

PDA Letter

Volume XLVII • Issue #10

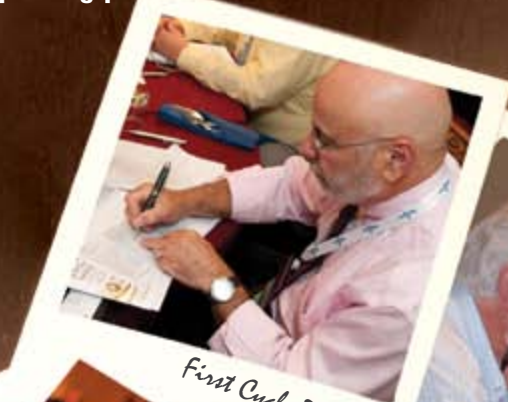
www.pda.org/pdaletter

November/December 2011

2011 PDA/FDA Conference Wrap Up



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PARENTERAL DRUG ASSOCIATION TRAINING AND RESEARCH INSTITUTE (PDA TRI)

Aseptic Processing Training Program

2012 Schedule:

Session 1:

Week 1: January 15-19
Week 2: January 22-26

Session 2:
Week 1: March 5-9
Week 2: March 26-30

Session 3:

Week 1: May 14-18
Week 2: June 4-8

Session 4:

Week 1: August 20-24
Week 2: September 10-14

Session 5:

Week 1: October 15-19
Week 2: November 5-9

The most comprehensive program in the preparation of sterile parenteral products

This two week comprehensive training program, taught by 20 industry leading experts in their fields, with over 300 years of combined experience, will give you and your personnel the training and information needed to properly evaluate and improve your aseptic processes to ensure sterile products. This program provides the perfect balance of hands-on laboratory and lecture training, equipping you with tools and actual experience you can bring home and apply immediately on the job.

For more information contact:

James Wamsley, Senior Manager, Laboratory Education
Tel: +1 (301) 656-5900 ext. 137 | E-mail: wamsley@pda.org

Location:

PDA Training and Research Institute
4350 East West Highway, Suite 150, Bethesda, MD 20814
Tel: +1 (301) 656-5900 | Fax: +1 (301) 986-1093

Benefits of Attending

- Learn to relate and incorporate each component of aseptic processing into one operation for an overall improved process and finished product
- Understand the theory and practice behind personnel gowning and aseptic technique qualification to minimize risk of product contamination by personnel
- Use proper environmental monitoring techniques combined with a good cleaning and disinfection program to avoid common sources of contamination in your facility
- Learn to incorporate proper documentation practices into your aseptic processing program to facilitate regulatory compliance

Learning Objectives

Upon completion of this course, you will be able to:

- Demonstrate an increased proficiency of techniques and skills relating to aseptic processing
- Evaluate and improve current aseptic processing procedures at your facility
- Limit risk for manual product contamination with airflow visualization studies
- Evaluate your environmental monitoring program to collect appropriate data, identify and interpret trends
- Incorporate proper gowning principles into a complete personnel qualification program
- Describe the importance of filter integrity testing when filtering water, gases, or proteinaceous solutions

SPACE IS LIMITED - REGISTER NOW:
www.pda.org/2012aseptic

The Parenteral Drug Association presents...



2012 PDA ANNUAL MEETING

*Manufacturing Innovation: Achieving Excellence in Sterile
and Emerging Biopharmaceutical Technology*

April 16-18, 2012

JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

Agenda Now Posted for the 2012 PDA Annual Meeting!

PDA is pleased to invite you to the 2012 PDA Annual Meeting. In its 66th year, this year's meeting will focus on the keystone of our industry: the manufacturing of quality products.

This meeting will commence with an opening plenary session featuring **David Shanahan**, President, *Mary Crowley Research Center* and President, CEO and Founder, *Gradalis* and **Ted Love**, MD, Executive Vice President, R&D and Technical Operations, *Onyx Pharmaceuticals* who will speak about the future of the biopharmaceutical industry and personalized medicine.

Highlights of this year's meeting include:

- 15 sessions broken out over three tracks
- 14 interest group meetings
- The Foundations Breakfast Sessions for those new to the industry and/or who want to refresh their knowledge on selected topics
- Breakfast Session: "Career Development Strategies"
- The *Single Use Systems Workshop* hosted immediately following the conference on April 18-19, 2012
- PDA TRI Courses hosted in conjunction with the conference on April 19-20, 2012
- And much more

Registration Now
Open for the 2012
PDA Annual Meeting!
Register Before
February 3, 2012 and
Save Up to \$400!

For details and to register, visit
www.pda.org/annual2012

EXHIBITION: April 16-17

POST-CONFERENCE WORKSHOP: April 18-19

COURSES: April 19-20



Cover



Cover Art Illustrated by Katja Yount

36 PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment

The third and last day of the *2011 PDA/FDA Joint Regulatory Conference* held in Washington, D.C. included traditional sessions wherein officials from the U.S. FDA provided updates on compliance matters and FDA Center initiatives.

40 Reasons for Missing the Mark of First Cycle Approvals

Regulators have between four to ten months to determine whether a new drug product or major manufacturing change is safe, efficacious and acceptable for approval.

42 Practical Recall Lessons Given at PDA/FDA

No matter how hard companies work and spend on ensuring product quality, recalls happen, so companies are advised to have plans in place to manage product recalls.

46 FDA PIC/S Its Friends

Since it became a member of PIC/S, the U.S. FDA has been exposed to additional regulatory support from the Organization.

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Get Involved with the *PDA Letter!*

Volunteer for the *PDA Letter* Editorial Committee

The *PDA Letter* Editorial Committee is looking for active PDA members to provide ideas and to comment on articles for the *PDA Letter*. For more information about this two-year volunteer commitment, please contact **Emily Hough** at hough@pda.org by December 15.

Authors Wanted!

The *PDA Letter* is looking for authors for the following topics:

Issue	Topic	Articles Due
March	1) Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology 2) Forecast for Targeted Drug Delivery Systems	January 20
April	Quality and Regulatory Legislation	February 3
May	Biofilm and Bioburden Management	March 2
June	Rapid Screening Methods: Review of Screening Methods and Regulatory Perspectives	April 2
July/August	Sterile Processing	May 14
September	FDA Organizational Changes	July 2
October	1) Biosimilars; Generics 2) Targeted Therapies	August 3
November/December	Reports from the <i>PDA/FDA Joint Regulatory Conference</i>	September 10

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



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2011 Strategic Plan Goals on Track

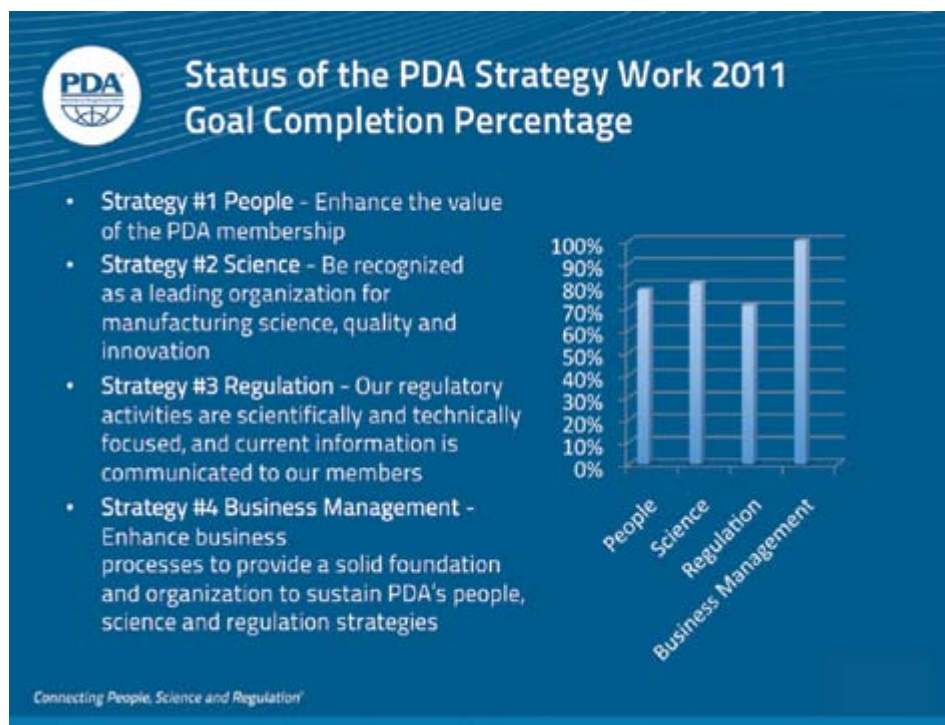
Richard Johnson, PDA

In the beginning of 2011, PDA published its updated strategic plan (see “PDA’s New Strategic Plan Unveiled,” page 6, January *PDA Letter*). We want to inform you how we are progressing on our 2011 strategy goals.

