gilberto Dalmaso**,\* PhD, A&L CO Industries

**Michela Ferrari**,\* Copan Italia

**Roberto Paroni**,\* Copan Italia



The 2008 Honor Award winners

# The PDA Journal and PDA Technical Reports—Separate But Equal

## TR-15 (Revised 2009): First E-TR, Publishes in June

**Richard Levy, PhD, and Walter Morris, PDA**

In 2009, the PDA Science and Regulatory Affairs Department, which includes the PDA publications staff and oversees the production of the *PDA Journal of Pharmaceutical Science and Technology* and PDA technical reports, made the determination that the technical reports should be separated from the Journal. We presented our rationale to the PDA Board of Directors, and they agreed.

This decision was based on a number of factors, foremost of which was the fact that the technical reports are produced through a peer review process entirely separate from that used to referee the Journal. The latter undergoes an academic review common to most scientific and other kinds of academic journals and is overseen by the Journal Editor. The technical reports, on the other hand, go through a different kind of peer review, beginning with the groups of experts, which PDA calls Task Forces, that draft the documents. They are also reviewed and critiqued by PDA advisory boards and the PDA Board of Directors. In recent years, PDA injected a “global review” into the process. This includes offering a draft of the technical report online for public scrutiny, requesting certain regulatory authorities to comment on the draft, and, in some cases, holding PDA workshops to elicit feedback. This entire process is managed by PDA staff.

Another important factor influencing our decision is the fact that PDA technical reports did not start out as “supplements” to the PDA Journal. In fact, this association was not made until the late 1980’s. In a strange twist of fate, recently published *Technical Report No. 15 (Revised 2009): Validation of Tangential Flow Filtration in Biopharmaceutical Applications* is the first TR to come out sans the link to the PDA Journal, and it was one of the first to be connected to the Journal back in 1992.

Finally, in light of the rapidly changing nature of scientific information exchange, specifically the shift to electronic publishing, PDA had a very tough decision to make regarding how to distribute the various products. Scientific journals like the *PDA Journal of Pharmaceutical Science and Technology* require mass visibility and access to make them relevant and successful, thus the move to publish the Journal electronically in partnership with HighWire Press. (Incidentally, the new website will launch on July 22, so stay tuned). PDA technical reports, while equally as scientific and/or technical as peer reviewed articles, represent major original works created by teams our members, often taking two or more years to produce. So, TRs are very valuable intellectual properties of members, and ownership of them is a special privilege granted only to our

members. In our final analysis, the new HighWire website will not offer the kind of security we need to protect our TRs from illegal distribution. We made the decision to offer them only through the PDA bookstore at [www.pda.org/bookstore](http://www.pda.org/bookstore). Since we were separating the TRs from the Journal online, it only made sense to separate them in name also, for all the reasons listed above. The most visible differences you will see will be on the front page and back inside pages of Technical Report No. 15 (Revised 2009), which by now we hope you have downloaded to your own PC. So, enjoy your first ever electronic PDA Technical Report No. 15, and more to come this year.

While the PDA staff and Board of Directors are confident this decision is the right one, we are interested in your feedback. Please let us know how you feel about the separation and about electronic access in general. Email us at [info@pda.org](mailto:info@pda.org), and make sure you include the words “Technical Reports” or “PDA Journal” in the subject line.

PDA members can access electronic TR-15 until June 30, 2009 for free at [www.pda.org/bookstore](http://www.pda.org/bookstore) (login is required). Hardcopies can be purchased by members for \$150. Nonmembers can purchase access at the same site.

PDA members should update their e-mail preferences in order to receive notices about new technical reports and PDA Journals. Go to [www.pda.org/email](http://www.pda.org/email). 



## PDA and PDA Taiwan Chapter Ink Deal for Closer Collaboration

### Agreement Also Establishes Link Between PDA and the Taiwan FDA

PDA reached a membership and information-sharing agreement with its chapter in Taiwan, which closely supports the Taiwan FDA (TFDA).

The agreement provides the TFDA access to PDA's technical information for internal use. All members of the PDA Taiwan Chapter, approximately 500 professionals, are officially joining the Global PDA and membership is extended to 9 executives of the TFDA and 1 executive of the IDB. This arrangement ensures that the PDA scientific information used by industry and regulators in Taiwan will be current and at the high standard established by the Global PDA Organization.

On April 21, 2009 at the PDA Annual Meeting in Las Vegas, Nev., the agreement was signed by TPDA President **Shin-Yi Hsu** and Chapter Secretary General **Tuan-Tuan Su** and PDA President **Robert Myers** and PDA Chair **John Shabushnig**.

"I am very pleased to see this effort brought to fruition," said PDA President Myers. "We have worked with the Chapter on this agreement for a period of time and now we can move forward and ensure that the industry in Taiwan can benefit from PDA's high quality technical materials."

"This agreement helps solidify the close relationship between PDA and the Taiwan Chapter," said PDA Chair John Shabushnig. "It also opens the door to closer relations between the global PDA organization and the Taiwan FDA. 🌐"



TPDA President  
Shin-Yi Hsu, Otsuka  
Pharmaceutical

## 2009 PDA/EMEA Joint Conference Looks At Ensuring Patient Safety through Supply Chain Control and GMP

### 3rd Conference Between EMEA and PDA Will Be Held in Berlin

PDA is pleased to announce that, so far, the *2009 PDA/EMEA Joint Conference* features 15 confirmed speakers from pharmaceutical authorities across Europe. These speakers are (alphabetic order):

- **Sabine Atzor**, Pharmaceuticals Unit, European Commission
- **David Cockburn**, Inspections Sector, EMEA
- **Paula Dillon**, Inspector, Irish Medicines Board
- **Lina Ertle**, Inspector, AFSSAPS, France
- **Tor Gråberg**, Chief Inspector, MPA, Sweden & Chair-elect PIC/S
- **Vjaceslavs Krauklis**, GMP inspector, State Agency of Medicines, Latvia
- **Catherine Lefèvre**, Inspector, AFSSAPS, France
- **Regine Leo**, GMP-GCP Inspector, Hannover, Germany
- **Karl-Heinz Menges**, Regierungspraesidium Darmstadt, Germany

- **Jacques Morénas**, Head of Inspections, AFSSAPS, France & current Chair PIC/S
- **Katrin Nodop**, Inspections Sector, EMEA
- **Francisco Peñaranda**, Inspections Sector, EMEA
- **Bronwyn Phillips**, Inspector, MHRA, UK
- **Annie Rietveld**, GMP Inspector, the Netherlands
- **Jean-Louis Robert**, Laboratoire National de Santé, Luxembourg & EMEA Quality Working Party.

Presentations will cover legislation, guidances and GMP initiatives under the conference theme of *Ensuring Patient Safety through Supply Chain Control and GMP*. Three parallel tracks at the conference will address (1) Supply Chain Quality, (2) Implementation of ICH Q8-9-10, and (3) high interest issues in Manufacturing and GMP.

The supply chain quality session will cover details on the proposed EC

"Pharmaceutical Package," how inspections of importers are handled, and the most common inspection findings and areas for improvement. The track on implementation ICH Q8-9-10 will address characteristics of successful filings for variations, industry and regulator perspectives, examples of QbD and inspections, and how inspectors are trained. The high interest issues in Manufacturing and GMP track will focus on the latest guidance and interpretation of GMP requirements for investigational medicinal products (Annex 13) and biological products (Annex 2), common inspection observations and issues, and the impact of the U.S. FDA's draft guideline on process validation in Europe.

This is the only inspection/GMP event in Europe with direct support from the EMEA. The meeting was held previously in London, and in 2008 in Budapest.

For more information, visit [www.pda.org/emea2009](http://www.pda.org/emea2009). 🌐

## Advisory Board *Watch* Working Together, Better and Harder for Members

**John Geigert, PhD, BioPharmaceutical Quality Solutions and Chairperson Program Advisory Board**

At the PDA Annual Conference in Las Vegas in April, the leaders of PDA's volunteer, technical advisory boards met to accomplish two important strategic goals:

- 1) To review a new, major PDA initiative, called "Paradigm Change in Manufacturing Operations" (PCMO<sup>SM</sup>)
- 2) To discuss areas of common, overlapping scientific interest

Leaders from the PDA Program Advisory Board (PAB), Biotechnology Advisory Board (BioAB), Regulatory Affairs & Quality Committee (RAQC) and Scientific Advisory Board (SAB) were all present.

The recent ICH tripartite harmonization guidance documents on pharmaceutical systems (ICH Q8, Q9 and Q10) are revolutionizing the industry. The emphasis is now on quality systems, process management, knowledge management and quality risk management. As such, the leaders of the advisory boards on hand in April discussed the challenge to our fellow PDA members of implementing these throughout the product's life cycle, and how the Association could facilitate "best industry practices" through its technical reports and programs. You will hear more about the PCMO initiative in the months ahead.

Our association is recognized in the industry and by the regulatory authorities as an unbiased science-driven pharmaceutical association. As such, we submit official responses to many relevant draft regulatory guidances throughout the year, as well as encourage the participation of the U.S. FDA and EMEA, and other regulatory authorities in our technical report processes, conferences and workshops. The rapid response by PDA in developing industry-wide workshops (three to-date) focusing on the U.S. FDA draft guidance entitled, *Process Validation: General Principles and Practices* issued in November 2008, and the quoting from PDA technical reports by regulatory authorities, illustrate the important role that PDA serves in the pharmaceutical industry.

The leaders also discussed ways to improve communication among the advisory boards and ways to more quickly identify significant topics that could better serve our members. Another joint advisory board meeting is scheduled at the *2009 PDA/FDA Joint Regulatory Conference* in September.

The following advisory board leaders and PDA staff persons joined me in attending the joint advisory board meeting in April:

### **AGAB Leader:**

**Janis Olson**, Senior Validation Consultant, EduQuest

### **SAB Leaders:**

**Harold Baseman**, CEO and COO, ValSource

**Lothar Hartmann**, PhD, Head of External Relations, F. Hoffman-La Roche

**John Shabushnig**, PhD, Senior Manager, Quality Systems & Technology, Pfizer

**Jens Eilertsen**, PhD, Senior Principal Scientist, Global Quality Development, Novo Nordisk

### **BioAB Leaders:**

**Jeffrey Baker**, PhD, Senior Director, Manufacturing Science, MedImmune

**Norbert Hentschel**, Head of Compliance and Validation, Boehringer Ingelheim

**Rebecca Devine**, PhD, Regulatory Consultant

### **RAQC Leaders:**

**Steven Mendivil**, Executive Director, Corporate Quality Compliance, Amgen

**Stephan Roenninger**, Global Quality Manager, Global Quality, F. Hoffman-La Roche

### **Board of Directors:**

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**Rich Levy**, PhD, Senior Vice President, Scientific and Regulatory Affairs, PDA

**Wanda Neal**, Vice President, Programs and Meetings, PDA

## Technology Trend

### Going Green Can Save the Green Stuff

Emily Hough, PDA

There was a time in the recent past when pharmaceutical companies were not concerned with “going green.” According to **Thomas Pagliuco**, Director, Energy, Schering-Plough, that time is over.

Appearing at a session on green manufacturing at Interphex on March 18, Pagliuco said that companies did not “go green” in the past because there wasn’t that drive for social responsibility, and though there were opportunities to be more efficient (and save money) savings were dismissed traditionally because energy management wasn’t a big concern in the pharmaceutical industry. He said energy management only accounts for roughly 45% of the cost of goods sold and 1% of revenue.

Currently Schering-Plough has a goal to reduce 10% of its 2008 Co2 emissions by 2013. “This is a great initiative because it gives us a chance to actually do the right thing and save money and so it makes it an easier sell. But nonetheless there is a balance between finding the business case and

*continued on page 14*

## IG Briefing

### Micro/EM IG Discusses Investigation Trends

Jeanne Moldenhauer, Excellent Pharma Consulting

The PDA Microbiology/Environmental Monitoring Interest Group met at the Annual Meeting in Las Vegas on April 20. We were very privileged at this meeting to have three great speakers, **Jim Akers**, PhD, President, Akers, Kennedy & Associates, **Ken Muhvich**, PhD, Principal Consultant, MicroReliance, and **Karen Ginsbury**, CEO, PCI Pharmaceutical Consulting. They all provided different perspectives on current trends in investigations. Akers talked predominantly about environmental trends. Muhvich gave some great information on trends with *P. acnes*. Ginsbury spoke about the whole process of performing an appropriate investigation. This was followed by a period for questions and group discussion.

Ginsbury left us with a quote from Dr. Sherlock Holmes, “It is a capital mistake to theorize before you have the data as you tend to twist the facts to meet the theory—rather than the theory to explain the facts.”

Thanks to all of these great speakers and to those who were gracious and attended.

### Filtration IG Hears Presentations, Facilitates Q&A

Russ Madsen, The Williamsburg Group

The PDA Filtration Interest Group met at the PDA Annual Meeting in Las Vegas on April 21.

*continued on page 13*

## Journal Preview

### Evaluation of Optical Spectroscopy Technology for Real-Time Monitoring in May/June Journal

The May/June PDA Journal includes an evaluation of BioVigilant’s™ IMD-A™, which utilizes optical spectroscopy technology for continuous, real-time environmental monitoring.

The first part of the article, written by **Michael Miller, Horatio Lindsay, Rene Valverde-Ventura, Michael J. O’Conner**, provides a review of the technology and comparative studies with conventional methods. The second part, co-authored by **Michael Miller, Michael Walsh, Jerry Shrake, Randall Dukes** and **Daniel Hill**, is a case study involving the use of the technology for environmental monitoring during aseptic filling, intervention assessments and glove integrity testing in manufacturing isolators.

Remember, the PDA Journal is available electronically at [www.pda.org/journal](http://www.pda.org/journal). Coming in July, the new Journal website, hosted by HighWire Press, will launch with new functions and capabilities.