I am glad to report that we are doing very well; our progress is illustrated in the graphic on this page.

Also, I wanted to let you, the members, know that we will be refining our goals for next year so we can ensure that PDA continues progressing on the strategic plan. We will update you periodically on our progress.

If you have additional questions about PDA’s strategic plan, you can access our updated strategic plan on our website at www.pda.org/AboutPDA/PDA-2015-Strategic-Plan.aspx. Feel free to email me if you have any questions at Johnson@pda.org. 



“Filtration Week” Draws Large Student Body


Additional Advance Course Scheduled for Spring 2012

The recent “Filtration Week” Training at PDA TRI has been successful. Twenty-one participants attended the “Filters and Filtration in the Biopharmaceutical Industry” Basic and Advanced Filter courses.

This high attendance rate shows the importance and criticality of sterilizing grade filtration as well as the need to understand how to choose, optimize and test filtration processes.

“The training was highly interactive and extremely enjoyable, as questions and discussions create an atmosphere of learning by the participants and faculty alike,” **Maik Jornitz**, faculty member, said. “Training is one of the most important activities, as any human error can diminish elaborate and costly process validation fulfillments.” The basic course was a two day lecture based course, and the advanced course was a three day mix

of lecture and hands-on lab training.

“The lab activities create ‘aha’ moments. When things go wrong, and we make sure they do, participants learn the most,” **Wayne Garafola**, faculty member, explained. Since the advanced course only has room for a limited amount of participants, there have been requests for an additional course. PDA TRI will try accommodating an additional advanced course in the spring of 2012. 

Past PDA Chair Vince Anicetti Becomes New PDA Fellow

Rich Levy, PhD, PDA

I am pleased to announce the appointment of **Vince Anicetti** as PDA’s first Fellow for the Science and Regulatory Affairs Department. In this new role, Vince will provide strategic input into

the scientific, quality and regulatory activities of PDA, including multiple PDA Advisory Boards. He will participate in and provide guidance to approved PDA Task Forces across the lifecycle of the

teams, as well as work with PDA’s Interest Groups. He will also participate in program planning committee and education activities, and provide technical and regulatory input and support to in-

continued at bottom of page 8

GET AHEAD THE HARD WAY



If you're looking for a continuing education shortcut, you'll have to look somewhere else.

RAPS Online University is the gold standard in continuing education for healthcare products regulatory professionals, but you're going to have to work at it. In fact, RAPS Online University is everything you want in online continuing education. Except easy.

We didn't set out to make it easy.
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In Memoriam: Honorary Member Doris Conrad

Walter Morris, PDA, with contribution from Russell Madsen, The Williamsburg Group and Amy Scott-Billman, GSK

Doris L. Conrad passed away on Oct. 25. Doris was a trailblazer for women in the pharmaceutical industry and within PDA.

Amy Scott-Billman, who knew Doris both as a colleague at GSK and through PDA, said of her: “Doris made many, many significant contributions to the pharmaceutical industry and to PDA specifically, in the areas of manufacturing, quality and compliance. Numerous colleagues throughout GSK and in the PDA community have benefited over many years from Doris’s considerable wealth of knowledge and unsinkable spirit. She will certainly be missed, but her valuable legacy will live on.”

Doris’s dedication to PDA resulted in her rise to key leadership positions, including serving as the first female on the Executive Committee, as Secretary, in 1984-1985. She was part of the team that authored PDA *Technical Report No. 4: Validation of WFI Systems* (1983). Her co-authors were Fred Carleton and Robert Kieffer.

In 1990, Doris was named the Chairperson of the first *PDA/FDA Joint Regulatory Conference*.

She was recognized for her hard work and dedication to PDA by receiving the Frederick J. Carleton Award in 1993, designated for a past or present member of the PDA Board of Directors whose services on the Board are determined by his/her peers as worthy of such recognition. That same year, Doris served as the Chair of the fourth *PDA/FDA Joint Regulatory Conference*.

Doris next co-chaired the *Task Force for Technical Report No. 22: Process Simulation Testing for Aseptically Filled Products* (1996), a document that has stood the test of time and is about to be released in revised form by PDA.

Doris received the ultimate recognition for her devotion to PDA when she was granted Honorary Membership in 1997—the first woman to receive this prestigious honor. Over the last 10 years, Doris participated in PDA strategic planning and conference planning for the *PDA Pharmaceutical Microbiology Conferences* and served on the *PDA Letter* Editorial Committee.

Doris spent over thirty years working for Beecham Laboratories/SmithKline Beecham/GSK Biologicals. She worked nine years as a director of QA/QC (1978-1987), 10 years as director of QA/QC anti-infective drugs (1987-1997), and 14 years as director of QA/QC North America (1989-2003).

In recent years, she was a QA systems and compliance consultant for sterile products, working out of the Philadelphia area.

Doris was laid to rest at the West Mount Laurel Cemetery in Bala Cynwyd, Pa., on Oct. 28. ☺



Past PDA Chair Vince Anicetti Becomes New PDA Fellow continued from page 6

ternal PDA departments as needed.

Vince is currently an Adjunct Professor with the Keck Graduate Institute of Applied Life Sciences teaching in the area of Biopharmaceutical Quality, following a successful 30-year career with Genentech in which he held a series of significant leadership roles. Most recently, he served as the Head of Biologics Quality for the Roche/Genentech Biologics’ manufacturing network comprising 10 large-scale

Biotech product sites in North America, Europe and Asia. In this role, Vince was responsible for QA/QC operations at each site and GMP compliance.

Vince holds a BS in microbiology and MS in clinical chemistry from San Francisco State University. He serves as an editor/reviewer for *BioQuality*. Currently, Vince is the leader of the PDA Biotech Interest group, a member of the *PDA Letter* Editorial Committee and co-

chair of the 2012 PDA Annual Meeting.

Vince will start begin this new, part-time role November 28. I am personally pleased that he will be joining us as an integral member of our Science and Regulatory Affairs Department. Please welcome and congratulate Vince when you have the opportunity. His new e-mail address will be anicetti@pda.org. ☺

The Parenteral Drug Association presents...



2012 PDA Europe Upcoming Activities and Events

7-8 February	Clinical Trial Materials	Conference, Exhibition	Basel, Switzerland
28-29 February	Microbiology/Endotoxins/RMM	Conference, Exhibition, Training Course	Berlin, Germany
6-7 March	QbD: Impact on Analytics	Workshop, Exhibition	Liverpool, UK
13-15 March	Parenteral Packaging	Conference, Exhibition, Training Course	Berlin, Germany
20 March	Visual Inspection	Interest Group Meeting	Berlin, Germany
21 March	Pharmaceutical Freeze Drying	Interest Group Meeting	Berlin, Germany
27 March	Pre-filled Syringes and Injection Devices	Interest Group Meeting	Berlin, Germany
To be announced	PDA/EMA Joint Conference	Conference, Exhibition, Workshop, Training Course	To be announced
5-6 June	Advanced Therapy Medicinal Products	Workshop, Exhibition	Lisbon (Cascais), Portugal
12-13 June	Monoclonal Antibodies	Workshop, Exhibition	Vienna, Austria
25-26 September	Visual Inspection	Conference, Exhibition, Training Course	Berlin, Germany
9-10 October	Pharmaceutical Cold Chain Management & Good Distribution Practice	Conference, Exhibition, Training Course	Berlin, Germany
30-31 October	Pharmaceutical Freeze Drying Technology	Conference, Exhibition, Training Course	To be announced
6-7 November	Parenterals 2012 Integrating Process, Technology and Regulation	Conference, Exhibition, Training Course	To be announced
13-14 November	Outsourcing/Supply Chain	Conference, Exhibition	Amsterdam, The Netherlands
4-5 December	Modern Biopharmaceutical Manufacturing	Conference, Exhibition, Training Course	Lyon, France

For latest info: <https://europe.pda.org>

Subject to change

Shortlist 2011-10-12

For general information,
please contact

PDA Europe, Adalbertstr. 9,
16548 Glienicke / Berlin, Germany
Tel: +49 (0) 33056- 23 77 10
Fax: +49 (0) 33056- 23 77 77
info-europe@pda.org

For exhibition information,
please contact:

Ailyn Kandora
Event & Program Manager
PDA Europe
Tel: + 49 (0) 33056-237719
kandora@pda.org



<https://europe.pda.org>



Volunteer

Maik Jornitz, Sr. VP, Marketing Bioprocess, Sartorius Stedim Biotech



PDA Join Date: October 1994

Why did you join PDA? First of all, I had the benefit of a mentor, the late **Theodore Meltzer**, PhD, who introduced me to PDA. Once introduced, I realized immediately the incredible value of the organization in regard to gaining knowledge, networking with peers, and discovering trends within the industry and regulations. I have been involved with many other organizations and attended other conferences, but have not experienced the open-arms approach of PDA.