### Research

- Shunmugaperumal Tamilvanan, Ganesh Shesrao Bangale, Jesudoss Jeya Ananthi, Vellaichamy Sivakumar, Ganesan Vinothapooshan, Madasamy Palanivelu, and Mabepalli Byrappagowbu Viswanathan, “Carvedilol-loaded Mucoadhesive Buccal Tablets: Influence of Various Mucoadhesive Polymers on Drug Release Behavior”
- Haiyan Liu and Jinchun Chen, “Indomethacin-loaded Poly(butylcyanoacrylate) Nanoparticles: Preparation and Characterization”
- Chinna Reddy Palem, Shweta Patel, and Varsha B. Pokharkar, “Solubility and Stability Enhancement of Atorvastatin by Cyclodextrin Complexation”
- Shagufta Khan, Praful Giradkar, and Pramod Yeole, “Formulation Design of Ranitidine Hydrochloride To Reduce its Moisture Absorption Characteristics”
- Russell E. Madsen and Theodore H. Meltzer, “Reverse-Phase, High Performance Liquid Chromatographic Method for the Determination of Tolterodine Tartrate in Routine Quality Control Samples”

### Technology/Application

- V. S. N. Murthy Dwibhashyam, P. Keerthi, J. Vijaya Ratna, and A. N. Nagappa “Critical Influences of Particles, Pores, and Prefilters in Sterilizing Filtration”

*continued on page 13*

## Recent Sci-Tech Discussions: Revalidation of Production Equipment

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](http://www.pharmweb.net/pwmirror/pwq/pharmwebq2.html).

### Revalidation of Production Equipment

**Assuming that no major change has occurred on production equipment (under routine maintenance), how often is revalidation (PQ) taking place? On an inspection by the authorities, we were cited for not scheduling a revalidation on equipment.**

**Thank you for your response.**

**Respondent 1:** Qualification/Validation of equipment is a mandatory regulatory requirement in the pharmaceutical industry although the [U.S. code of federal regulations] does not explicitly mention it in those words. (I am not sure if it is specifically mentioned in the Orange guide.)

However, I do not see the need for requalification/revalidation, except in the following situations:

1. Major maintenance
2. Performance deterioration beyond acceptable means, indicated by repetitive breakdowns/calibration failures
3. Product failures that could likely be the result of equipment performance

Having said that, I have also been on the receiving end of such observations, recently in a customer audit for an equipment that was qualified within the last 10 years. I see it becoming an "expectation" in the coming future.

I would like to add a question on a related topic. On a recent audit to a vendor site, I noticed that the vendor equipment was inadequately qualified in 1987; critical components were not identified, not verified against design specifications, performance was not checked. Moreover, the concept of equipment qualification was not as advanced in those days as it is today. However, since they have been able to

use the equipment for more than 22 years successfully for intended purpose (albeit with preventive and breakdown maintenance), is it fair for me cite this as an observation? If yes, what should be considered as a satisfactory response to such an observation? Thanks.

**Respondent 2:** There is no fixed revalidation time period—it is basically up to you to determine your own policy and create your own schedule. The revalidation period of any one piece of equipment will depend on how "critical"—what the quality impact that the equipment operation is to the process—and usually how easily any deviation from the proper operation can be detected (risk analysis). By way of examples: Temperature measuring equipment and autoclaves ensuring product quality/sterility should probably be revalidated every six months, a cartooning [*sic*] machine on a packing line probably five plus years (or more). After performing a risk analysis you could perform high risk every six months, normal risk every 12 months and low risk every three years. Up to you really.

**Respondent 3:** [Questioner], The EU requirement is that there should be a periodic review of facilities, equipment, systems, processes and cleaning to confirm that they remain valid. Where no significant changes have been made to the validated status, the review with evidence that the facilities, etc., meet the prescribed requirements fulfills the requirement for revalidation. The question is how often is periodic? My experience, not more than five years, and often as short as every two years. Even if there have not been any changes it is necessary to carry out a formal review—document what has been checked and conclude that the validation status is current. Of course the report will be signed by QA and the relevant

department manager.

**Respondent 4:** Have you documented in your validation review that revalidation is not required? You should detail your approach to so called revalidation in your site validation master plan. You should cover the need (or not) to revalidate in your annual product review and in your periodic, i.e., documented equipment, reviews.

**Respondent 5:** I suggest that you [or rather the inspector] looks at the PIC Guidance, PI006-3, on *Validation Master Plan Installation and Operational Qualification Non-sterile Process Validation Cleaning Validation*.

There, it is made clear that equipment is not validated or revalidated, it is qualified. Processes are validated or revalidated.

Paragraph 5.6 of that guidance entitled, *Re-Qualification*, states "Modifications to, or relocation of, equipment should only follow satisfactory review and authorization of the documented change proposal through the change control procedure. Part of the review procedure should include consideration of requalification of the equipment. Minor changes or changes having no direct impact on final or in-process product quality should be handled through the documentation system of the preventative maintenance program."

To my understanding, this means that if a piece of equipment is not modified, moved or suffers a major repair there is no need to do anything provided it is contained within an adequate maintenance and calibration regime. The important thing is to keep adequate records of the calibration and maintenance. I think that this is yet another example of overkill that is being created by inspectors, many of whom have never worked in industry.

**Respondent 6:** Dear [Respondent 1], The intention of revalidation periods or frequencies is to establish that the equipment remains suitable for the drug products (or APIs) processed in them, or in the case of manufacturing support systems that they continue to be capable of supporting the adequate performance of manufacturing equipment, including ensuring that the equipment or support system documentation remains current.

We are all aware of the many changes in manufacturing uses, schedules and corrective and preventive maintenance repairs that equipment and systems go through during their lifecycle. We are as well aware that major or critical changes to manufacturing equipment or support systems may require requalification. Because historically reviewing the equipment systems had been somewhat neglected during regulatory inspections (except for sterile or aseptic manufacturing), it is increasingly an expectation of regulatory agencies that the validation system policy or procedure includes periodic reviews of the qualification status of manufacturing and support systems to ensure the site remains in a “validated state.”

In a very well designed equipment maintenance/engineering system, QA would get yearly performance reports for each piece of critical equipment, equipment training and manufacturing support systems with an assessment or recommendation for the requalification of the equipment when needed. QA can concur or not, thus retaining the final determination for the need for requalification as modern quality management systems would require.

Under this scenario, the equipment qualification system would be at par with the GMP requirement of evaluating on a yearly basis (at a minimum) the performance of manufacturing processes to determine the need for changes to specifications or process control parameters, and/or the need for revalidation. So when you inspect a facility and find that the equipment qualification documents have not been updated since 1987, this would be of great concern as it suggests

a weak and ineffective QA oversight of the qualified status of a facility.

I hope my comments were helpful.

**Respondent 7:** [Questioner] and All,

This is a clear example of the weakness of a validation system that does not encompass the life cycle of the system.

**Global Life-Cycle Validation:** Had a full life cycle approach been used with DQ, (BQ/IQ), [sic] OQ, PQ, MQ (maintenance qualification), and CQ (closure qualification), after PQ, you would have initiated the MQ phase and used appropriate data collection to establish that the system was maintained in its “is valid state.” In such approaches, there is no “revalidation” only the ongoing MQ data collection and trending that establishes the system is functioning in its “is valid” state.

**PQ—One Phase of Validation/Revalidation But NOT Revalidation:** If one truly revalidates a production system, then one should start with a verification that the equipment still meets its design tolerances. Then, one should verify that each part of the production system operates within its operational qualification “envelope.” Finally, one should verify that the performance of the production system is still inside of the allowable “outcomes” envelope established during initial PQ.

Hope the preceding observations will help you going forward.

**Respondent 8:** Related to this subject of equipment requalification, our cent [sic] environmental monitoring system has been challenged by the U.S. FDA that the laminar flow hoods over the filling needles has to have a direct fixed-air sampler to detect viable particulates. The older approach of using a setting plate inside the hood was “not acceptable” as nowadays the European manufacturers are all required to do so. This means interruption of the operation line and 3 Q’s of such additional monitoring device. Does any one have had the same issue as ours in aseptic filling facility qualification? 🍷

#### IG Briefing, continued from page 11

Two formal presentations were followed by a Q&A session and general discussion of topics of interest. “Alternative Virus Filter Validation Strategies: A Little Extra Effort During Validation, Yields a Minimum Cost of Goods for the Life of Your Process,” was presented by **Paul Genest**, Millipore. **Jerold Martin**, Pall, gave a presentation called “Rationales and Myths of Pre-use Integrity Testing.” 🍷

#### Journal Preview, continued from page 11

- Michael J. Miller, Horatio Lindsay, Rene Valverde-Ventura, and Michael J. O’Conner, “Evaluation of the BioVigilant™\_IMD-A™, A Novel Optical Spectroscopy Technology for the Continuous and Real-time Environmental Monitoring of Viable and Nonviable Particles. Part I. Review of the Technology and Comparative Studies with Conventional Methods”
- Michael J. Miller, Michael R. Walsh, Jerry L. Shrake, Randall E. Dukes, and Daniel B. Hill, “Evaluation of the BioVigilant\_ IMD-A™, A Novel Optical Spectroscopy Technology for the Continuous and Real-time Environmental Monitoring of Viable and Nonviable Particles. Part II. Case Studies in Environmental Monitoring during Aseptic Filling, Intervention Assessments, and Glove Integrity Testing in Manufacturing Isolators” 🍷

Technology Trend, continued from page 11

doing the right thing,” Pagliuco said. He continued, “We all use energy to some degree, some more than others. Somebody in the manufacturing process is going to use more energy than somebody in an office environment.

ity per unit. With 1,000 fume hoods in use at the site, the company is saving \$600,000 per year.

“Retro-commissioning” is another “low cost/no cost” discussed by Pagliuco. Requiring no capital invest-

“reduces the stress on the grid,” and that helps keep the system up and running and improves reliability, said Pagliuco.

**Paul Lukitsch**, Regional Facilities Manager and Energy Manager, Millipore, also shared his company’s experience so far with a sustainable energy program, implemented in 2006.

*“There is no savings too big or too small. I’ve heard ‘it’s only \$100.’ Well, when you add \$100 times 50,000 people—it starts to be a big deal.”*

There is no savings too big or too small. ‘I’ve heard ‘it’s only \$100.’ Well, when you add \$100 times 50,000 people—it starts to be a big deal.”

One of the important first steps to “going green,” Pagliuco said, is to make energy data more visible. That allows energy to be bought more efficiently and enables facilities to know the baseline and benchmarks of where they are in terms of efficiency/inefficiency and where changes or improvements should be made. Schering-Plough did this by looking at how operations were run in facilities, labs and offices.

Pagliuco discussed one case where Schering-Plough was able to make a simple change to a piece of equipment at one facility to save over half-a-million dollars. This “no cost/low cost opportunity” for Schering-Plough presented itself at the firm’s Kenilworth, N.J. site and involves the use of fume hoods. Each hood requires about the same amount of energy it takes to power 2000 households annually, Pagliuco said. After careful consideration, the firm found that it could successfully run the fume hoods at a 20% reduced velocity, saving the firm roughly \$600 in electric-

ment, “retro-commissioning” focuses on how equipment is operated and maintained. Through the initiative, Schering-Plough has been able to generate savings in its office, laboratory and manufacturing facilities.

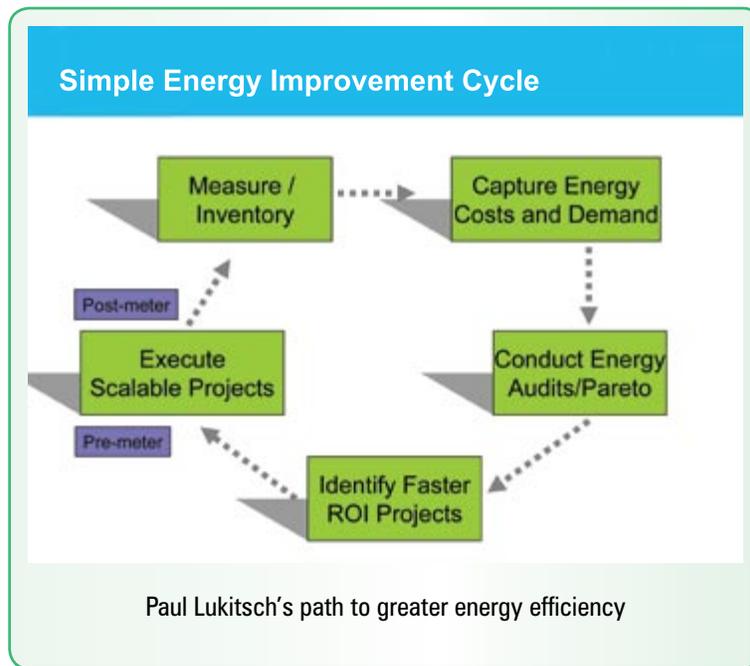
Yet another tactic that Schering-Plough is deploying is “demand response and

When beginning an energy management program, energy costs need to be captured carefully. “You want to start by measuring and inventorying, and you want to do a very careful job of this—double, triple check your work and have it audited by outside folks.” The next step, he said, is to conduct energy audits. He said that when Millipore executes scalable projects, it meters or measures before the start of the project and measures after it to calculate the work that has been done and advancements that have been made to accomplish its goals.

In the first year of the energy management program, Millipore started with the quickest return on investment and lower capital projects. For Millipore, that meant looking at its use of compressed air, lighting, energy metrics and exit signage.

Lukitsch said that it was very important to work on the compressed air system and measure what is used since it is the most expensive utility in the facility. “The overall efficiency of the typical compressed air system can be as low as 10-to-15%,” he said. “For every dollar you

spend on energy, 85-90% is lost to heat and mechanical losses.” The answer was not to buy a more efficient compressor, but to invest in simple air flow meters and leak detection equipment. “A leak is an extremely expensive proposition,” he said. “I guarantee you will find numerous leaks that you cannot hear with



load shedding.” Under this strategy, a site receives a daily report regarding the price of a kilowatt hour for the next day. At the aforementioned Kenilworth site, managers use the information to better distribute its energy usage to times when the price of electricity is lower. An added benefit of this strategy is that it

the naked ear; an ultrasonic leak detector is the tool of choice.” After a leak is found, Lukitsch said, it is repaired and then periodically checked.

Regarding lighting, Millipore came up with several strategies to save money. Lukitsch said that these simple changes are easy to make and should be implemented right away.

The simplest was switching to compact fluorescents in lieu of incandescent bulbs. “You should be doing this at your house, you should be doing this everywhere you work,” Lukitsch asserted. “That is a lighting no-brainer. You shouldn’t need to convince anybody that this is the right thing to do.”

In addition, the firm installed occupan-

cy sensors and individual motion controls for lights. “These can be bought at a local hardware store. They save energy.



Put them in all your conference rooms, put them in all your common areas, put them in your office areas.”

Another easy fix was the lighting for

exit signs, which usually employ incandescent bulbs and never shut off, burning electricity 24/7. Millipore changed them to light-emitting diode (LED), which is saving the firm “an enormous amount of energy.”