Of your PDA volunteer experiences, which have you enjoyed the most? It is difficult to boil it down to one experience, as there are many. The interest group meetings are always an excellent platform of exchange and learning. Task forces are focused and intense working sessions with experts, which creates knowledge enhancement. Meeting familiar faces at the Annual Meeting or the PDA/FDA Joint Regulatory Conference is always a pleasure.

How has volunteering in PDA benefited you professionally? PDA conference presentations and networking have created a knowledge gain which I would have not experienced without PDA. I am able to distribute the knowledge within my company, and I am known for it. It is not only a great feeling to be able to utilize the gained knowledge to support others, but it also helps support the company I work for. As part of a vendor organization, it has allowed my firm to move closer to industry's needs.

Which PDA conference/training course is your favorite? I very much enjoy the Annual Meeting and the PDA/FDA and PDA/EMA joint conferences; the networking is outstanding. Again, it is a pleasure to meet familiar peers as well as new members. In regard to the training course, I have to be biased and list the Filtration Training course that I teach. The reason is that I always enjoy the interaction, discussions, questions and team work within this course. It is a learning experience for both students and faculty.

What would you say to somebody considering PDA membership? Join! I have never regretted my decision to join. I am enthusiastic about the organization due to its support of the industry and regulators on a global basis, the ability to interact with colleagues and experts, volunteer opportunities which raise one's learning curve, and, last but not least, the PDA staff. These people have become friends over the years, and I respect them highly. 🍷

Anders Vinther, VP, Head of Quality Biologics Operating Unit, Genentech



PDA Join Date: 1995

Interesting fact about yourself: I am very interested in wines, and when I was deciding a career path I was accepted into the enology program at a wine university. I chose chemical engineering and the biopharmaceutical industry instead. My interest in wine has continued, however, and, I like visiting wineries when traveling around the world.

Why did you join PDA? At the time I was leading QC in my company and wanted to better understand the regulations and guidelines and influence them more in a scientific direction. PDA was, and still is, the premier organization for this dialog with the health authorities. I asked PDA how I could volunteer, and I quickly became involved with task forces and program planning committees.

Of your PDA volunteer experiences, which have you enjoyed the most? I have tried many things and liked all of them, because I work with great colleagues from companies and health authorities from around the world. Together, we advance science and regulations. PDA is really about what the tagline says—*Connecting People, Science and Regulation*®. The first exciting experiences I had were leading the out-of-specification task force and arranging the PDA/FDA Joint Regulatory Conference when the FDA draft guidance on aseptic processing came out. Most recently, my work as a member of the Board of Directors and the Executive Committee as Treasurer and now Chair Elect has been really rewarding.

How has volunteering in PDA benefited you professionally? Through my work with PDA, I have developed a great network with peers in industry and amongst health authority professionals. When there is a question I'd like to discuss, my fellow PDA members are never more than a phone call or email away. My current job at Genentech and Roche happened only because of my connections through PDA.

Which PDA conference/training course is your favorite? I have always liked the PDA/FDA Joint Regulatory Conference and have attended for probably more than 15 years. Also, the PDA/EMA Joint Conference is great. For both of them, I think the key thing is that you leave feeling that you are up-to-date on quality and regulatory matters.

What would you say to somebody considering PDA membership? Join now! You will immediately have almost 9,500 colleagues, access to a wealth of information and can help shape the future of pharmaceutical and biopharmaceutical science, quality and regulations. 🍷

2010 Honor Awards Recipients

The PDA Honor Awards are bestowed on members who provide exceptional leadership and service to the Association, and have been awarded at the Annual Meeting since 1958. The 2010 award winners were announced at the *2011 Annual Meeting* in April, and they will be highlighted in each *PDA Letter* until next year's event. This month we highlight the Frederick D. Simon Award.

Frederick D. Simon Award

This award is named in honor of the late Frederick D. Simon, a previous PDA Director of Scientific Affairs. It is presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology*.

The paper, *Root Cause Analysis of Tungsten-Induced Protein Aggregation in Pre-filled Syringes* was chosen by the Fred Simon Award Committee. It was published in the January/February 2010 issue of the *PDA Journal*.



Janice Davis, PhD



Erwin Freund, PhD



Yijia Jiang, PhD



Wei Liu, PhD



Anthony Mire-Sluis, PhD



Linda Narhi



Yasser Nashed-Samuel, PhD



Robert Swift



Gianpiero Torraca



Aylin Vance



Zai-Qing Wen, PhD

SoCal Chapter's Multilocation Supply Chain Event a Hit

Ruchika Raval, Global Biopharmaceutical Research

The PDA Southern California Chapter's third multilocation event was a resounding success, as approximately 170 attendees at five sites heard talks by speakers presenting live from three of the sites. This format has eliminated many challenges of member access to the chapter programs.

The chosen locations where Amgen's Thousand Oaks facility north of Los Angeles, Calif., Hilton Hotel in Irvine, Calif., Genentech's facility in Oceanside, Calif., Amylin Pharmaceutical facility in San Diego, Calif., and a U.S. FDA office in Washington D.C.

The August 30 half-day event called *Supply Chain Security in the Pharmaceutical Industry* provided insight on the current issues companies face while securing their supply chains; short- and long-term solutions were presented.

PDA Southern California Chapter President **Saeed Tafreshi** emphasized the importance of this topic, as it challenges the integrity of our industry, and invited the participants of this event to take part in supporting the industry by finding more efficient methods within processes in order to offset the added cost of securing the supply chain. The opening presentation was provided by FDA's **Steven Wolfgang**, PhD, whose new Office of Drug Security and Recalls (ODSIR) was formed this year to address all issues related to the drug supply chain.

Wolfgang shared FDA's latest thinking on the drug supply chain and discussed how FDA intends to develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets. FDA will continue to expand its capabilities in intelligence gathering and use, with an increased focus on risk analysis and thoroughly modernized IT capabilities.

At the Irvine/Airport Hilton Hotel, **Gerard Pearce** provided an introduction to Rx-360 and presented the scope and

current accomplishments of Rx-360's audit program.

At the Amgen conference center, **Kevin Siver**, PhD, presented on behalf of **Martin VanTrieste**.

To secure the supply chain, Siver said that it was important to :

- Have common sense
- Embrace the best practices
- Adopt advanced technologies
- Collaborate with other stakeholders

For best practices, Siver presented an image of a tamper-evident seal with a unique identifier. He also said that cargo theft should be thought of as part of supply chain management. He said that even though pharma companies do not typically oversee truck drivers and the company to which they belong, it is now becoming increasingly important to do so. He also recommended applying a pedigree to secure raw materials. Siver concluded, "Let us not be content to wait and see what will happen, but give us the determination to make the right things happen."

From the Irvine/Airport Hilton Hotel, **Lucy Medeiros Cabral** discussed risk-based strategies for managing and determining oversight levels for suppliers and contract manufacturing operations. She demonstrated an approach to ensure meeting the quality requirements

and how to apply an adequate level of resources upfront at the initiation of the contract approval stage and later during Quality Agreement negotiation. Lucy shared a case study and examples for each level of oversight which resulted in a very comprehensive best practice example.

All the professionals involved with this event benefitted from multiple views of this critical topic. This event was sponsored by Global Biopharm Regulations, Technical Safety Services, and Irvine Pharmaceuticals. Support also came from: Kyoto America, GXP Manager, Doe & Ingalls, Irvine Pharmaceuticals, Micronova, RSS Calibration, Bausch & Stroebel, and Lonza.

PDA's Who's Who


Lucy Medeiros Cabral, Senior Director, Head Global Supplier Quality Management, Genentech

Gerard Pearce, Executive Vice President, SQA Services

Kevin Siver, PhD, Director of Quality Assurance, Amgen

Saeed Tafreshi, President, Intelitec Corporation

Martin VanTrieste, Senior Vice President of Quality, Amgen

Steven Wolfgang, PhD, Acting Associate Director, Risk Science, Intelligence and Prioritization, CDER, Office of Compliance, Office of Drug Security, Integrity and Recalls 



Most attendees caught the meeting at work-site spaces; pictured here Amgen's Conference Center

PDA Reengages in Singapore

Richard Johnson, PDA

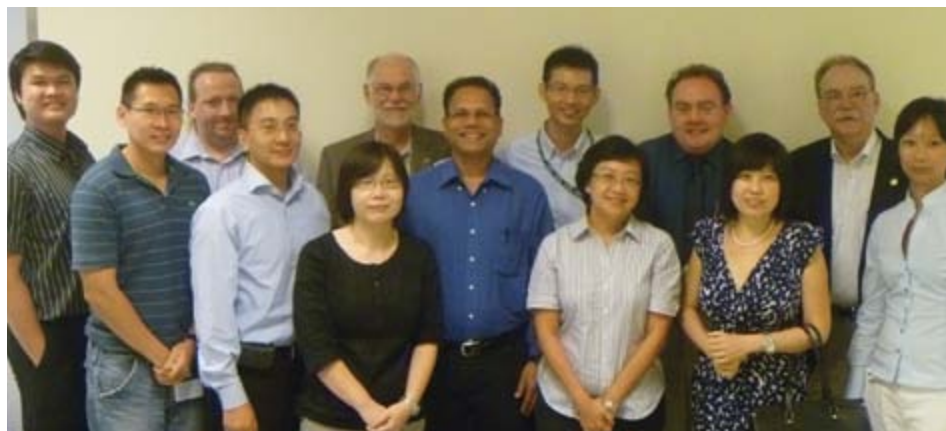


In October, I traveled to Singapore with PDA's **Georg Roessling**, PhD, Sr. VP-Europe. Singapore is a dynamic pharmaceutical hub, and PDA currently has many members there.

Our trip had two purposes:

1. Meet with current/prospective PDA members to determine the level of interest and opportunity for re-activating a Chapter in Singapore
2. Meet with PIC/S Expert Committee to discuss future training opportunities

Both objectives were met.



Restarting the PDA Singapore Chapter

On October 13, Georg and I met with a group of people at Baxter BioScience Singapore, and there were fruitful discussions about and enthusiasm for the idea of restarting a PDA chapter in Singapore.

Some participants included:

Joe Brady, PhD, DPS Engineering

Tony Budianto Bee, Sartorius Stedim

Emily Cheah, PhD, Biomedical Research and Support Services

Sannie Chong, PhD, Health Sciences Authority

Stephen Hsu, PhD, GlaxoSmithKline

Franklin Huang, SQ., USANA Health Science

Dinesh Khokal, PhD, Health Services Authority

Gary Khoo Soo Hean, Baxter BioScience

Wayne Lee, PhD, Pall Life Sciences

Lim Meng Lip, MSD International

Daisy Teo, Pfizer

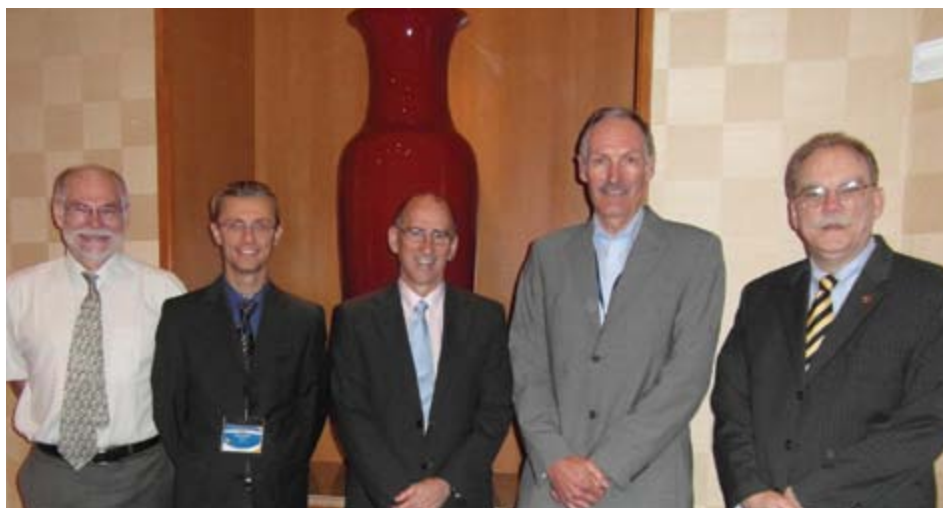
Juergen Wagner, Baxter BioScience

Lawrence Yap Wei Khla, Baxter BioScience

Lam Yeng Chin, Baxter BioScience

PDA and PIC/S Training Collaboration

On October 14, Georg and I met with members of the PIC/S API Expert Committee to discuss potential PDA collaboration for training activities in 2012. The discussions were very favorable, and PDA and PIC/S will be developing concrete proposals based on the discussions. 🌐



(l-r) Georg Roessling, PDA; Lionel Viornery, AFSSAPS; Douglas Fenwick, TGA; Michel Keller, Swissmedic; Richard Johnson, PDA



Faces & Places: 2011 PDA/FDA Joint Regulatory Conference

Opening Plenary Session



(l-r) Deborah Autor, U.S. FDA; Susan Schniepp, OSO Biopharmaceuticals Manufacturing

Latest News and Inspection Findings in Biotech



(l-r) Richard Friedman, U.S. FDA; Laurie Graham, U.S. FDA; Patricia Hughes, U.S. FDA; Azita Gerhardt, Abbott Laboratories

Recall Lessons



(l-r) John Finkbohner, MedImmune; Karthik Iyer, U.S. FDA; Raymond Godlewski, MedImmune; Israel Santiago, U.S. FDA

FDA Center Initiatives



(l-r) Amy Giertych, Baxter Healthcare; Armando Zamora, ORA; Elaine Morefield, CDER; Christopher Joneckis, CBER; Bernadette Dunham, CVM; Steve Silverman, CDRH

FDA Centers' Compliance Office Updates



(l-r) Robert Dana, PDA; Armando Zamora, ORA; Ann Ferriter, CDRH; Eric Nelson, CVM; Mary Malarkey, CBER; Steve Lynn, CDER; Richard Friedman, CDER

WELCOME

2011 PDA/FDA Joint Regulatory Conference

Plenary Sessions, Concurrent Sessions,
and Exhibits





Faces & Places: 2011 PDA/FDA Joint Regulatory Conference

Breakout Sessions

OIP 101 & Foreign Inspections



(l-r) Ann Marie Montemurro, U.S. FDA; Robert Sausville, U.S. FDA; Mai Huynh, U.S. FDA; Walter Batts, U.S. FDA

ICH Q11



(l-r) Steven Mendivil, Amgen; Betsy Fritschel, Johnson & Johnson; Patrick Swann, U.S. FDA

Update on GMP and Quality Guidance



(t-b) Katrin Nodop, EMA; Louise Johnson, Takeda Pharmaceuticals; Brian Hasselbalch, U.S. FDA

Drug Safety



(l-r) Gerald Dal Pan, U.S. FDA; David Cummings, U.S. FDA; John Ayres, Eli Lilly & Company

Good Inspection Practices – Domestic



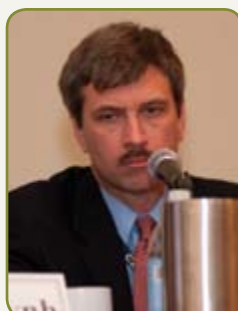
(l-r) Zena Kaufman, Abbott Laboratories; Monica Caphart, U.S. FDA; Elizabeth Leininger, E Leininger Consulting

GMP by Life Cycle Phase



(l-r) Elizabeth Leininger, E Leininger Consulting; Vince Mathews, Eli Lilly and Company; Amnon Eylath, Ariad Pharmaceuticals

Standards



(l-r) Scott Colburn, U.S. FDA; David Cummings, U.S. FDA; Christopher Joneckis, U.S. FDA; Jon Clark, U.S. FDA; Mai Huynh, U.S. FDA

WHO Update



(l-r) Sabine Kopp, World Health Organization; Maria Guazzaroni Jacobs, Pfizer; Kara Follman, Pfizer

Accountability in a Global Environment



(l-r) Cesar Matto, U.S. FDA; Susan Schniepp, OSO Biopharmaceuticals Manufacturing

First Cycle Review – II



(l-r) Darrin Cowley, Amgen; Laurie Norwood, U.S. FDA; Amy Giertych, Baxter Healthcare

Regulatory Science



(l-r) Vicki Seyfert-Margolis, U.S. FDA; Timothy Crowder, GlaxoSmithKline



Faces & Places: 2011 PDA/FDA Joint Regulatory Conference

Passport Raffle



Fun & Networking



Gala Reception



list in half!
We've imagined our regulatory filing going smoothly

Please Welcome the Following Industry

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Ali Afnan, Step Change Pharma