In their second year, Millipore started to delve into natural gas savings, and purchased renewable energy credits from a wind farm. In the third year, Lukitsch said that they are looking at renewable energy—wind, solar and possibly solar hot water.

As of March, Millipore had completed a wide variety of energy efficiency projects totaling

over 400 million kilowatt hours a year. ☺

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*Annual Meeting Offers Predictions of Industry Future, continued from page 11*

Performance metrics in light of the stark dollar figures supported Morrison's assertion that the United States wasn't necessarily benefiting from its higher rate of spending. OECD data for 2004-2005 reveals that U.S. female life expectancy—79.8 years—was lower than the same in Japan (85.2), Spain (83.1), France (83.0), Canada (82.2), Germany (81.3), the United Kingdom (80.4) and Korea (80.0). Infant mortality in the United States was 6.5 per 1000, compared with 3.3 in Japan and under 5.0 in Spain, France, Germany and Canada. The United Kingdom was not far behind its American cousin at 5.2 per 1,000, but still significantly better. Even a country the size of Korea had a better infant mortality rate than the United States at 6.3 per 1,000. Another troubling OECD metric for the United States was the percentage of overweight Americans in 2004-2005, 66.3%.

Morrison's message echoed a familiar sentiment heard throughout the United States, particularly during presidential elections: The health care system is broken and needs drastic reforms. He added to that notion an important caveat, and that is, without major changes, U.S. health care will be overwhelmed by a "triple tsunami of chronic care" related to growing obesity (heart disease, diabetes, etc.), cancer and depression (which he called "pandemic"). These problems, he said, are not isolated to the United States, but, as the data shows, the U.S. system is possibly the least capable of coping among major industrialized nations.

#### Pharma Not Largest Cost Driver Anymore

Another problem for the United States is how primitive the health care system is with respect to deploying information technology. It was ironic to be at a meeting about how the microchip has impacted pharmaceutical manufacturing only to learn that the gatekeepers for the drugs—the doctors and hospitals—are not utilizing basic modern IT tools.

"We have a pathetically low penetration in primary care of information technology," asserted Morrison. He explained

that only 19% of U.S. primary care practices reported utilizing IT systems for at least 7 out of 14 important functions (i.e., Rx alerts, access hospital records, access test results, ordering tests, ordering prescriptions, etc.). The source of this data is a 2006 Commonwealth Fund International Health Policy Survey of Primary Care Physicians. Of the seven countries involved in the study, only Canada was worse than the United States with 8% reporting IT usage for at least 7 of the 14 functions. German primary care practices were several rungs above the U.S. at 32%, followed by Netherlands at 59%. Australia, the United Kingdom and New Zealand greatly outpaced the U.S. with 72%, 83% and 87%, respectively.

Morrison's data didn't paint a completely bleak picture. For the pharmaceutical industry, in fact, survey data indicates perceptions about the costs of drugs are changing. Data from a 2008 Harris Interactive, Strategic Health Perspectives poll showed that health plan executives in the United States no longer see the cost of prescription drugs as the primary cost driver, which was not the case earlier in the decade.

According to the poll, from 1999-2005, prescription drugs were the biggest factor driving up the price of health care. In 2002, 65% of the execs surveyed blamed prescriptions. From 2006 to 2008, hospitals were viewed as the primary cost driver, according to these executives. Prescription drugs still ranked as the top reason according to 24% of the execs, but clearly, perceptions are changing.

Morrison noted that the cost of injectable drugs has been singled out by some execs in recent years, with 12% blaming that cohort of therapies as the primary cost driver.

In conclusion, Morrison believes that he election of President Obama might signal serious change in U.S. health care. He noted that three-quarters of the voters choosing health care as their primary issue voted for Obama.

"I would argue that the Obama administration is certainly a tipping point compared to where we've been over the last eight to ten years," he said.

While information technology has not taken health care delivery by storm, the impact of IT and the microchip in general is evident everywhere in the pharmaceutical industry.

#### FDA: Here to Help... You Implement IT

Touching on the U.S. FDA's requirements for computer systems were Center for Biologics Evaluation and Research Division of Manufacturing and Product Quality officials **Nicole Trudel** and **J. David Doleski**. The speaking tandem helped reorient the opening session audience back to the world of manufacturing and compliance following Morrison's thought-provoking, if not disturbing, exegeses on health care.

Trudel outlined a number of manufacturing functions for which computer systems are used in the pharmaceutical/biopharmaceutical industry, including:

- Process Monitoring and Control (Distributed Control Systems): "used in your process; you use them to monitor various parameters and control your manufacturing steps."
- Environmental Monitoring and Control (Building Monitoring Systems)
- Databases: Quality Systems (Tracking Deviations, Change Control, Investigations)
- Databases: Laboratory Information Management Systems
- Materials Management/ Resource Planning Systems
- Automated Visual Inspection Systems

"Some of the trends we see when we go on inspections or when we look at the submissions that come in, we are seeing a lot of distributed control systems," said Trudel. "They are very big. More and more companies are installing them and using them in their process." In addition, she noted, automated visual inspection

systems are becoming more prevalent. Well-established facilities tend to have the most computer and automated systems in place, she said.

Doleski reviewed the three primary regulations for computer systems: 21 CFR Part 11: Electronic Records; Electronic Signatures, 21 CFR Section 211.68: Automatic, Mechanical, and Electronic Equipment, and 21 CFR Sections 820.70(i) and 820.72: Quality System Regulations.

Regarding the previously controversial Part 11, Doleski refreshed the audience's memory regarding the narrow interpretation of the rule, encapsulated in a 2003 guidance. "We intend to exercise enforcement discretion with regard to Part 11 requirements for validation, audit trails, record retention, and record copying in the manner described in this guidance and with regard to all Part 11 requirements for systems that were operational before the effective date of Part 11 (also known as legacy systems)," said Doleski. "We will enforce all

predicate rule requirements, including predicate rule record and recordkeeping requirements."

Trudel continued the discussion of regulations by highlighting a December 2008 revision to 211.68. FDA added new paragraph (c) to the rule:

*Such automated equipment used for performance of operations addressed by § 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation.*

Explaining the paragraph, Trudel said, "The addition of this paragraph actually to me just acknowledges the fact that our industry is incorporating the use of computer systems more and more. What it essentially says there is in lieu of having verification a team of individuals when

operations are conducted by automated system or computer system, only one person is required for verification." She noted that the relevant regulations were updated accordingly as well.

### Type C Meetings also for Computers

Computer systems should be discussed in Type C meetings, which are a category of meetings established under the Prescription Drug User Fee Act. The Type C meeting specifically is for manufacturing processes and facilities.

Doleski characterized the Type C meeting as a "good opportunity for companies to get some advanced feedback from FDA prior to embarking on the construction of a new facility or major revisions to your current facility or manufacturing process."

When discussing computer systems at a Type C meeting, firms should do the following, according to Doleski:

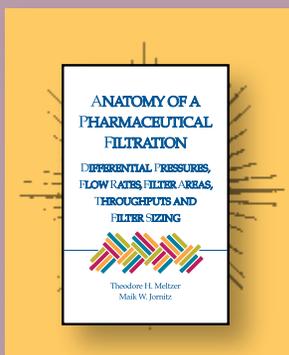
- Describe the functionality, as well as the validation plan

## New Releases from the PDA Bookstore

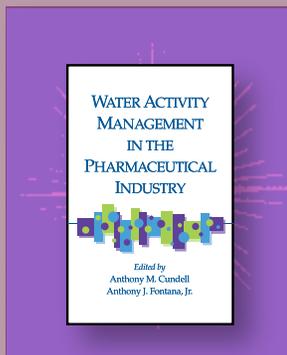
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#### Pharmaceutical Filtration: The Management of Organism Removal

By Theodore H. Meltzer, PhD and Maik W. Jornitz  
Item no. 17235  
Member: ~~\$250~~ **\$220**, Nonmember: \$309

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- Present diagrams (network, functional, data flow, process): at least the highest level
- Describe limits and alarms
- Discuss records and signatures

Regarding the validation plan, “a good level of detail” is the summary portion of the validation plan/protocol, Doleski said. The number of lots manufactured to validate the system, particularly for distributed control systems, should be disclosed.

FDA also will want to preview all the documents related to the computer system, including:

- User Requirements
- Design Specifications
- Gap Analysis
- System Configuration
- Systems Integration
- Data Generated by System

To conclude their presentation, Trudel and Doleski shared a number of inspection violations, cited on inspection reports (483s) and warning letters (see sidebar for a sampling of the violations presented).

#### 2009 Annual Meeting Closes with Technology’s Promise

The final two talks of the 2009 PDA Annual Meeting looked at the future of technology in the industry.

**Bob Lenich**, Director, Process Systems & Solutions, Emerson Process Management, demonstrated how strategic deployment of technology during each stage of manufacturing and control can help companies achieve “the right product, first time, every time.”

Lenich concluded that there are “compelling business opportunities” in life science manufacturing. Firms need to “optimize manufacturing work activity.” In addition, they must “integrate data in the context of both the process and manufacturing.” Finally, firms must be adept at making “data available to where it is needed, especially in process development and manufacturing.”

Closing out the session was Amgen Quality VP and PDA board member **Martin VanTrieste**. Echoing some of Morrison’s predictions, VanTrieste noted that a “major storm is on the horizon” for the pharmaceutical industry, much of which is going to be driven by concerns over health care costs and pressures from “look-a-likes.”

Technology will provide much of the solution, according to VanTrieste. One way this will materialize is a “move away from people to process-dependent, proactive quality and regulatory systems.” VanTrieste asserted that many of the solutions are “right in front of our eyes, but we are reluctant to embrace them.” They include robotics, isolators, and real-time monitoring (e.g., on-line instantaneous micro detection, rapid sterility tests and on-line integrity testing).

Overall, the 2009 PDA Annual Meeting provide a lot of food-for-thought. Sandwiched between these thought-provoking plenary sessions were break-out sessions sating attendees with topic-specific knowledge to help them perform their daily jobs. Be sure to take a look at photos from the meeting in the “Faces and Places” on pages 38-40. 

## Computer-Related Inspection Citations

The following are computer-related inspection citations included on recent U.S. FDA 483s and warning letters. The citations were presented by CBER compliance officials **Nicole Trudel** and **J. David Doleski** on April 20 at the opening session of the 2009 PDA Annual Meeting.

1) The approved and validated Excel spreadsheet, automatically generated for the calculation of [an in-process specification], was manually altered by the laboratory technician; this person is not authorized for such changes and the approved and validated automated process was not followed.

2) For the Quality Control functionality test for [the product], a [calculation/function] is created from Excel spreadsheet. The Quality Assurance unit has not approved the spreadsheet, and its functionality has not been verified through a formal process.

[Presenter Note: The QA Department was unaware of the use of the spreadsheet.]

3) The distributed control system, which also serves as the building management system, is designed to categorize and trigger various alarms, but it is not designed to properly archive data; For example, alarm data on various servers has been lost due to lack of storage space.

4) DCS system for some unit operations (purification, concentration, CIP): Validation of DCS system early in product development

- Process changed over time
- Upgrade of system (hardware and software upgrades, but no major change in functionality)
- Batch record: Information captured on paper and electronically
- During inspection, a comparison of paper batch records and DCS recipe revealed two divergent processes – paper vs. electronic
- Two sets of process limits were completely different – Firm relied on paper-based limits
- Much wider tolerances for DCS system (alarms were never triggered, even when outside the process limits as defined by the batch record)

5) Warning Letter citation: *You failed to exercise appropriate controls over computer or related systems to assure that changes in master production are instituted, and input and output from the computer or related system of formulas are checked for accuracy and maintained [21 CFR 211.68(b)], in that there is no documentation to support software manufacturing changes performed to the [redacted] code used in the manufacturing of [redacted].*

6) Warning Letter citation: *You failed to establish test procedures or other laboratory control mechanisms designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity and to assure that any deviation from the written test procedures or laboratory control mechanisms shall be recorded and justified [21 CFR 211.160(a) and (b)].*

## A Look at the Past, Future of Regulatory Affairs

Bob Dana, PDA

It's the end of May as I write this update, and I realized it's been some time since I had an entry for the Quality and Regulatory Snapshot. (In the next issue of the *PDA Letter*, you'll be able to read some of my thoughts and reflections of the first half of the year in my alter ego—that of being responsible for PDA's training and education programs.) I pondered a bit about what this column should address, and I thought I'd try to follow a similar theme as I will do in next months in the TRI Update section—what's gone on in the past few months, and what may lie ahead.

For those of you who attended the PDA Annual Meeting and the pre-meeting workshop on Regulatory Trends and Contamination Control Technologies in Las Vegas, Nev., in June, some of this may be old news. For those who weren't able to be with us in Las Vegas, you may find some of this look backwards to be of interest.

At the workshop, FDA's **Rick Friedman** provided some information on regulatory findings associated with FDA inspections of Sterile Product Manufacturing Operations. In David Letterman-like fashion, Rick provided a pared down "Top Ten" list. Rick's list was the "Top Five"—the top five citations in inspections of these types of operations in Fiscal Year 2008. The list is reproduced below:

5. Quality control unit responsibilities and procedures are not in writing or fully followed [21 CFR 211.22(d)].
4. Inadequate equipment design, size or location [21 CFR 211.63]
3. Inadequate equipment cleaning, sanitizing and/or maintenance [21 CFR 211.67(a)]
2. Inadequate system for envi-

ronmental monitoring [21 CFR 211.42(c)(10)(iv)]

And the number 1 finding is (drum roll please):

1. Inadequate validation of sterile manufacturing [21 CFR 211.113(b)]

Rick went on to present examples of Warning Letter citations arising from inspections of sterile drug product manufacturing operations. Some examples of these citations, which support the frequent citation list include:

Design of the filling line requires frequent interventions, and the operator repeatedly put a hand in to move stoppers in the bowl using forceps.

Operators carry sterile stoppers from Class 10,000 areas to filling lines in Class 100 areas on trays that are not sanitized. These trays are stored on carts in a Class 10,000 Sterile Storage Room for extended periods. The trays are placed directly over the sterile hopper when charging the stoppers.

Utensils and equipment that directly contact sterile product were found to have defects which create a challenge for sterilization.

Rick was kind enough to allow me to use his slides for the **Inspection Trends/Regulatory Affairs** Interest Group meeting during our Annual meeting, and the complete presentation can be seen at the Interest Group website [**Note:** To view the presentation, please go to [www.pda.org/MainMenuCategory/ScienceandTechnology/Interest-Groups/ListofInterestGroups/Inspection-Trends.aspx](http://www.pda.org/MainMenuCategory/ScienceandTechnology/Interest-Groups/ListofInterestGroups/Inspection-Trends.aspx).] I suspect most of our readers will look at the list and the complete set of Warning Letter citations and say "we don't have these kind of problems in our shop." Still, these findings

come from somewhere, so readers might find it to be a good idea to just have a review of their operations to see.

And now a look forward to think about what might be happening in the coming months. As everyone is aware, we have a new Administration in the U. S. and new leadership at the Food and Drug Administration. Commissioner **Margaret Hamburg**, MD and Principal Deputy Commissioner **Joshua Sharfstein**, MD will no doubt have their own set of priorities for FDA and that will no doubt impact both FDA and the regulated industry. I suspect that the issues surrounding the global supply chain and how the players in that supply chain will work together to further strengthen systems to ensure the quality of excipients, active pharmaceutical ingredients (APIs) and drug products will continue to be another area of significant interest in the coming months.

In the area of global cooperation; we can hopefully look forward to agreements which will provide regulatory authorities the opportunity to do their jobs effectively and efficiently while reducing the burden associated with inspections from multiple regulatory authorities on manufacturing sites. One such agreement which has the potential to do just that was just recently announced. The EDQM has established bilateral confidentiality agreements with the U.S. FDA and the Australian Therapeutic Goods Administration (TGA) respectively to share non-public information regarding inspections of active pharmaceutical ingredients and excipient manufacturers. According to the announcement, these agreements will facilitate the participation of the three ►

*continued on the following page*

## IG Briefing

### Inspection Trends/Regulatory Affairs Interest Group Reviews FDA Inspection Findings

Bob Dana, PDA

The Inspection Trends/Regulatory Affairs Interest Group met on April 22 during the 2009 PDA Annual Meeting.

The meeting began with IG Leader **Bob Dana**, Sr. VP, Regulatory Affairs & TRI, PDA, reviewing a presentation given by CDER's **Rick Friedman**, Director, Division of Manufacturing & Product Quality, FDA, at the April 19 PDA Workshop on Cleanroom Technology and Contamination Control. The presentation listed the top five citations arising from FDA inspections of sterile drug product operations in 2008.

Examples of regulatory findings related to sterile products which appeared in warning letters were also presented, and the December 2008 changes in the drug product GMPs related to sterile products were highlighted.

[**Note:** Visit [www.pda.org/MainMenuCategory/ScienceandTechnology/Interest-Groups/ListofInterestGroups/Inspection-Trends.aspx](http://www.pda.org/MainMenuCategory/ScienceandTechnology/Interest-Groups/ListofInterestGroups/Inspection-Trends.aspx) to view slides from the presentation.]

Following the review of the presentation, an open discussion was held. Topics and points addressed included:

- Some FDA investigators have begun spending more time on the shop floor during inspections. They have spent more time on facility tours and observing actual operations and have been interviewing shop floor operators. This raises the question as to what's being done to ensure operators are adequately trained in how to interact with investigators
- How to address the pushback during internal and contractor audits/inspec-

tions that "FDA looked at that and didn't issue an FDA483 – why do we need to change"

- Differing interpretations of the regulations by various regulatory agencies and individual investigators, and how to address the difficulties this lack of harmonization causes
- Some investigators seem wed to the letter of the law, others seem more willing to evaluate the significance and impact of failing to comply with all provisions of SOPs if there are rational explanations and patient safety is not compromised
- The importance of management commitment and the responsibility senior management has for ensuring operations are properly resourced. ☺

## International Pharmaceutical Quality

The Dialogue Turns to Regulatory Inspections • The March/April issue is available at: [www.ipq.com](http://www.ipq.com)

Bill Paulson, IPQ

The increasing diversity of inspectors and regulatory agencies with which drug manufacturers must deal and the shift to a more quality systems-oriented compliance paradigm are forces prompting firms to clarify and refine their practices for inspection handling.

Regulators, in turn, are seeking to streamline the inspection process and are actively speaking out at public forums on how firms can help.

The advice from European and U.S. inspection experts on what companies should and should not be doing is markedly similar. The basic advice from both sides of the Atlantic is to clarify what investigators are asking for and what they are finding and to openly volunteer information that mitigates the concerns raised.

Firms are also being advised that investigators want to talk directly

to those involved in the operations under review and that putting up barriers to this open communication is generally counterproductive to a good inspection outcome. Likewise viewed as counterproductive are company efforts to direct or redirect the inspection process.

Operating under a more quality system/risk management-oriented framework, regulators are making it clear that compliance is not about the absence of manufacturing deviations and risks, but how firms are addressing them (*IPQ, July/Aug. 2008*). The new regulatory framework is prompting manufacturers to rethink how they are managing inspections and to enhance their communication skills to ensure that the strength of their quality system is conveyed to the inspector. ☺

*A Look at the Past, continued from previous page*

organizations in a pilot project involving European regulators, the U.S. FDA and TGA aimed at rationalizing international GMP inspections. The scope of the agreements includes exchange of information relating to active pharmaceutical ingredients and excipients used in the manufacture of medicinal products. Non-public information shared between the organizations is provided on a confidential basis and all parties have undertaken to protect any non-public information received.

I'm sure there will be more announcements to come. In the meantime, as always, we welcome your feedback on this issue of the Quality and Regulatory Snapshot, and would be happy to hear your thoughts for future topics and opportunities to improve. Until next time. ☺

## New Member Breakfast, Volunteer Luncheon Informs Members on Benefits

Hassana Howe, PDA

PDA hosted the 4<sup>th</sup> Bi-Annual New Member Breakfast and the 3<sup>rd</sup> Bi-Annual Volunteer Luncheon at the 2009 PDA Annual Meeting in Las Vegas, Nev. The Membership Advisory Board, chaired by **Susan Schniepp**, Vice President of Quality, Quality Systems, Javelin Pharmaceuticals, plans these events every year in an effort to orient PDA members with their member resources. The success of these events can be attributed to the Membership Advisory Board members, speakers and PDA staff members involved.

For the New Member Breakfast, Board Member, **John Shabushnig**, PhD, Sr. Manager/Team Leader, Quality Systems & Technical Services, Pfizer, and long-time New England Chapter volunteer **Louis Zaczkiewicz**, Principal Consultant, GxP Quality Consulting, gave insightful presentations on their PDA membership experiences and



informed members how to utilize PDA's membership opportunities.

At the Volunteer Luncheon, Director of Publishing, **Walt Morris**, PDA, gave a brief overview to highlight the various ways members can impact the industry through PDA.

Following this, PDA premiered a Volunteer Spotlight movie that highlights members and what they get out of volunteering. You can view this online at [www.pda.org/getinvolved](http://www.pda.org/getinvolved). Special thanks

to **bioMérieux, Inc.** for sponsoring this volunteer luncheon.

If you are a new PDA member and were unable to attend the breakfast, you can view the PDA Membership Orientation presentation online at [www.pda.org/membership](http://www.pda.org/membership). For more information on how to volunteer please visit [www.pda.org/getinvolved](http://www.pda.org/getinvolved). The next PDA New Member Breakfast and Volunteer Luncheon will be hosted at the 2009 PDA/FDA Joint Regulatory Conference in September. If you would like more information please visit [www.pda.org/pdafda2009](http://www.pda.org/pdafda2009) or contact the Membership department at [info@pda.org](mailto:info@pda.org).

We thank all the PDA volunteers who made these events possible. The events were successful and memorable to all. We look forward to making the next New Member Breakfast and Volunteer Luncheon just as successful at The Renaissance in Washington, D.C.! 🍷



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## PDA Japan's Chapter Meetings Deemed Successful, Draws Big Crowds

Yoshiaki Hara, Sartorius-Stedim

PDA's Japan Chapter has held several successful meetings from the end of 2008 to early 2009.

At its Annual Chapter meeting, on November 11-12, 2008, 350 attendees, along with the speakers from the Ministry of Health, Labour and Welfare; Pharmaceuticals and Medical Devices Agency (PMDA) Office of Compliance Standards GMP Expert **Takashi Nagashima**; **John Shabushnig**, PhD, Sr. Manager/Team Leader, Quality Systems & Technical Services, Pfizer, and presentations by nine PDA Japan Chapter Task Forces (API, Sterile product GMP, Quality Assurance/Quality Control, Development QA, Bio-Virus, Electronic Record/Electronic Signature (ERES), Kansai Studying, Technical education, Medical device), assured that the meeting concluded with much success.

Shabushnig's presentation on risk management operation was very detailed.

The PMDA investigator presented specific inspectional points with actual examples.

Next, the Chapter held a Symposium on Aseptic Processing on November 13, 2008 with Shabushnig as the speaker. With 120 participants including local inspectors, the event was successfully held as a collaborative activity with the PDA Japan Chapter Sterile Product GMP Task Force.

Shabushnig's presentation covered many aspects of Aseptic Processing from general considerations of layout and flow to Quality Risk Management and information Source concepts. At the end of the symposium, a panel discussion was carried out and numerous questions and discussions were raised. According to the evaluation results, more than 95% of participants appreciated the event and its contents.

PDA's Japan Chapter collaboration with PMDA, the review and GMP inspectional body of MHLW, started in February 2009. PMDA investigators participated in the PDA Japan committee groups as a part of a PMDA scheme to heighten their inspectional skill. This is "phase 1" of the collaboration between the PDA Japan Chapter and PMDA. An official letter from the PMDA Office Director **Yuichi Shimmi** to **Katsuhide Terada**, PhD, Professor, School of Pharmaceutical Sciences, Toho University and the PDA Japan Chapter Chair, stated the desire for PMDA to educate their personnel. They have already joined the following four committees of "Sterile product GMP," "API," "ERES," and "Bio-Virus." At the moment, twelve investigators have joined.

Through this initiation, we at the Japan Chapter have every intention of having a close relationship with PMDA. 🇯🇵



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## How to Keep Your Employees Happy and Productive in the Midst of a Recession

Donna LaMar, PhD and Betsy Laney

In light of today's economic landscape, it's more important than ever for companies to have happy and productive employees. When employees are loyal and engaged in the company, profits are higher. Conversely, when people feel unmotivated or undervalued, the company suffers. Additionally, studies show that engaged employees miss less work, perform better, and are more supportive of changes and willing to make them happen.

But keeping employees happy in any economy is hard work. Why? Because happiness is, primarily, an inside job. In other words, happiness comes from within a person. However, friends, family and employment can add to or detract from someone's happiness level. So if the workplace is stressful and/or painful things are happening, such as "back-stabbing" and gossiping, employees' production goes down.

Happy employees are also satisfied and feel a sense of accomplishment in their work. They like themselves and what they do, and they find satisfaction from their work—a sense that what they do is important and meaningful. Such feelings reduce stress, which is a major factor of productivity.

In order to make your workplace one where happiness and productivity thrive, consider the following guidelines.

### Be a "Good" Employer

A "good" employer is one who sets clear expectations to employees, including what is to be done, when it is to be done by, and where it goes after they complete their responsibilities. Within these expectations, you need to set clear boundaries, demonstrate healthy leadership and provide sound

direction. This means spelling out rules, regulations, policies and procedures. While you can usually accomplish this by creating a comprehensive employee manual, a good employer or manager will also use the "personal touch" by talking with employees in a group and in one-on-one settings.

Whatever expectations you set, make sure they are consistent with all employees. Include such things as clocking-in early, break times, lunch hours, etc. For example, is it acceptable to clock in early and leave work early? Are breaks mandatory? Will an employee be "docked" if they consistently take too long for lunch? The more issues and expectations you outline, the fewer problems arise, which leads to productive workers.

### Help Employees to Feel Valued

Be encouraging to your employees and offer praise when appropriate. Thank employees for doing a good job and let them know that you value them. Should something go wrong or someone makes a mistake, don't "punish" the person. Rather, talk to the person, teach the correct procedures and offer encouragement and further teaching when needed. Remember that punishing people only makes things worse in that the employee may become angry and bitter and may want to sabotage their work to get back at the company. If errors continue after correction, then you may need to evaluate that person to make sure he or she is a good fit for the job.

As an employer, you have an excellent opportunity to make a difference in your employees' lives. This may mean a smile, asking how their family is or asking about their interests or problems. If you

sense that someone is depressed, help that person get the necessary resources, as employees with depression have higher absenteeism, increased health problems and decreased performance. Remember that we are all humans working together to get through life. We need to care about each other to get the best results.

### Create a Productive Atmosphere

The physical layout of the office is important to maximizing productivity. People need enough room to work, the correct supplies/materials and a comfortable and pleasant environment. Make sure all equipment is designed ergonomically so that it positively motivates workers by helping them with their needs to do the work.

Ecotherapy is another element of a productive environment. Some factors of ecotherapy include:

- Make sure the environment has live green plants. People feel better about themselves, their jobs and the work they perform when they feel a connection to nature around them. In fact, workers who are near plants or windows report significantly higher job, boss and co-worker satisfaction than those without. They also report being happier. If live plants are not an option, pictures or murals of outdoor scenes have some benefit.
- Give employees healthy air to breathe. Indoor air pollution is a serious problem in buildings. Change air filters regularly, and if appropriate, allow employees to keep their windows open.
- Utilize real sunlight when possible. If offices or workspaces don't have window access, install full spectrum

or plant light bulbs in all fixtures, including overhead florescent lights.

- Offer healthy food choices in the cafeteria or break room. Healthy food helps people think better, improves mood and increases energy levels. Do a healthy food challenge at work to encourage people to eat better. Also, have a restaurant bring in healthy food occasionally for a catered lunch.
- Allow employees to personalize their work space, within reason. We all need a place to call our own.
- Make the workplace family friendly. Life balance is a major stressor for people. Therefore, allow workers to take time off for school events or to stay home with mildly ill children without using sick or vacation days. If possible, offer child care near or on premise. Research has shown the employer can subsidize the care because it saves so much money from decreased absenteeism. Offer 13 weeks of maternity leave and also some paternity leave, and have elder care resources and referral services and/or dependent care assistance plans in place.

### Get People Involved

Create a comprehensive employee manual that is clear and simply written. In it include procedures for handling every imaginable scenario, including family emergencies. Ask employees for their ideas for the manual so they feel a sense of ownership with the company.

Additionally, help employees feel involved by having regular meetings where everyone can voice their opinions and concerns. This has an added benefit in that the company can gain valuable information about products and concerns that will hurt the bottom line. Also, host special employee events where the family can be involved, such as picnics, fairs, workshops, etc. The more sense of “family” you can create, the more productive people will be.