Cristina Agolino, Sanofi Pasteur

Magaly Aham, MedImmune

Jenny Aharonov, Bio-Technology General

Jun Aketagawa, Seikagaku Biobusiness Corporation

Nakao Akio, CM PLUS Corporation

Jabir AL Abdulsalam, Royal Court Affairs

Yahya Al-Adi, Sultan Qaboos University Hospital

Fahad Gazzay AlHarby, Saudi FDA

Leena Al-Hawash, Arab Company for Drug Industries and Medical

Ahmed Al-Kindi, Sultan Qaboos University Hospital

Saeed Abdulrahman AlShafie, Saudi FDA

Edwin Alston, Novartis

Gabriel Anderson, Novartis

Bruno André, GlaxoSmithKline

Kwame Ansah, UCB

Midori Anzai, Nippon Becton Dickinson Company

Heidi Archila, Citra Labs

Toos Arends, Healthcare Inspectorate

Vida Arya, Amgen BioVex

Aude Arzel, LFB Biotechnologies

Avi Avigdor, Bio-Technology General

Nancy Baez, Allergan

Paul Baldwin, Intervet Pharma

Dan Bandiera, Celgene Corporation

Debra Barngrover, Biologics Consulting Group

Peter Barr, Avid Radiopharmaceuticals

Prerna Barsainya, MSD International

Randall Barton, Nanoviricides

Franck Benoit-Gonin, Sanofi Pasteur

Christoph Berger, Swissmedic

Richard Berglund, Eli Lilly

Simon Bergmann, CMC Biologics

Olav Berkelmans, Penske Logistics

Susan Bernhard, Elan Pharmaceuticals

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Lynn Betts, Paragon BioServices

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Henrik Birk, JLI Vision

Dennis Blaquera, Bionovo

Ken Blashka, Genzyme

Timothy Boeger, Covidien

Susanne Born, Eli Lilly

Frans Bosselaar, Baxter Healthcare

Michael Bowley, Ferring Pharmaceuticals

Brian Boyd, PolyMedix

Jerry Brandewie, Brandewie

Derek Brandt, Sensile Medical

Harvey Brandwein, Pall Corporation

Ellen Brunbech, Novo Nordisk

Gretchen Brunner, Genzyme

Audrey Brussel, Sanofi Aventis

Kimberly Buczynski, Biogen Idec

Ben Bulishak, Sanofi Pasteur

Jeffrey Burmeister, Sanofi

Thomas Burns, Eli Lilly

Timothy Bustillos, Baxter

Erin Butler, Greiner Bio-One

Timothy Butterfield, Isis Pharmaceuticals

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Claudia Cabrera, Genentech

Doina Caderas Boschetti, Pevion Biotech

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Gisela Canales, EMD Millipore

Carolyn Cardin, Ironwood Pharmaceuticals

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Sarah Cavin, American Stelmi Corporation

Prerona Chakravarty, Linde

Kristopher Chaney, Eli Lilly

Kalpna Chaturvedi, Bristol Myers Squibb

Tracy Chen, Anacor Pharmaceuticals

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Celeste Chia, Roche

Shilpa Chitnis, Johnson & Johnson

Christine Cho, Boehringer Ingelheim

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Caterina Ciccioni, Novartis

Jeff Clark, PACE Bio Solutions

Sharon Colacino, Genzyme

Gregory Cole, Roche/Genentech

Jessica Cole, FDA

Anne Conneely, EBEWE Pharma

Jorge Cordero-Monroig, Bausch & Lomb

Cheryl Crain, Regeneron

Anthony Crawford, DSM Pharmaceuticals

Sherrie Curtis, Genentech

Dana Dallas, Defense Logistics Agency

Kiem Dang, Medtronic

Jesper Davidsen, Novo Nordisk

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James DeBois, Multiview

Monica DeCamillo, Merck & Co.

Gal Dela, Bio-Technology General

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Karen Donhauser, Fibrocell Science

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Christophe Dubuis, Merck Serono

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Brian Duncan, Sandoz

John Durham, Borealis Pharma Consulting

Juergen Ebner, ViruSure

Jennifer Lynne Edwards, Eden Biodesign

Marcel Elverding, TOPA Packaging

Greg Eppink, Abbott

Cameron Erikson, Citra Labs

Angel Estrada, Hospira

Gerhard Ewald, Hameln Pharma

Helena Ezzahid, Sofrigam

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Daniel Farrell, F. Hoffman - La Roche
Geraldine Felicia, Bristol Myers Squibb
David Ferrazza, EMD Millipore
Malgorzata Filipowicz, Dendreon Corporation
Ken Fiorelli, Otsuka America Pharmaceutical, Inc
Cristiana Fracassini, Eli Lilly
Mark Francis, DDL
Kari Frantzen, Nordion
Sue Free, Genentech
Travis Frick, Novartis
Peter Fudacz, Baxter
Kenji Fujino, Kyowa
Daisuke Fujisawa, Vaisala
Rachael Fuller, Covidien
Rolando Garcia, Lantheus Medical Imaging
Arne Geitner, Kuehne+Nagel
Joe George, Genentech
Liz George, Lantheus Medical Imaging
Dorte Gerlif, Novo Nordisk
Abe Germansderfer, Gilead
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Bryan Glick, Apple
Bethany Glyde, Ben Venue Laboratories
Nadav Goldstein, Bio-Technology General
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Subhash Gore, Matrix Laboratories
Monica Gortler, Bio-Technology General
Marc Gorzellik, Bio-Rad Medical Diagnostics
Subho Goswami, BD
Caroline Goussen, LFB Biotechnologies
Olympia Graham, Shire Pharmaceuticals
Sue Graumlich, GE Healthcare
Joanke Graveland-Bikker, Crucell
Andrew Green, Laminar Medica
Rachel Gretchen, Johnson & Johnson
Philippe Grimm, Biosafety Consulting & Vitrology
Heike Gruen, West Pharmaceutical Services
Fatima Guemazi, GlaxoSmithKline
John Guley, Complya Consulting Group
Juan Gutierrez, Bristol-Myers Squibb
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Magan Khakharia, Microfilt
Sarwat Khattak, Grifols Biotherapeutics
Magda Kholousi, Allergan
Kaoru Kimura, Becton Dickinson
Joel Kise, Auromedics
Robert Kiss, Genentech
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Elizabeth Kneller, Keranetics
Marianne Knox, W. L. Gore & Associates
Regina Kofler, Lambda
John Korovessis, Gilead Sciences
Brad Korte, Baxter Pharmaceutical Solutions
Michael Krahe, Bayer Pharma
Joerg Krings, Envirotainer
Victoria Krochik, Westpharma
Stephanie Kurtz, Veltek Associates
Kathy Kuskowski, Nycomed
Sheila Kwarteng, Neoprobe Corporation
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Phoung Lai, MassBiologics
Stephanie Laidig, Johnson & Johnson
Theresa Lamanec, Norwich Pharmaceuticals
Chris Lamb, Biosolutions Services
Diana Landa, Teva
Horst Langhammer, Boehringer Ingelheim
Shannon Langley, Bausch + Lomb
Christelle Laot, FedEx Express
Marianne Lavin, Teva
Lauren Layne, Genentech
James Leary, Sanofi Pasteur
Helen Lee, Baxter HealthCare
Sang-Keon Lee, Whain Systech
Sang Su Lee, Berna Biotech
Katherine Leitch, Merck
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Lauren Long, Merck
Katy Lorineau, ViruSure
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Bernhard Luy, Meridion
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Sumit Majumdar, Becton Dickinson
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Robert Marolt, Farmadent
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Felix Martinez, Ikaria
Felix Martinson, Covidien
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Ileana Matos, VWR Advanced Instrument
Jason Mattia, West Pharmaceutical Services
Patrick McCarthy, EMD Millipore
Theresa McCarthy, Pfizer
Michelle McCaulley, OSO BioPharmaceuticals
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Dawn McIver, MicroWorks
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Alex Miller, Life Technologies
Howard Miller, AWS Bio-Pharma Technologies
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Karthik Ramani, Biocon
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Peter Roberts, Bio Products Laboratory
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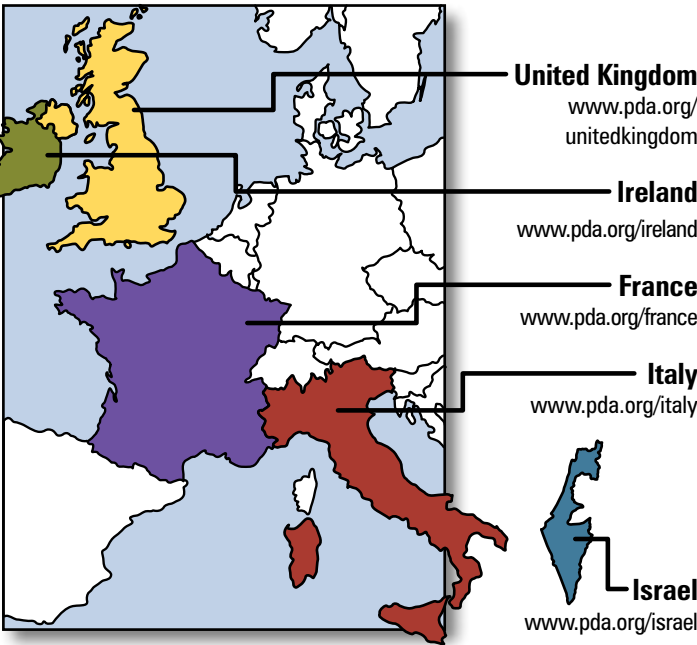
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Nicole Walker, Panther Life Science Logistics
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Mario Ziltener, Kuehne+Nagel
Aukje Zimmermann, Merck Sharp & Dohme