Finally, have a designated charity where people can donate both money and

time. This helps each person to see the larger picture. Research indicates that people feel better and have better lives when they volunteer. It also helps the company’s bottom line by increasing employees’ performance and demonstrating to the community that the company cares.

### Keep ‘Em Happy; Keep ‘Em Working

When workers feel that they are a dynamic and essential part of the team,

they are more productive and willing to go the extra mile for their customers and co-workers. Therefore, give praise openly, set goals appropriate to the work and always take your employees’ needs seriously. By respecting and listening to your staff, you’ll be giving them the motivational push they need to stay loyal and committed to the company’s goals. And when you have a happy and productive workforce that is eager to contribute, your company can weather any economic storm. 🌊

### About the Author

**Donna LaMar**, PhD, and co-founder **Betsy Laney** are psychologists who created The Farm, an educational, mental health and preventive program for youth and families. They help people learn and grow, as well as heal from traumas, abuse and neglect. Working with animals, plants and nature, LaMar and Laney provide a unique form of eco-therapy and counseling to overcome life’s challenges. In addition, LaMar is working on her book, *If Marie Can Do it, So Can I!* about transcending abuse. For more information on their work, visit: [www.LivingFarm.org](http://www.LivingFarm.org) or call: 231-924-2401.

Send in your feedback on *Tools for Success* section.  
Email Emily Hough at [hough@pda.org](mailto:hough@pda.org).

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### Hassana Howe, PDA

PDA is dedicated to helping you—our valued Member—get the best deal during these tough economic times. That is why we are offering a two-year membership at a reduced price of \$449, giving you a savings of \$49.

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### Career Center

We are dedicated to helping you make successful connections to build and enrich your career. Through our everyday career resources and our PDA Career Fairs, we’ll help you connect and network with industry leaders and company representatives.

*continued on page 29*

# Volunteer Spotlights

## Amy M. Scott-Billman



VP, Global Regulatory Strategy, Immunotherapeutics, GlaxoSmithKline

**Education:** BS, Microbiology, Penn State University; MS, Biotechnology, Johns Hopkins University

**PDA Join Date:** 1992

**Areas of PDA Volunteerism:** PDA Board of Directors: 2005–present; RAQC member (2000-2007; Chair 2004-2006); BioAB member(2005-present); TRI Advisory

Committee member (2007-2008); PDA/FDA Conference Planning Committee member (1998–2004; Chair 2000)

**Interesting Fact about Yourself:** I was an U.S. FDA reviewer and inspector from 1987–1996. I was the one that convinced Mary Malarkey and Bob Sausville to get out of the lab and into the regulatory track at CBER! I enjoy travel, athletics (current passion is tennis), music, chocolate, friends and family (I am a confirmed Soccer Mom). I also played waterpolo in college.

**Why did you join PDA and start to volunteer?** As a reviewer and inspector with the U.S. FDA, I had often attended and very much enjoyed the PDA/FDA Joint Regulatory Conference and decided to join as a full member in the early 90s. My volunteer activities all began with one question from Jim Lyda just after I left the FDA and joined the industry in 1996. At a PDA/FDA conference, he asked me if I wanted to be more involved with PDA activities, including: speaking, moderating and serving on the PDA/FDA Conference Planning Committee. I said “Sure, would love to” and it all evolved from there—thanks Jim!!

**Of your PDA volunteer experiences, which stand out the most?** There are so many experiences that stand out, not the least of which is building such a great network of colleagues that provide a never ending source of information, support and also considerable fun! However, the most significant experience both professionally and personally must be my service on the Board of Directors which has allowed me to have a full view of the organization and the valued opportunity to have an impact on the strategic direction.

**How has volunteering through PDA benefited you professionally?** It has afforded me with an incredible network of colleagues as well as many opportunities for remaining knowledgeable about the cutting edge technologies and rapidly evolving regulatory environment. We can all get so engrossed in the day-to-day activities of our own jobs that

we forget to take a step back and make ourselves aware of the larger environment in which we work. The resources that PDA has made available to its membership and my volunteer activities have allowed me to maintain a critical connection to the world of the pharmaceutical industry outside of my company and beyond biologicals (my primary focus at GSK).

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*The resources that PDA has made available to its membership and my volunteer activities have allowed me to maintain a critical connection to the world of the pharmaceutical industry outside of my company and beyond biologicals.*

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**Which member benefit do you most look forward to?** I very much enjoy the PDA Newsletter every month and the new IPQ publication, but I must say that my favorite benefit is the PDA/FDA and Annual Conferences, which both provide great educational networking opportunities as well as a forum to relax a bit with colleagues and friends.

**Which PDA event/training course is your favorite?** PDA/FDA Joint Annual Conference as it allows exposure and access to the U.S. FDA in a setting, which I believe, they appreciate and in which they feel comfortable to speak openly. As a former “FDAer” it also gives me a great opportunity to catch up with old friends and chat about the latest views on the direction of the Agency.

**What would you say to somebody considering PDA membership?** If you want access to the latest information regarding the science, the challenges and the opportunities facing the global pharmaceutical industry; as well as access to an enormous global network of experts in a broad variety of technical disciplines, and numerous opportunities to become involved in shaping the strategic and scientific path of the industry, then PDA is the place for you!

PDA Volunteer Spotlights are available online: [www.pda.org/spotlight](http://www.pda.org/spotlight)

## Ursula Busse, PhD



Head of Project Office, Global Bio-Pharmaceutical Operations, Novartis

**Education:** PhD, in molecular and cellular biology; MBA, Université Laval, Québec City

**PDA Join Date:** August 25, 2003

**Areas of PDA Volunteerism:** PDA Annual Meeting Program Committee member (since 2006); PDA Canadian Chapter Officer (2005-September 2006), PDA Biotech

Interest Group (member)

**Interesting Fact about Yourself:** I was born and grew up in Northern Italy (Lago Maggiore) as the daughter of a German physicist. I studied biology in Germany (Tübingen) where I met my future husband, a Canadian, whom I joined in Canada (Québec City) in 1988. During my 18 years in Québec, I finished my studies and worked for small start-up biotech companies, first as a scientist and later on in quality assurance/regulatory affairs. As a family of five (I have three sons presently aged 7, 13 and 16 years), we moved back to Europe in 2006 where I joined Novartis Pharma in Basel as a project manager for biotech projects in Global Regulatory CMC. In July 2008, I changed to my current position as Head of Project Office for Global BioPharmaceutical Operations, Novartis. Having grown up and lived in different countries, I am fluent in four languages. In my free time I enjoy practicing sports, reading and playing the piano.

**Why did you join PDA and start to volunteer?** I joined PDA while attending one of their PDA/FDA Joint Regulatory conferences in Washington, D.C. in 2003. A year and a half later, I gave a presentation at a PDA conference in Rome and attended the PDA Annual Meeting in Chicago, where I got in touch with members of the staff and the

organizing committee. I was then invited to join the Program Planning Committee for the 2006 Annual Meeting, and also contacted the Canadian Chapter to ask if I could be involved in the organization of events in Canada.

**Of your PDA volunteer experiences, which stand out the most?** Actively participating in the PDA Annual Meeting's organization is surely what I enjoy most, and it is an experience I have had the chance to renew every year for a couple of years now. It is also a nice occasion to meet at least once yearly with other PDA volunteers and enjoy spending some time together, be it over drinks or on the dance floor!

**How has volunteering through PDA benefited you professionally?** It has put me into contact with people from other companies all over the world (networking), and has also enabled me to stay informed of new technical developments. Part of my current job is to organize workshops,

for which I can benefit from my experience in the PDA Program Planning Committees.

**Which member benefit do you most look forward to?** Access to scientific, technical and regulatory information is an important part of what PDA can provide to me.

*Access to scientific, technical and regulatory information is an important part of what PDA can provide to me. .*

**Which PDA event/training course is your favorite?** Although I have not had the chance to attend that conference for a while now, my favorite is clearly the PDA/FDA Joint Regulatory conference in Washington, D.C. For the quality and content of presentations, the possibility of direct interactions with employees from FDA, interesting and sometimes challenging discussions between industry and regulators, and also for its location in the wonderful city of Washington, D.C.!

**What would you say to somebody considering PDA membership?** Want to keep abreast of the most recent technical and regulatory developments? Extend your network of contacts to other interesting people within the industry and regulatory bodies? Share your experience and knowledge with colleagues from all over the world in international meetings? Then go for it!

### *PDA is here to help, continued from page 27*

Looking for a new job? Post your resume for free on the PDA Career Center site, search our career database and visit our career resources to get started—[www.pda.org/careers](http://www.pda.org/careers).

#### **Convenient Online Resources**

Members-only access to PDA's online membership gives you direct access to conference presentations, draft technical documents, informational archives, the PDA consultant and membership directories and much more.

#### **Community Groups**

Boost your technical, regulatory and leadership expertise by actively participating in PDA task forces, interest groups, committees and local chapters. Make your mark and advance the industry and influence the regulatory process—[www.pda.org/getinvolved](http://www.pda.org/getinvolved).

#### **Local Resources**

All PDA members have free memberships to their local chapter. Chapter activities are the best way to

network with local peers while attending affordable educational forums and conferences. Find your local chapter—[www.pdachapters.org](http://www.pdachapters.org).

If you have any questions regarding your membership please contact us: + 1 (301) 656-5900 or [info@pda.org](mailto:info@pda.org). ☺



# 2010 PDA Pharmaceutical Cold Chain Management Conference

April 12-15, 2010 | Bethesda, Maryland  
Conference | Exhibition | Course

## 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 regarding cold chain management? Such as:

- Solved an unusually difficult technical or logistics problem
- Qualified a difficult transport or storage process
- Developed a unique material, component or process that benefits cold chain professionals and the pharmaceutical/biopharmaceutical industry in their handling of temperature-sensitive products
- Improved the process for measuring and/or monitoring temperature during the transport or storage of temperature-sensitive products

If so, submit your abstract to become a presenter at the *2010 PDA Pharmaceutical Cold Chain Management Conference!* Share your expertise and advance your career.

Abstracts must be non-commercial in nature, describing new developments or processes that significantly contribute to the body of knowledge relating to pharmaceutical cold chain management and technology. Industry case studies with data demonstrating advanced technologies, efficiencies or solutions for Good Distribution Practices and integrated supply chain management will receive special consideration. All abstracts will be reviewed by the Program Planning Committee for inclusion either as a podium presentation or in a poster session and the Committee reserves the right to reject any abstracts that do not contribute to the objectives of the overall program.

**Abstracts must be received by July 31, 2009 for consideration.  
To submit your abstract today visit us online at [www.pda.org/coldchain2010](http://www.pda.org/coldchain2010)!**

Submit a scientific abstract for podium or poster presentation at the *PDA 2010 Pharmaceutical Cold Chain Management Conference*, which will be held April 12-13, 2010 at the Hyatt Regency in Bethesda, Maryland. All submissions have required fields which need to be satisfied; incomplete submissions will not be considered.

Please include the following information with your abstracts:

- |                         |  |
|-------------------------|--|
| > Title of abstract     | > 2-3 paragraph abstract, summarizing your topic (200 word max)  |
| > Presenter's biography | > Delivery method of presentation (podium or poster)   |
| > Additional presenters | > Target audience (by job title or department)   |
| > Full mailing address  | > Explanation of specific take-home benefits your target audience can use immediately on-the-job               |
| > Professional title    | > Key objectives of your topic and what new information you will present that has not been presented elsewhere |
| > Phone number          |  |
| > Fax number            |  |
| > Email address         |  |

Upon review by the Program Committee, submitters will be advised in writing of the status of their abstract after September 15, 2009.

### QUESTIONS?

Contact PDA:

**Leon Lewis**

Assistant Manager, Programs and Web seminars

Tel: +1 (301) 656-5900 ext. 149 | Fax: +1 (301) 986-0296

Email: [lewis@pda.org](mailto:lewis@pda.org)

### 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 Nahid Kiani at [kiani@pda.org](mailto:kiani@pda.org) or +1 (301) 656-5900 ext.128.

[www.pda.org/coldchain2010](http://www.pda.org/coldchain2010)

## Chapter Contacts

The following is a list of the PDA Chapters, organized by the regions of the world in which they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and his or her email address. Where applicable, the Chapter's website is listed. More information on PDA Chapters is available at [www.pda.org/chapters](http://www.pda.org/chapters).

### Asia-Pacific

#### Australia

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Email: [robert.caunce@hospira.com](mailto:robert.caunce@hospira.com)  
[www.pdachapters.org/australia](http://www.pdachapters.org/australia)

#### Japan

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#### Korea

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#### Taiwan

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Email: [shinyi.hsu@otsuka.com.tw](mailto:shinyi.hsu@otsuka.com.tw)  
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### Europe

#### France

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#### Ireland

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#### Israel

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### Italy

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### United Kingdom

Contact: Siegfried Schmitt, PhD  
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[www.pdachapters.org/unitedkingdom](http://www.pdachapters.org/unitedkingdom)

### North America

#### Canada

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Email: [vagiha\\_hussain@baxter.com](mailto:vagiha_hussain@baxter.com)  
[www.pdachapters.org/canada](http://www.pdachapters.org/canada)

#### Capital Area

Areas Served: DC, MD, VA, WV  
Contact: Allen Burgenson  
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[www.pdachapters.org/capitalarea](http://www.pdachapters.org/capitalarea)

#### Delaware Valley

Areas Served: DE, NJ, PA  
Contact: Art Vellutato, Jr.  
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[www.pdadv.org](http://www.pdadv.org)

#### Metro

Areas Served: NJ, NY  
Contact: Lara Soltis  
Email: [lsoltis@texwipe.com](mailto:lsoltis@texwipe.com)  
[www.pdachapters.org/metro](http://www.pdachapters.org/metro)

#### Midwest

Areas Served: IA, IL, IN, KY, MI, MN, MO, ND, OH, SD, TX, WI  
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Email: [peter\\_noverini@baxter.com](mailto:peter_noverini@baxter.com)  
[www.pdachapters.org/midwest](http://www.pdachapters.org/midwest)

### Mountain States

Areas Served: CO, ID, KS, MT, NE, NM, OK, UT, WY  
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[www.pdachapters.org/mountainstates/](http://www.pdachapters.org/mountainstates/)

### New England

Areas Served: CT, MA, ME, NH, RI, VT  
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### Puerto Rico

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### Southeast

Areas Served: AL, AR, FL, GA, LA, MS, NC, SC, TN, VA  
Contact: Michele Creech  
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[www.pdachapters.org/southeast](http://www.pdachapters.org/southeast)