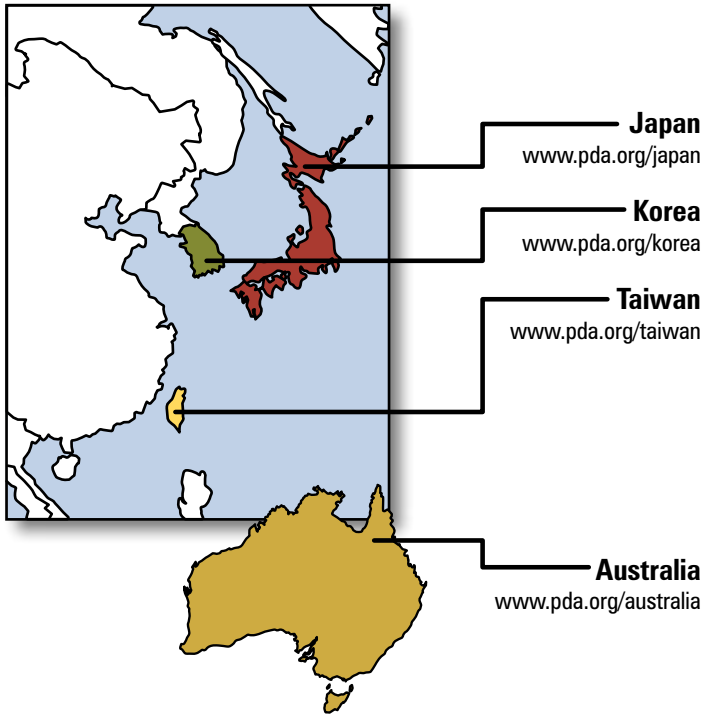
PDA Chapters

The following are PDA's Chapters, organized by the regions of the world in which they are located. For more information on the Chapters, including their leaders and upcoming events, go to their websites which are listed below.

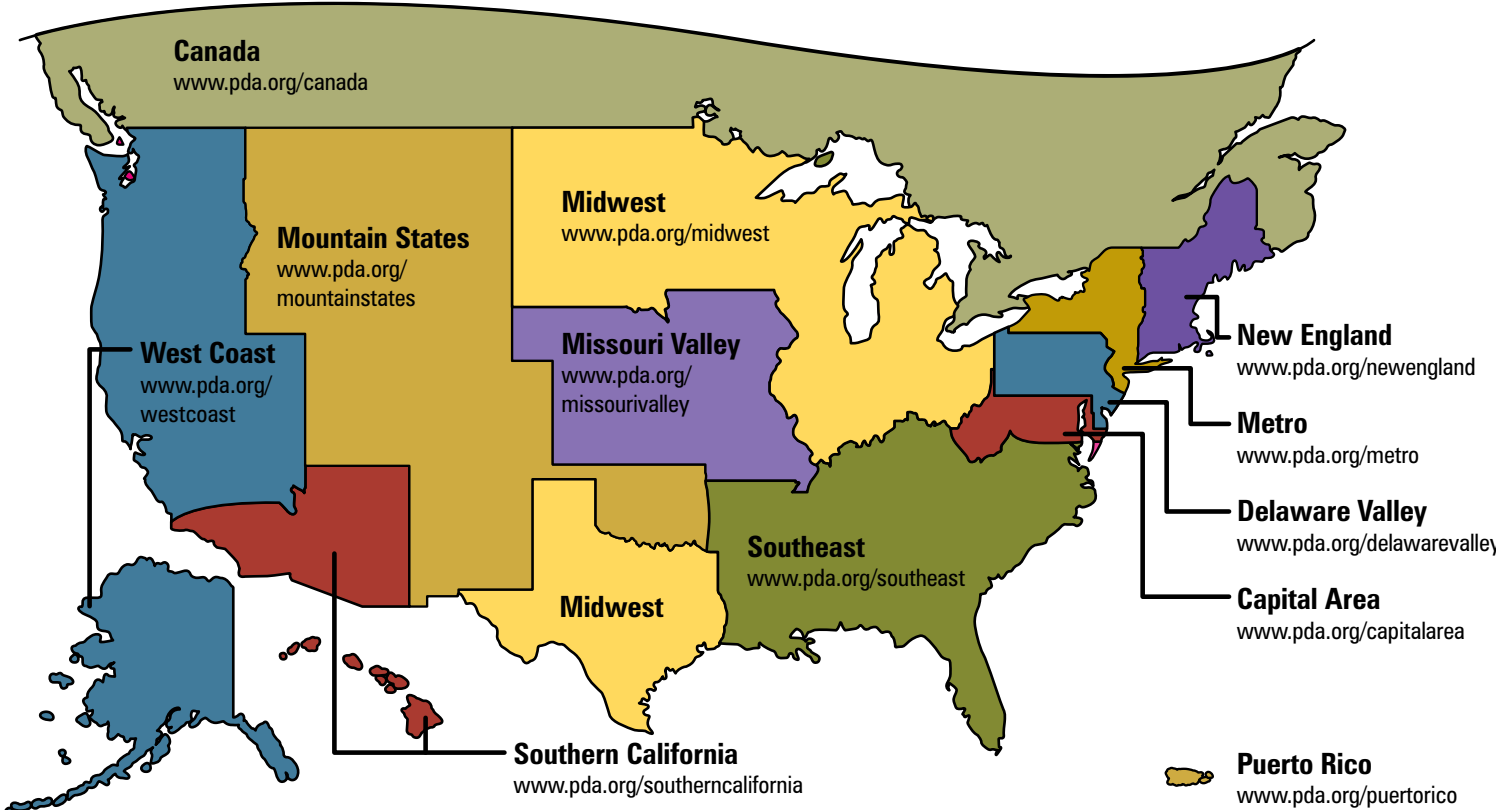
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Are You Executive Level Material? 10 Tips to be More Promotable

Jean Kelley

Any successful executive will tell you that there's a game in business. If you're not willing to play the game, you can't win at it. So while many people aspire to reach the executive level in their company, they won't. In fact, most people don't make it past the \$80,000 per year income level simply because they don't play the game.

Why won't they play? *"I hate business politics,"* they say. But who said "business politics" had to be a negative thing? For example, if your boss does something commendable in the company, invents something new or makes a great speech, it's okay to congratulate him or her. That's not being political or a "kiss up"; it's called being gracious and having decorum—two things that will help you climb the corporate ladder.

Aside from your technical skills or job-specific abilities, other big components of the game include your comportment, how you look, how you speak, your attitude and your daily habits. Following are the key tips to consider in order to make it into the executive level suite.

1 Claim Your Space

When you're walking in the office, you need to look purposeful and centered. Scurrying, looking harried or trying to blend into the background will make you appear as though you lack confidence. Instead, walk with your full height and claim the space around you.

People need to view you as someone on a mission—a mission to the top.

2 Build Your Confidence

Contrary to popular belief, confidence is not about self-esteem or self-worth. In fact, someone can have a low level of self-esteem and still become a high-level executive, as the person's low self-esteem could be driving them to succeed. True confidence is simply the belief that you can do things well. If you doubt your ability to do things well, simply look back at your record of accomplishment. Use those past successes as a way to build your confidence so it's apparent to others as well.