### Southern California

Areas Served: AZ, CA, HI  
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[www.pdachapters.org/southerncalifornia](http://www.pdachapters.org/southerncalifornia)

### West Coast

Areas Served: AK, CA, NV, OR, WA  
Contact: Elizabeth Leininger  
Email: [eleininger@gmail.com](mailto:eleininger@gmail.com)  
[www.pdachapters.org/westcoast](http://www.pdachapters.org/westcoast)

# Please Welcome the Following Industry

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**Hiroshi Akimoto**, Daiichi Sankyo

**Sara Alonso**, Crystal Pharma

**Shawn Anderson**, New England Student Chapter

**Linus Andersson**, Q-Med

**Caroline Ansermet**, B. Braun Medical

**Roger Asselta**, Genesis Packaging Technologies

**Laura Bacigalupi**, Associates of Cape Cod

**Noureen Bano**, Pall

**Steve Bao**, Valsource

**Thomas Barnes**, Bnbkennel

**Jason Becker**, Sanofi Pasteur

**Fred Bickel**, ProPharma Group

**Avril Bland**, Pharmaceutical Services Corp

**Nancy Brady**, Abbott Medical Optics

**Christian Campos**, Octapharma

**Matthew Carbery**, Meridian Medical Technologies

**Eric Carlson**, Covington & Burling

**Karin Chaing**, Millipore

**Ujjal Chakravarty**, Novartis (CibaVision)

**Hsiao-Wui Chan**, Taiwan Green Cross

**James Chan**, Lotus Pharmaceutical

**Ben Chang**, Sunway Scientific

**Jenny Chang**, Sanofi-Aventis

**Celine Chang**, Sanofi-Aventis

**Hsiu Chi Chang**, Purzer Pharmaceutical

**Yite Chang**, Standard Chem. & Pharm.

**Amy Chang**, United Biomedical

**Ching Hsiung Chang**, Shun-Yi Machinery Engineering

**Wen Tsan Chang**, Union Chemical & Pharmaceutical

**Jing Chien Chang**, Weidar Chemical & Pharmaceutical

**Calvin Chang**, Synmosa Biopharma

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**Ming-De Chao**, Nang Kuang Pharmaceutical

**Whitney Chen**, Nang Kuang Pharmaceutical

**Victor Chun-Tsui Chen**, Wu Fu Laboratories

**Diane Chen**, Adimmune

**Tenn-Tzong Chen**, Institutes of Nuclear Energy Research

**Bin-Ken Chen**, Yung Shin Pharm

**Jackson Chen**, Wu Fu Laboratories

**Waye Chen**, Y F Chemical

**Vicky Chen**, Sanofi-Aventis

**Chih Jen Chen**, Kelu Trading

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**Donald Chen**, Lotus Pharmaceutical

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Pharmaceutical

**Psue LE Chen**, Jen Sheng Pharmaceutical

**Lancy Chen**, General Biologicals

**Chin Jen Chen**, General Biologicals

**Michael Chen**

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**Camelia C.J. Chen**, Industrial Development Bureau

**Yu-Hsuan Chen**, Bureau of Food and Drug Analysis

**Yuhua Chen**, SCI Pharmtech

**Paul Chen**, China Chemical and Pharmaceutical

**Chun Ren Chen**, Chia Nan University of Pharmacy and Science

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**Heidy Chen**, Orient Europharma

**Chia Nung Chen**, Sunyou Biotech Pharma.

**Gan Lin Chen**, Yung Shin Pharm

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**Pen Chung Chen**, Nang Kuang Pharmaceutical

**Pen-Sung Chen**, Nang Kuang Pharmaceutical

**Huey Fang Chen**, Harvest Consulting

**His-Ho Cheng**, Grape King

**Jui Yuan Cheng**, Wyeth

**Hsiow Cheng**, Taiwan Pharmaceutical Manufacturer's Association

**Joyce Cheng**, Merck Sharp & Dohme

**Yu Ching Cheng**, Kojar Pharmaceutical

**Jui-Ching Cheng**, TTY Biopharm Company

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**Man Chi**, Taiwan Otsuka  
Pharmaceutical

**Jen-Ron Chiang**, Centers for Disease  
Control

**Shu Tuan Chiang**, Chuang Song Zong  
Pharmaceutical

**Liana Chiang**, Everest Pharm.  
Industrial

**Chung-Han Chiang**, Taiwan  
Liposome

**Huseh Chu Chiang**, Jen Sheng  
Pharmaceutical

**Yi Shi Chiang**, Taiwan Liposome

**Cheng Hsin Chien**, Adimmune

**Chia-E Chien**, Juiti

**Yu Ju Chien**, China Chemical &  
Pharmaceutical

**Hui-Chen Chiu**, Sun Laboratories

**Angela Chiu**, Lotus Pharmaceutical

**Shu-Mei Chiu**, Mycenax Biotech

**Shu Ling Cho**, Chen Ho  
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**Yu Shia Chuang**, GenuineChemical  
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**Buck Chung**, Y F Chemical

**Douglas Claney**, Cephalon

**Peter Clarke**, Savient Pharmaceuticals

**Robert Comerford**, Shire

**Carlyn Cox**, Wyeth

**Nelson Crank**, APP Pharmaceuticals

**Jorgen De Bondt**, Pfizer

**Toshio Deguchi**, Ostuka  
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**Danielle Desmarais**, New England  
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**Shiou-Shiow Fam**, Institutes of  
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**Yun Hsin Fan**, Hua Shin Chemical  
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**Dean Gibson**, Profile Pharma

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**Alberto Gonzalez**, Genentech

**Ryusuke Gotoda**, Hitachi Plant  
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**Harald Gruen**, West Pharmaceutical  
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**Meei-Jyuan Guo**, National Health  
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Technology

**Jason Hersh**, KleinHersh

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**Jerad Holcomb**, Hollister-Stier  
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**Stephen Hopp**, Agilent Technologies

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**Chen-Ming Hsiao**, Syn-Tech Chem.  
& Pharm

**Rong Bin Hsieh**, Syn-Tech Chem. &  
Pharm

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**Wen-Chin Hsieh**, Centers for Disease  
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**Ruey-Tsung Hsieh**, Oasis Chemical  
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**Chu-Huang Hsieh**, Everlight  
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**Yu Hui Hsieh**, Eusol Biotech

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**Otto Hsu**, General Biologicals

**Hussein Hsu**, Weidar Chemical &  
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**Chia Yuan Hsu**, Hwa Kuo Pharmacy

**Kuokuang Hsu**, Taiwan Otsuka  
Pharmaceutical

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*continued from previous page*

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**Chanwing Hsu**, Panbiotic Laboratories

**Tsung Che Huang**, Ho-Jing  
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**Molly Huang**, Yung Shin Pharm.

**Michael Huang**, Mycenax Biotech

**Yuan-Ru Huang**, Taiwan Veterans  
Pharmaceutical

**Jane Huang**, Taiwan Veterans  
Pharmaceutical

**Denny Huang**, Chunghwa Chemical  
Synthesis & Biotech

**Chi-Nan Huang**

**Su Yuan Huang**, Pei Li Pharmaceutical

**April Shu Yi Huang**, Root Chemical  
Pharmacy

**Chu Ping Huang**, Sunkem Fine  
Chemical Company

**Shou Hsiung Huang**, Amaranthine  
Effect

**Po Wei Huang**, Yuan Chou Chemical  
& Pharmaceutical

**Hengui Huang**, ScinoPharm Taiwan

**Yen-Chieh Huang**, Shou Chan  
Industrial

**Hau Jie Huang**, Bureau of controlled  
Drugs

**Tera Hung**, Environmental Protection  
Bureau Taichung County

**Li Yu Hung**, Chiu Jern Chemical

**Maan Tzww Hwang**, Mey See  
Pharmaceutical

**Yu-Ming Hwang**, Centers for Disease  
Control

**Jena Hwang**, Jen Sheng Pharmaceutical

**Johnny Hwang**, Purzer Pharmaceutical

**Gie Lieh Hwang**, GenuineChemical  
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**Mitsuyasu Ida**, Ajinomoto

**Yasuhito Ikematsu**, Hitachi Plant  
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**Koichi Ikesue**, Hisamitsu  
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**Atsutoshi Ikesue**, Hisamitsu  
Pharmaceutical

**Mitzie Isenhour**, Talecris  
Biotherapeutics

**Hideki Ito**, Astellas Pharma

**Naoharu Iwasaki**, Millipore

**Bi Cheun Jang**, Pei Li Pharmaceutical

**Zhu Jianming**, Changzhou Yabang-  
QH Pharmchem

**Matsuo Kamitani**, Hitachi Plant  
Technologies

**Randy Kang**, Jen Sheng  
Pharmaceutical

**Su-Chin Kao**, Weidar Chemical &  
Pharmaceutical

**Toshiyuki Katsura**, Ajinomoto

**Hideaki Kawada**, Ostuka  
Pharmaceutical Factory

**Ina Kessler**, Boehringer Ingelheim

**Megan Kinney**, Genzyme

**Makoto Kitano**, BioReliance

**Christian Klock**, Sanofi Pasteur

**Hui Hsiung Ko**, Panion & BF Biotech

**Tian Tze Ko**, Chung Mei  
Pharmaceutical

**Min Chun Ko**, Global Medical  
Solutions

**Hua Sheng Ko**, Chin Teng  
Pharmaceutical

**Sharona Kolender**, Rafa Laboratories

**Tsuneo Komatsubara**, Takeda  
Pharmaceutical Company

**Hyesuk Kong**, FDA

**Yasuto Koyama**, Shionogi

**Sung-Ting Kuan**, Tolin  
Pharmaceutical Industries

**Chen Nong Kuo**, Panion & BF  
Biotech

**Meng Kai Kuo**, Pei Li Pharmaceutical

**Lien-Yao Kuo**, Yung Shin Pharm.

**Yu-Tzu Kuo Wang**, Wei Li  
Pharmaceutical

**Hideki Kurashima**, Nihon Pall  
Scientific and Laboratory Services

**Andy Ladwig**, E2Joy

**Chun Fu Lai**, Everest Pharm. Industrial

**Hung Yi Lai**, Panion & BF Biotech

**Chi-Feng Lai**, IBL Pharmaceutical

**Peter Lai**, United Biomedical

**Kam Tong Law**, Zhengjiang Chiral  
Medicine Chemical

**Paul LeClaire**, Bayer

**Li Fan Lee**, IBL Pharmaceutical

**Ya Hui Lee**, Eusol Biotech

**Hsiang Lan Lee**, Taiwan Takeda  
Industries

**Jimmy Lee**, Millipore

**Hsun-Chi Lee**, Y F Chemical

**Elaing Lee**, Standard Chem. & Pharm.

**Nettie Lee**, General Biologicals

**Hom Lee**, Kojar Pharmaceutical

**Eddy Lee**

**Joe Lee**, Kojar Pharmaceutical

**TsaiHung Li**, Sanofi-Aventis

**Hsien-Ta Li**, Ta Foong Vaccines &  
Biotech

**Se-Chun Liao**, Everest Pharm.  
Industrial

**Wu Chih Liao**, Taiwan Tanabe Seiyaku

**Mei-Hsiu Liao**, Institutes of Nuclear  
Energy Research

**Hsu Chen Liao**, Hui Chun Tang  
Pharma. Works

**Brian Lihou**, Design Space  
InPharmatics

**Wang Lin**, Astrazeneca

**Chih Yong Lin**, Yung Shin Pharm.

**Chien-Liang Lin**, Department of  
Health

**Shao Wen Lin**, Taiwan Tanabe Seiyaku

# Leaders to the PDA Community

- Ben Yuan Lin**, Chung Mei Pharmaceutical
- Bih-Jeng Lin**, First Elite Enterprise
- Hsue-Chen Lin**, Chang Kuo Chou Pharmaceutical
- Cheng Hung Lin**, Eusol Biotech
- Meihwa Lin**, Daiichi Sankyo Taiwan
- Chia-Ling Lin**, Sheng Chun Tang Pharmaceutical Industrial
- Ming Jong Lin**, Panion & BF Biotech
- Tong Lu Lin**, Grape King
- Chu Shin Lin**, Oriental Chemical Works
- Mao-Sen Lin**, Chen Ta Pharmaceutical
- Ming Der Lin**, Purzer Pharmaceutical
- Wen Jen Lin**, School of Pharmacy College of Medicine N.T.U.
- Kung Hwa Lin**, New Chemical and Pharmaceutical
- Jeremy Lin**, St. Shine Optical
- Rei-Wei Lin**, The Taiwan Medical News
- Shan Yang Lin**, Yuanpei University
- Huey Ying Lin**, Hui Chun Tang Pharma. Works
- Han-Min Lin**, Taipei Veterans General Hospital
- Wuu-Jyh Lin**, Institutes of Nuclear Energy Research
- Casper Lin**, Purzer Pharmaceutical
- Lichin Lin**, Taiwan Biotech
- Chih-Yung Lin**, Yung Shin Pharm.
- Howard Lin**, Syn-Tech Chem. & Pharm.
- Wen Yen Lin**, Caleb Pharmaceuticals
- Shyh-Shyan Lin**, National Health Research Institutes
- Chih-Chan Lin**, TTY Biopharm Company
- Tong Ho Lin**, Lotus Pharmaceutical
- Pi-Yun Lin**, King To Nin Jiom Medicine Maf.
- Tsae Liang Lin**, Taiwan Otsuka Pharmaceutical
- Hsiu Chih Lin**, Taiwan Otsuka Pharmaceutical
- Long Shi Lin**, Ming Ta Chemistry Pharmacy
- Tzu Chao Lin**, Ming Ta Chemistry Pharmacy
- Shu-Mei Lin**, Weidar Chemical & Pharmaceutical
- Fang- Liang Lin**, Kojar Pharmaceutical
- Wan-Shen Lin**, SCI Pharmtech
- Chang-Yueh Lin**, Taiwan Liposome Company
- Yih-Shyong Lin**, Oasis Chemical Industries
- Wennine Lin**, Ming Ta Chemistry Pharmacy
- Pai-Wea Lin**, Ming Ta Chemistry Pharmacy
- Greg Liposky**, MedImmune
- Joy VK Little**, PDA New England Chapter
- Mei-Fang Liu**, Oasis Chemical Industries
- Chih-Yu Liu**, Oasis Chemical Industries
- Wen Huang Liu**, Sanyo Pharmaceutical Industrial
- Chih-Piaj Liu**, TTY Biopharm Company
- Ming Yu Liu**, Siu Guan Chem. Ind.
- Meng Po Liu**, Center Laboratories I
- Jessie Liu**, Center Laboratories
- James Liu**, YenChen Machinery
- Chin Tsai Lo**, Kuang Hsing Biotech
- Dianna Lo**, Millipore Asia Taiwan Branch
- Pro-Long Lo**, Institutes of Nuclear Energy Research
- John Lohr**, Alcon
- Joseph Chi Chung Lu**, PharmEng International
- Teresa Lu**, Chang Kuo Chou Pharmaceutical
- Huan Hao Lui**, Taiwan Tanabe Seiyaku
- Shu Chei Lui**, Synpac-Kingdom Pharmaceutical
- Arthur Lyons**, New England Student Chapter
- Cheng Liang**, Ma Hua Shin Chemical Pharmaceutical Works
- RongQin Ma**, Zhengjiang Chiral Medicine Chemical
- Victoria Macazaga**, Laboratorios Clausen
- Melissa Malonson**, New England Student Chapter
- Leisha Martin**, Medicis
- Hiroyuki Maruyama**, Eli Lilly
- Atsushi Matsumoto**, Kyowa Hakko Kirin
- Hironori Matsuoka**, Toray Industries Inc. Okazaki Plant
- Diana Mauro-Martin**, Millipore
- Iain McGhee**, Novartis
- Erere Medu**, Robert Gordon University
- Lin Meihwa**, Daiichi Sankyo
- Thomas Menzel**, Bausch & Lomb
- Makoto Miyajima**, Daiichi Sankyo

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**Editor's Note:** Due to the large number of new members and page constraints, the rest of the New Member List will be run in the July/August issue.

## PDA/FDA Conference Keynote Speakers to Address Pharma's Future

### Industry Member, Lawyer, Banker to Focus On Challenges that Must Be Overcome Within Industry

PDA is pleased to announce that **Michael W. Bonney** of Cubist Pharmaceuticals, **Jacqueline R. Belk Scott, JD, ML**, of the National Academy for State Health Policy, and **Barbara Ryan** of the Deutsche Bank Securities, will kick start the *2009 PDA/FDA Joint Regulatory Conference* as keynote speakers during the Opening Plenary Session on Monday, September 14.

These three individuals have extensive knowledge and experience within the realm of the bio/pharmaceutical world. At the meeting, they will address the future of the bio/pharmaceutical industry, including the challenges we must overcome, most specifically in the manufacturing segment of the industry, in order to be successful.

Bonney has served as the President and Chief Executive Officer and as a member of the Board of Directors for Cubist Pharmaceuticals since June 2003. From

January 2002 to June 2003, he served as the President and Chief Operating Officer. From 1995 to 2001, he held various positions of increasing responsibility at Biogen, including Vice President, Sales and Marketing from 1999 to 2001. Bonney is a director of NPS Pharmaceuticals, and serves on the Boards of Trustees of the Beth Israel Deaconess Medical Center and Bates College. He is also a member of the Biotechnology Industry Organization Health Section Governing Body.

Scott, JD, ML serves as a Senior Program Director at the National Academy for State Health Policy (NASHP). Scott holds appointments at the Harrison Institute for Public Law at the Georgetown University Law Center, and Nyack College in Washington D.C. She concentrates her health policy work in the areas of coverage, access, disparities and vulnerable populations. Before com-

ing to NASHP, Scott spent 10 years as a Senior Fellow and Adjunct Professor at Georgetown where she concentrated her work on the legal and policy areas of public health law, children and family law, and race and gender equity.

Ryan is a Managing Director at Deutsche Bank Securities, and joined the firm (formerly Alex Brown & Sons), in April 1992 as a senior analyst covering the Large Cap U.S. Pharmaceutical Industry. Barbara has been covering the United States Pharma sector for 25 years (since 1982). Barbara has been recognized by the Wall Street Journal All-Star Analyst survey, and is a four-time member of the Institutional Investor All-America Research Team.

The *2009 PDA/FDA Joint Regulatory Conference* will be held in Washington, D.C., September 14-18. To learn more, visit [www.pda.org/pdafda2009](http://www.pda.org/pdafda2009). 

## Learn about Sporicides and Disinfectants Without Leaving the Office

Web Seminar • August 20 • 1p.m.-2:30p.m. EST

Jason Brown and Leon Lewis, PDA

**Jim Polarine** will present a web seminar on "Disinfectants and Sporicides to Address Mold and Bacterial Endospore Outbreaks" on August 20 from 1p.m.-2:30 p.m. EST.

Polarine's web seminar presentation will discuss the effects of sodium hypochlorite, quats, phenolics, alcohols, and hydrogen peroxide peracetic acid products against various molds such as *Aspergillus*, *Penicillium* and *Trichophyton*. Efficacy data on bacterial spores such as *Bacillus subtilis*, *Bacillus cereus*, and *Clostridium sporogenes* will also be presented and discussed. Time-kill studies as well as some hard surface data will be utilized to convey the results of efficacy studies conducted. This presentation will also cover some case studies from customers

with molds and bacterial endospores. Contact times, cleaning and disinfection methods, and methods to prevent mold and bacterial endospore contamination will be discussed

Polarine is a technical service specialist focused on microbial control in cleanrooms and other critical environments at Steris. He has lectured in North America, Europe, Asia and Puerto Rico on issues related to disinfection and sanitation in clean rooms. Polarine is a frequent industry speaker, a biology and microbiology instructor at the University of Illinois, and has worked on several book publications and article publications related to cleaning and disinfection and contamination control.

For more information about this web

seminar and other 2009 web seminar topics please visit [www.pda.org/webseminars](http://www.pda.org/webseminars). 

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Visit [www.pda.org/webseminars](http://www.pda.org/webseminars) for more information.

# Three Major Pharma Markets Represented at Visual Inspection Forum

Bethesda, Md. • October 19-22 • [www.pda.org/visual2009](http://www.pda.org/visual2009)

David Fredericks, Amgen and Roy Cherris, Bridge Associates International

Globalization. That is the buzz word in front of everyone involved in the business community these days. For the pharmaceutical and biotech industries, this global paradigm certainly is forefront in the minds and business plans of many of us.

In our quest for success, we must be able to angle our way through the maze of obstacles and challenges that the global marketplace presents. Among them are the stringent quality requirements for particulate matter control and container/closure defect inspection for our global products. Our success will be determined by our ability to navigate the many regulatory huddles, harmonize inspection practices and successfully adopt the newly emerging technologies.

The *2009 PDA Visual Inspection Forum* is a continuing series which is presented

each year alternating between the United States and Europe. Last year it was held in Berlin, Germany and continues to be a superior event focusing on this important topic. If these global challenges are impacting you and your business model, then the *2009 PDA Visual Inspection Forum* is a must have for your calendar this fall on October 19-20 in Bethesda, Md.!

This fall's conference is lining up to provide access to the newest thoughts in visual inspection technologies, presented by the leaders in these developing techniques. This year's conference will also feature representation from all three major pharmaceutical markets namely Japan, the European Union and the United States. The conference will again be followed by the TRI course, "An Introduction to Visual Inspection"

(October 21-22), which has received excellent acclaim by previous attendees.

Prepare yourself for a comprehensive learning experience and speak with the industry leaders in visual inspection technologies, philosophies and requirements. Please plan to join us on October 19-20 in Bethesda, Md. for an enlightening two days with old and new friends and business acquaintances. ☺



## May Top 10 Bestsellers

1. **Practical Aseptic Processing: Fill and Finish, Volume I and II - New!**  
Edited by Jack Lysfjord  
Item No. 17283, PDA Member \$425, Nonmember \$530
2. **PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation**  
Item No. 01039, PDA Member \$100, Nonmember \$225
3. **Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics**  
By Scott Sutton, PhD  
Item No. 17242, PDA Member \$235, Nonmember \$289
4. **Biological Indicators for Sterilization Processes**  
Edited by Margarita Gomez, PhD and Jeanne Moldenhauer  
Item No. 17268, PDA Member \$280, Nonmember \$349
5. **Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded, Volume I and II**  
Edited by Richard Prince, PhD  
Item No. 17280, PDA Member \$375, Nonmember \$465
6. **Risk-Based Compliance Handbook**  
By Siegfried Schmitt, PhD  
Item No. 17281, PDA Member \$210, Nonmember \$259
7. **PDA Technical Report No. 44, Quality Risk Management for Aseptic Processes**  
Item No. 01044, PDA Member \$150, Nonmember \$250
8. **Radiation Sterilization: Validation and Routine Operations Handbook**  
By Anne F. Booth  
Item No. 17277, PDA Member \$225, Nonmember \$279
9. **Risk-Based Software Validation: Ten Easy Steps**  
By David Nettleton and Janet Gough  
Item No. 17256, PDA Member \$225, Nonmember \$279
10. **Technology Transfer: An International Good Practice Good Guide for Pharmaceutical and Allied Industries**  
Edited by Mark Gibson  
Item No. 17218, PDA Member \$265, Nonmember \$329

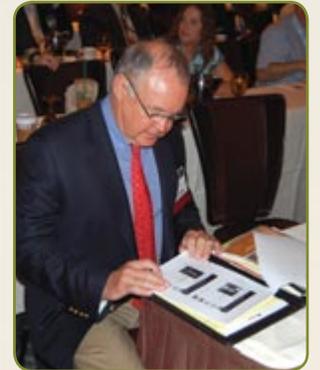
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# 2009 PDA ANNUAL MEETING Faces and Places: Conference Sessions



Bob Dana, PDA; Karen Ginsbury, PCI Pharmaceutical Consulting; Don Elinski, Lachman Consulting; Tor Gråberg, Medical Products Agency; Steve Mendivil, Amgen; Junko Sasaki, Dainippon Sumitomo Pharmaceuticals; Stephan Roeninger, F. Hoffman-La Roche



Bob Myers, PDA



John Shabushnig, Pfizer



Kris Evans, Amgen; Amy Scott-Billman, GlaxoSmithKline; Rebecca Devine; Rick Friedman, FDA



Ed Tidswell, Baxter; May Suet-Mui Tang, May Consulting Services; Gaël Péron, Sartorius Stedim; Jeffery Johnson, New Age Industries/AdvantaPure



Nicole Trudel, FDA; J. David Doleski, FDA; Ian Morrison; Ian Elvins, Loza Biologics



Stefan Köhler, AstraZeneca; Miquel Galan, Telstar Lyo; Stefan Sundström, AstraZeneca; Martyn Becker, Martyn Becker Associates



Tracy Meffen, Angiotech



Marsha Hardiman, BSI Management Systems; Robert Lutskus, Imclone Systems;  
Tim Coleman, Lonza Bioscience; Michael Miller, Eli Lilly



Gerald Budd, Phoenix Imaging; John Shabushnig, Pfizer



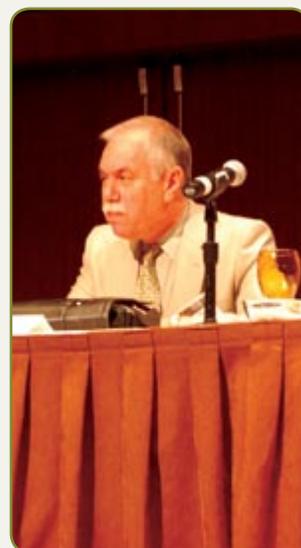
Christopher Procyshyn, VanRx Pharmaceuticals; Thomas Viot, BD Pharmaceutical Systems; Mattias Haag, EnergoRetea



Frank Kohn, FSK Associates; Amy Scott-Billman, GlaxoSmithKline;  
Rebecca Devine; Jane Halpern, Genoclea Biosciences;  
John Finkbohner, MedImmune



Former FDA Colleagues  
Joyce Bloomfield, Merck;  
Kris Evans, Amgen



Michael Gross,  
Chimera Consulting





The only thing missing are the blue suede shoes! Jerry Boudreault, Drug Development Resource, and wife, Carolyn, renewed their vows at an Elvis chapel in Vegas during PDA's Annual Meeting



Rebecca Devine; Maik Jornitz, Sartorius Stedim Biotech; Bob Myers, PDA; Shin-Yi Hsu, Otsuka Pharmaceutical; Tuan-Tuan Su, PDA Taiwan Chapter; John Shabushnig, Pfizer, are present for the signing of the information sharing agreement between PDA and TPDA



Sunrise in Vegas by Walter Morris, PDA

# Microbiology Meeting Showcases Posters and Exhibits

Bethesda, Md. • October 5-7 • [www.pda.org/microbiology2009](http://www.pda.org/microbiology2009)

Scott Sutton, PhD, Vectech Pharmaceutical Consultants

The PDA's 4<sup>th</sup> Annual Global Conference on Pharmaceutical Microbiology will be held at the Marriott Bethesda North Hotel & Conference Center on October 5-7. This year's program looks to be the strongest to date with a balanced offering of podium presentations, poster presentations, vendor exhibits and networking opportunities. The theme this year is particularly timely—"Bringing Microbiology to the Manufacturing Floor," as we do not need to look very deeply to find many examples of the difficulties resulting from too little consideration of microbiology in product production.

The first day's keynote speaker, **Stephen Denyer**, PhD, Head, Welsh School

of Pharmacy, Cardiff University, is an international expert on pharmaceutical microbiology with a particular interest in microbial pathogenicity and medical device infection, microbial detection and antimicrobial systems. His presentation, "Pharmaceutical Microbiology - The Move from the Laboratory to the Manufacturing Floor," will set the tone for the conference and is one that should not be missed.

The second day's keynote speaker will explore the topic of biofilms and their importance in industrial, medical settings and pharmaceutical settings. **Paul Sturman**, PhD, Industrial Coordinator, Center for Biofilm Engineering, Montana State University, will briefly describe the mechanisms of biofilms

formation and the methods used to study them, and then focus on what makes them so difficult to control and eradicate. This presentation is sure to be useful to those of us interested in water quality or cleaning studies.

Each day, following the keynote speakers, conference participants will be faced with a dilemma of sorts—choosing the sessions which are your favorites as the program offers parallel concurrent

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*The PDA microbiology meeting also provides a good opportunity to meet with vendors.*

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sessions and there are plenty of great topics to choose from. For a listing of the topics and timing for each session, make sure to go to [www.pda.org/microbiology2009](http://www.pda.org/microbiology2009) for details on the individual presentations.