3 Speak Up

During meetings, always weigh in on the topics discussed. Don't leave a meeting without having an opinion about something or you will quickly get a reputation for being "wishy-washy" or not concerned with the company's success. If you're in a meeting and the discussion turns to something you're unfamiliar with or is not part of your department's duties, look engaged anyway. Always remember that the people above you are watching you, and everything you do—or don't do—counts.

4 Build Social Capital

Building social capital across the board is critical to your upward mobility. Not only should you build social capital with people within your department, but you should also build it with people in other

departments and in other companies who might be a resource for you. Social capital simply means building connections with people. Find out some personal information about others, such as their hobbies, their birthday and their kids' names... and then talk about those items occasionally to build rapport. Remember this: People don't care how much you know until they know how much you care. When you're on your way up the ladder, you need to treat people like people and not like objects. Get to know your peers. You never know if one day a peer will be your boss, and even if they aren't, they can make your work life very stressful.

5 Learn About Business

To make it in business you have to know about business. This includes reading about your industry as well as other industries to learn how different companies handle things. If you're well-read you can give examples from other industries and companies of what worked and what didn't. Remember that in order to be promotable you have to be on top of your game at all times; being knowledgeable is one way to display your competence.

6 Do What Others Won't Do

In every department there are a few things that need to get done (or that are important to the boss), but no one wants to do them. Find out what those are... and then volunteer for the tasks. Yes, some people will call you a "kiss up," but that's okay. Ultimately, you have to

please your boss and to some extent your peers and direct reports, not the naysayers who have little chance of reaching the top.

7 Get a Mentor

If your company has a mentoring program, take advantage of it. If you don't have access to such a program, get a mentor on your own. Look through your network of people and find someone who is at or near the level you aspire to be. Invite the person out to lunch and talk business with them. Learn what they did to get where they are. When you feel enough rapport and comfort with the person, ask if he or she will mentor you. Most people are honored by the request and will say "yes." If the person declines the request, don't take it personally. Simply find someone else to learn from.

8 Look Professional

Tattoos and piercings are popular these days, and if you want one, by all means get one. However, when you're at work, keep the tattoo under your clothing as much as possible and remove visible piercings from your face or tongue. Today, it's extremely rare to see executives with visible tattoos and piercings. Twenty years from now, it

may be more common and acceptable to see tattoos and piercings in the executive suite, but for now, keep them hidden at work if you work in a corporate setting.

9 Dress at the Top of Your Level

People do judge you by how you look. For example, if you're in a position or company where everyone wears jeans and t-shirts, you should dress a notch higher. If you're a man, wear khakis and golf shirts, and if you're a woman, wear slacks or a skirt with a tasteful top. A good rule of thumb is to dress as if you were meeting with your top client. What attire would be professional yet comfortable to accommodate a key client meeting? Additionally, no matter where you work, casual day does not mean shorts and flip-flops. If an executive sees you dressed like that, they're going to view you as a "kid." Even an iPod in your ear can make you look like a kid. When you're on your way up (usually in the 25-40 age bracket), the last thing you want is to be called a kid.

10 Communicate Effectively


How you communicate, both verbally and in writing, can make or break your career potential. Using poor gram-

mar, foul language or an inappropriate tone make you appear less intelligent. Most executives are very polished when it comes to their communication skills. If your communication skills are lacking, find a resource (a class, a book, a mentor or a coach) to help.

Get Ahead Today

Realizing your goal of attaining an executive level position is possible. You simply need to go beyond your technical or job-specific skills and add some focus to your executive presence. After all, you can't become an executive if you don't act or look like one. By concentrating on these ten areas and keeping your skills up to date, you'll reach the executive suite sooner than you ever thought possible.

About the Author

Jean Kelley is the founder of Jean Kelley Leadership Alliance. Her Faculty and Trainers have helped more than 750,000 leaders and high potentials up their game at work in the US and in Canada. Coupled with her books, *Dear Jean: What They Don't Teach You at the Water Cooler*, and *The Get a Job Keep a Job Handbook*, Jean has earned the name North America's workplace coach. For information on leadership programs and availability email jkelly@jeankelley.com or go to www.jeankelley.com. 

Latest Hot-Job Postings

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Merck, West Point, Pa.
Director Quality Assurance—Drug Delivery Devices

Merck, West Point, Pa.
Project Development Engineer

GlaxoSmithKline, South Brussels, Belgium
Director Global QP

Merck, West Point, Pa.
Director Regulatory Affairs—Drug Delivery Devices

Merck, West Point, Pa.
Senior Development Engineer

PDA Survey *Results*

PDA Tribromoanisole (TBA)/Trichloroanisole (TCA) Industry Benchmarking Survey

PDA TBA Task Force

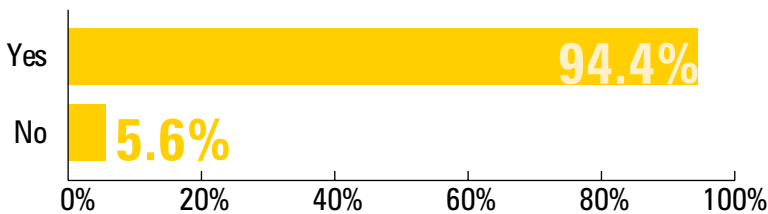
TBA (or TCA) tainting is relatively new to the consumer healthcare and pharmaceutical industries. TBA is a highly volatile chemical that is detected at parts per trillion concentrations as a musty, moldy odor. Since early 2010 there have been multiple drug and consumer healthcare product recalls connected to TBA. A lack of experience with such taints in these industries led to the formation of a PDA-sponsored task force to develop risk mitigation strategies.

These recalls were connected to wooden pallets constructed of lumber treated with the antifungal agent and wood preservative tribromophenol (TBP). These pallets were used to transport/store packaging components at manufacturing sites in Puerto Rico. Fungal growth on the TBP-treated wooden pallets with a high moisture content resulted in the biomethylation of TBP to TBA. TBA was absorbed into the walls of high density polyethylene plastic containers accumulating in the container headspace. This has been associated with a small number of complaints related to odor and nausea.

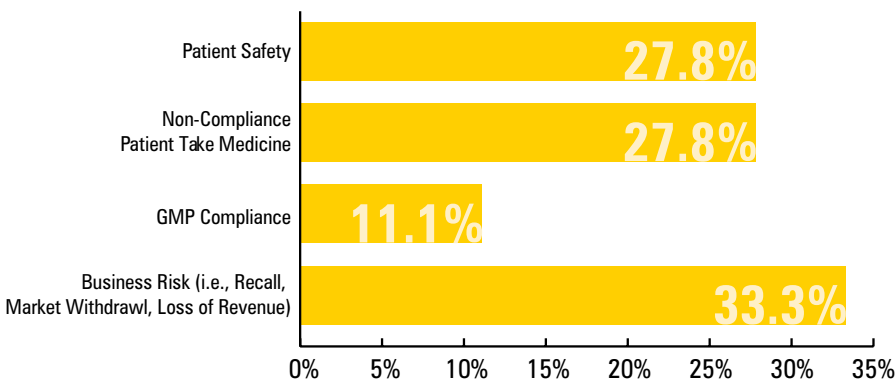
The PDA TBA Task Force prepared a survey to benchmark knowledge of TBA (or TCA) odors and taints and risk mitigation actions taken within industry. The survey was distributed by PDA to 27 pharmaceutical, consumer healthcare and biotechnology manufacturers, as well as packaging suppliers represented on the Task Force, and 70% of the companies responded to this survey. This 32-question survey covered the following areas: (1) Complaints Handling System, (2) Analytical Methods, (3) Supply Chain Controls, and (4) Regulatory Focus. A sample of Q&A from each section is highlighted below.

Section 1: Complaints Handling System (Sample Questions)

Have you evaluated your customer complaint data for potential trends in complaints for product odor/taint?

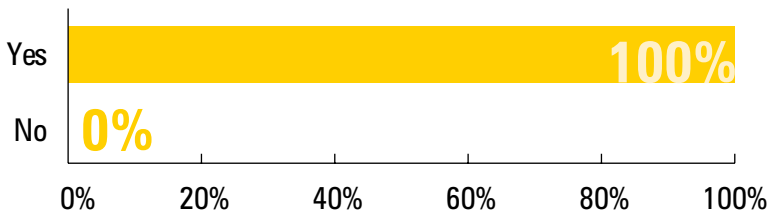


What would you consider to be the greatest risk with these odors/taints? Select one of these.