An important aspect of vigorous scientific organizations is the opportunity for as many participants as possible to contribute to the content of the discussions at the meeting. Past attendees enthusiastically praised the use of poster sessions to achieve that goal. So, do not miss the poster session at this year's conference. With about 30 posters (approximately a 50% increase from the previous year) the poster sessions offer an opportunity for many more people to influence the discussion by interacting directly

with presenters. The subject matter represented in this year's poster session is very broad as well, covering topics ranging from basic science through regulatory science in virtually all areas of pharmaceutical microbiology. This is a great opportunity to get an in-depth description of some of the most current research underway.

The PDA microbiology meeting also provides a good opportunity to meet with vendors. While the meeting is large enough to attract a variety of vendors, it is not so large that the exhibit hall is a gauntlet to be run to find the vendor of interest. The microbiology meeting is always a good opportunity to learn about new products of interest or to

visit with vendors who might be able to provide a product or service to address a particular need in your lab.

Finally, all meetings are an opportunity to meet new people and catch up with friends. The presentations will be filled with people you know (or should know) in the audience, and the Monday night gala is always an opportunity for meeting new colleagues.

The organizing committee has made every effort to bring a strong program to the 4<sup>th</sup> Annual PDA Microbiology Meeting this October. I think we all would agree that the experience has been a rewarding one and hopefully the result is one that you will find useful. 🍷

## Training Opportunities Following the Microbiology Conference

Three training courses on pharmaceutical microbiology will be given on October 8 following PDA's 4th Annual Global Conference on Pharmaceutical Microbiology. The courses are on "Environmental Monitoring," "Microbiology of Water in a cGMP Environment," and "Microbiological Issues."

To learn more, visit [www.pda.org/microbiology2009](http://www.pda.org/microbiology2009)

## TRI's Instructors Inform Annual Meeting Crowd with Demonstrations and Courses

Stephanie Ko, PDA

The Training & Research Institute made quite an impact with its involvement at the *2009 PDA Annual Meeting* in Las Vegas, Nev. Attendees were educated with courses and demonstrations that covered a range of training topics currently critical to the industry.

To capture an up-close glimpse of the kinds of training that TRI offers, conference participants and exhibitors crowded our little corner booth to grab a chocolate bar and view the much-anticipated demonstrations by our TRI instructors. **David Matsuhiro**, President, Cleanroom Compliance, and lead instructor for our Aseptic Processing Training Program, treated onlookers to a display of proper **gowning techniques**. Dave also stirred quite a bit of excitement throughout the exhibit hall with Cleanroom Compliance's giveaway of a 37 inch LCD television to a lucky winner of PDA's passport drawing. **Mark Trotter**, Project Manager, Biotech Services Group, Sartorius-Stedim Biotech, and instructor for "Virus Clearance" Course and Workshop and "Biosystems Fundamentals, Bioreactors, Fermentation and Cell Culture – Theory and Practice," received quite a draw with his speech on **filter integrity testing**.

The third demonstration was presented by **Art Vellutato, Jr.**, VP, Technical Support Operations, Veltek Associates, and president of PDA's Delaware Valley Chapter. Art is the instructor for "Developing and Validating a Cleaning and Disinfection Program for Controlled Environments," and "Aseptic Processing Training Program." In addition to being the only individual with the knack (and courage!) for making PDA's announcements over the conference exhibit hall, Art gave a lively demonstration of **disinfectant efficacy testing**. Finally,



David Matsuhiro  
Cleanroom Compliance



Mark Trotter  
Sartorius-Stedim Biotech



Art Vellutato, Jr.  
PDA's Delaware Valley Chapter

**Jeanne Moldenhauer**, PhD, Excellent Pharma Consultants, instructor for the TRI courses "Rapid Microbiological Methods" and the "Aseptic Processing Training Program," led a demonstration with Battelle on **Rapid Microbiological Methods**. If you, like many, were captivated by any of the four educational

demonstrations, consider taking a step further by registering for the courses taught by the speakers. You won't be disappointed!

We are especially thankful to the committed individuals who stayed the remainder of the week for in-depth training from TRI. Attendees took advantage of the opportunities for expert led education and the wide range of courses offered. These courses were specially selected for our Annual conference and are only scheduled once this year. If you missed this opportunity, you should consider having these courses brought directly to your organization with in-house training:

- "Auditing for Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing"
- "Quality Programs – the Path to Continuous Improvement"
- "Media Fills for Aseptic Processing"
- "Risk Estimation in Aseptic Processing"
- "Practical and Effective Application of Design Review as a Risk Management Tool"
- "Cleanroom Management"
- "Development and Implementation of Qualification and Validation Programs – A Risk and Science Based Approach"
- "Introduction to HACCP an Other Risk-Based Systems as applied to Aseptic Pharmaceutical Manufacturing"

If you would like another opportunity to combine the benefits of attending a conference and training course in a single trip, consider joining us for the PDA/FDA Joint Regulatory Conference scheduled in September in Washington, D.C. 🇺🇸

## Upcoming PDA Training and Research Institute Courses

### Pharmaceutical and Biopharmaceutical Microbiology 101

July 27 – 31, 2009  
Bethesda, Maryland

### Fermentation/Cell Culture Technologies Training Workshop

July 28 – 30, 2009  
Bethesda, Maryland

### Rapid Microbiological Methods

August 3 – 7, 2009  
Bethesda, Maryland

### Application of Disposables in Biopharmaceuticals

August 25 – 26, 2009  
Bethesda, Maryland Open

### Safety Ventilation in Biotech and Pharmaceutical Cleanrooms; Risk Assessment of Airborne Contamination

September 9 – 11, 2009  
Bethesda, Maryland Open

### Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

September 10 – 11, 2009  
Bethesda, Maryland Open

### 2009 PDA Regulatory Conference Courses

September 17 – 18, 2009  
Washington, DC

### Pharmaceutical Water System Microbiology

September 29 – October 1, 2009  
Bethesda, Maryland

### Fundamentals of D, F, and z Value Analysis

October 5 – 6, 2009  
Bethesda, Maryland

### Validating a Steam Sterilizer

October 7 – 8, 2009  
Bethesda, Maryland

### Microbiological Issues in Non-Sterile Manufacturing

October 8, 2009  
Bethesda, Maryland

### Microbiology of Water in a cGMP Environment

October 8, 2009  
Bethesda, Maryland

### Environmental Monitoring

October 8, 2009  
Bethesda, Maryland

### PDA's 4th Annual Global Conference on Pharmaceutical Microbiology Training Courses

October 8, 2009  
Bethesda, Maryland

### 2009 Aseptic Training Session 5

October 12 – 16 and November 9-13, 2009  
Bethesda, Maryland

### 2009 New Brunswick Course Series

October 19 – 21, 2009  
New Brunswick, New Jersey

### Sterile Filtration in the Biopharmaceutical Industry

October 27 – 29  
Bethesda, Maryland

### Advanced Environmental Mycology Identification Workshop

October 28 – 30  
Bethesda, Maryland



**PDA** Parenteral Drug Association

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**New! CEUs available in 2009!**



PDA is approved by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Following full attendance, completion and submission of the appropriate evaluation form(s), certificates will be mailed within four to six weeks of the event. Continuing Education Units (CEUs) will be awarded as follows: 0.15 CEUs for 1.5 hours per Web Seminar.

## QbD Questions Answered at Upcoming Conference

Siegfried Schmitt, PhD, Parexel; Michiel Rook, Global ConSeptS; Volker Eck, PhD, PDA

This is our motto for the highly interactive PDA Workshops and Exhibition with respect to Quality by Design (QbD), September 22–23, in Frankfurt-Offenbach, Germany. The conference is focused on practical aspects of QbD.

The planning committee is privileged to have many distinguished experts from very different sectors of the pharmaceutical industry committed to present. For example, key personnel from the French Health Authority (AFSSAPS) will provide a “hot-off-the-presses” update on what was presented and decided in Yokohama, Japan, at the International Conference on Harmonisation meeting, which will take place just before this workshop. The intent is to provide you an idea of how any new ICH decisions could affect your day-to-day activities.

Another exciting moment will be the presentation of a “sneak peak” at the mock development sections of the Common Technical Document (CTD)—both for drug substance (S1) and drug product (P1)—by an expert group of the European Federation of Pharmaceutical Industries and Associations (EFPIA). This mock submission is based on real data and is meant to facilitate “QbD-type” submissions.

Knowledgeable people from Abbott and Wyeth will guide you through the nuts-and-bolts of QbD in a step-by-step exercise. The use of QbD principles in the development of both an API and an injectable drug product and the core data necessary to be integrated into the CTD will be extensively explained and illustrated.

This is your chance to get answers in applying QbD to development projects at your company. The workshops will offer ample time and space to have intense dialogue with the experts from EFPIA as well as from competent authorities like EMEA, MHRA and AFSSAPS. These resources will be at your disposal during the workshops.

### Join the Coffee Shop Discussions

Each afternoon of the workshop will be organized into coffee shop-style discussions to facilitate a organic discussions of the issues presented in the preceding morning sessions. Participants will be free to join or leave each “coffee table” as they like and follow their own personal agenda. A moderator and a scribe will be present at each table to facilitate and record discussions. Summaries of the coffee shop discussions will be captured and made available to the participants later on in the workshop.

Furthermore, conference delegates will get exposed to several aspects of QbD that must be considered in any QbD-driven project. The following lectures are examples of these highly informative presentations:

### “An Integrated Qbd Approach for Scientifically Based Process Development Enabling Risk-Based Approaches”

The presentation is based on case studies and will show the application of QbD to bioprocess development as well as to chemical process development. For biopharmaceutical processes, it will be demonstrated how dynamic process conditions help to gather scientific knowledge for the determination of parameters to define the design space and make sure that scale-up works. These key parameters must be extracted from raw data, preferably in an online context. Therefore the presented QbD approach not only covers online measurement of the process variables but also the online exploitation and validation of the process, hence, combining PAT tools, the determination of the design space and Design of Experiments(DoE) with dynamic processing. Continuous processing, which is mainly applied in chemical processes, enables knowledge-based and precise processing. This method gives the possibility to generate a maximum of production process knowledge in a minimum of time by using continuous

working lab scale plants. Critical Process Parameters (CPP) are worked out by a systematic description and verified by DoE. The information is generated in three steps:

1. Estimation by experts
2. Data analysis
3. Experimental work based on DoE

With this methodology cause-effect relationships can be easily followed in complex processes and process chains. On this scientific basis, a risk based approach can be applied, taking into account the ICH Q9 principles. It will be shown that quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle. The risk management is generated again in three steps:

1. Risk assessment
2. Risk control
3. Risk review

Quality risk management supports a scientific and practical approach to decision-making. The authors will demonstrate the risk ranking and risk filtering by practical examples and during the workshops.

### Quality by Design in Formulation and Process Development for a Freeze-Dried Parenteral: A Case Study

The National Institute for Pharmaceutical Technology and Education in the United States and U.S. FDA are collaborating on a case study regarding formulation and process development for a representative freeze-dried parenteral as a means of providing guidance on a Quality by Design approach. Sodium ethacrylate was chosen as a model compound. This presentation will include a progress report on this project illustrating identification of a target product profile, identification of quality attributes, as well as the risk analy-

sis process. You will understand better, what FDA has in mind, when it comes to QbD for lyophilised injectable drug products.

#### **Qbd/PAT Implementation Strategy in Drug Product Manufacturing on an Already Existing Commercial Product**

The presentation will go into the possible strategies of QbD/PAT implementation and the strategy which Novartis is following. The reason they are trying to implement PAT will be shown to be reducing the incoming variability in order to deliver predefined quality each and every time. The utilization of quality risk management tools for finding the CPP will be demonstrated. This includes fishbone diagrams and Failure Mode and Effects Analysis's. IT and automation infrastructure are necessary for using Multi Variant Data Analysis (MVDA) during manufacturing. The

need for MVDA in manufacturing as a confirmation of the established design space will be described. Risk management tools are very helpful in the search for the CPP. Before the implementation of a control strategy those will have to be known in order to prevent installa-

shown that process analysers should only be utilized when they are capable of increasing process understanding. MVDA is a powerful tool for monitoring the manufacturing process, increasing process understanding and acting as a confirmation of the established design space. You will be able to learn more about this also during the workshops.

These abstracts are just a few of the exciting lectures and interactive workshops the meeting is composed of. You cannot miss this opportunity to interact with industry leaders and QbD experts and get your questions answered. If you are curious to learn more, please get an up-to-date agenda, all the speakers and topics from the PDA website.

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tion of too many process analysers and the associated problem of handling enormous amounts of data. It will be

We look forward to welcoming you at the conference. ☺

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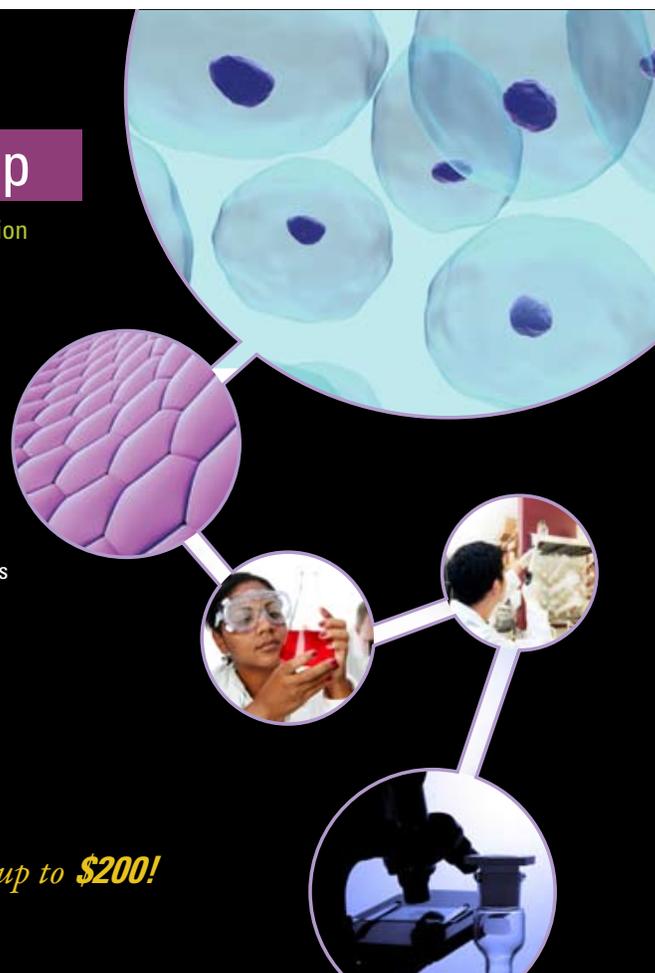
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