Section 2: Supply Chain Controls (Sample Questions)

Do you require your suppliers to use wooden pallets that are Heat Treated (HT), not TBP/TCP treated?



continued at top of page 30

Tech Trends

Baxter Beats 2010 Emissions Goals

Emily Hough, PDA

In late July, Baxter announced that it had surpassed its 2010 net greenhouse gas emissions reduction goal from operations by decreasing emissions by 7% in absolute terms and 29% indexed to revenue compared to 2005.

Baxter's 2010 goal was to reduce greenhouse gas emissions by 20%, indexed to revenue compared to 2005. The firm's 2015 goal is to reduce greenhouse gas emissions 45% indexed to revenue compared to 2005.

Baxter's **Elizabeth Noonkester**, Corporate Communications, Baxter said that the firm achieved this goal by focusing on energy conservation, employing high-efficiency technologies like cogeneration of heat and electricity, using biofuels and other renewable energy sources, and purchasing of carbon credits.

According to the firm's website, "the company's sustainability programs and performance support Baxter's mission to apply innovative science in the development of medical products and specialty therapies that save and sustain patients' lives."

Noonkester said that environmental stewardship has been central to Baxter for more than three decades. Baxter has implemented programs across the product lifecycle, from product development and supplier management to manufacturing, transport and end-of-life, to continue to improve the company's environmental performance. "Baxter recognizes that multinational companies can help to address climate change by understanding their impacts and decreasing their total greenhouse gas emissions through innovative reduction programs," she said. "These are core elements of Baxter's sustainability efforts."

One of Baxter's main focuses is increasing energy efficiency in its manufacturing operations. The company uses a "lean" energy program to drive enhancements throughout Baxter. The company's global energy management initiatives have resulted in total savings of approximately \$31 million since 2005, including \$500,000 in 2010.

Baxter also applies innovative energy-saving technologies. In 2010, the company launched a new cogeneration unit at its Castlebar, Ireland, facility. The 3 megawatt unit uses natural gas reciprocating engines to generate electricity, hot water and steam. These units are typically 30 percent more energy efficient than traditional generators.

In a June 2011, Chairman and CEO Letter, **Robert L. Parkinson, Jr.**, Chairman and Chief Executive Officer, Baxter, said that the firm is increasingly "implementing green principles into our manufacturing and other operations." Indeed it has. According to the firm's 2010 Sustainability Report, in 2010, Baxter created an internal Global Supplier Sustainability Council to provide oversight for implementing the company's Global Supplier Sustain-

continued at top of page 34

Journal Preview

2010 Adventitious Workshop Highlighted

The Nov/Dec Journal is supersized with 36 manuscripts from the proceedings of the *2010 PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop*. Program Planning Committee members **Arifa Khan**, **Patricia Hughes** and **Michael Wiebe** served as volunteer guest editors to help the authors prepare their articles for submission. These articles did not pass through the regular peer-review process for the Journal as they are proceedings from a live event.

Editorial

Arifa S. Khan, et al., "Introduction to Workshop: Adventitious Viruses in Biologics—Detection and Mitigation Strategies"

Conference Proceeding

Shasta McClenahan, et al., "Regulatory Approaches for Control of Viral Contamination of Vaccines"

C. S. Ranucci et al., "Adventitious Agent Risk Assessment Case Study: Evaluation of RotaTeq for the Presence of Porcine Circovirus"

Mark Moody, et al., "Mouse Minute Virus (MMV) Contamination—A Case Study: Detection, Root Cause Determination, and Corrective Actions"

Kurt Brorson and Anthony Lubiniecki, "Summary of Breakout Session E"

Mark Lutgen, "Chlorine Dioxide Remediation of a Virus-Contaminated Manufacturing Facility"

Arifa S. Khan, "Current Testing Methods and Challenges for Detection of Adventitious Viruses"

Jens-Peter Gregersen, "Theory and Practice of Conventional Adventitious Virus Testing"

Ivar J. Kljavin., "Broadening Our Expectations for Viral Safety Risk Mitigation"

Andrew P. Byrnes and Hannelore Willkommen, "Breakout Session C Summary: Current Virus Detection Methods"

Crystal Jaing, et al., "Detection of Adventitious Viruses from Biologicals Using a Broad-Spectrum Microbial Detection Array"

Christine Uhlenhaut, et al., "Use of DOP-PCR in Non-Specific Virus Detection"

Hailun Ma and Arifa S. Khan. "Detection of Latent Retroviruses in Vaccine-related Cell Substrates: Investigation of RT Activity Produced by Chemical Induction of Vero Cells"

Kathryn King and Michael Wiebe. "PDA Cell Substrate Task Force: Emerging Technologies for Virus Detection Technical Document—A Progress Report"

John Eltermann, "Adventitious Agents: Issues and Considerations during Pre-Approval Reviews and Inspections"

Robert Sausville and Chantal Cazeault. "Summary of Breakout Session B: Regulatory Expectations for CGMP"

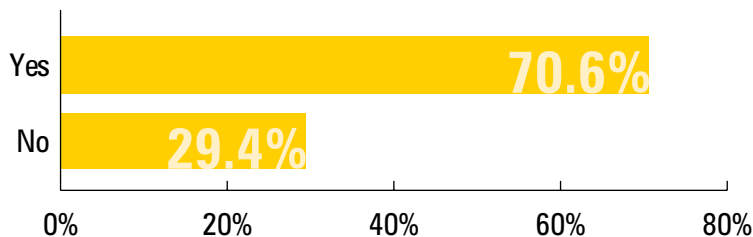
Robert D. Kiss, "Practicing Safe Cell Culture: Applied Process Designs for Minimizing Virus Contamination Risk"

Jim Skrine, "A Biotech Production Facility Contamination Case Study—Minute Mouse Virus"

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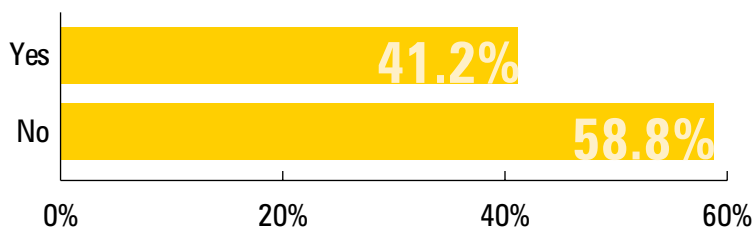
PDA Survey Results continued from page 28

Do you require your pallet suppliers to use only wood from countries that do not allow the use of TBP/TCP for wood treatment (i.e., United States or Europe)?

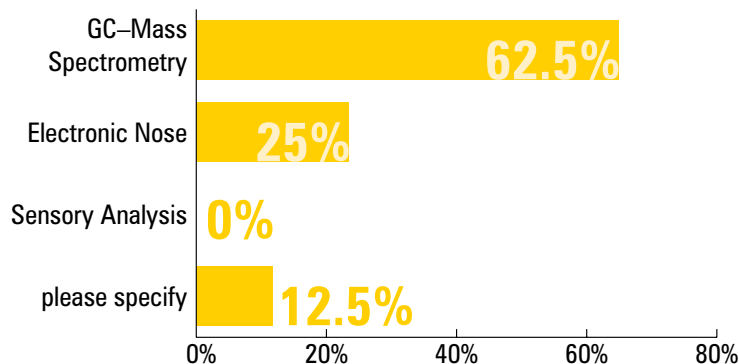


Section 3: Analytical Methods (Sample Questions)

Have you started considering extraction and detection methods for TBA or TCA? If YES, answer Question below.



What are these methods?

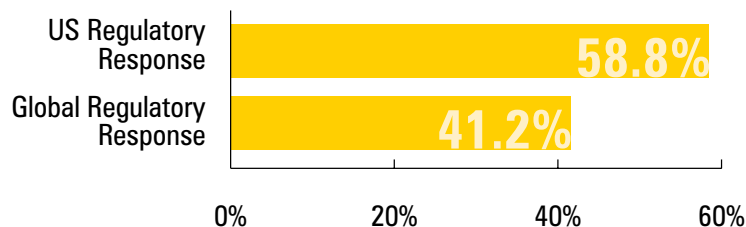


Other specified

1. GC/Mass Spec and Sensory Assessment

Section 4: Regulatory Focus (Sample Question)

Do you believe this is just a focus for the U.S. regulators or are you aware of other global regulators responding to these taints?



The Parenteral Drug Association presents...

2012 PDA Europe Parenteral Packaging

The main Topics of the Conference:

- Container Materials: Glass and/or Polymer
- New Types of Containers and Application Systems
- Container Integrity: Testing for Development and Online in Manufacturing
- Final Container Testing
- Case Studies: From Components, Processes and Product Qualities

Training Courses on „Container Closure Development“ and „Selection and Utilization of Glass Containers in Pharmaceutical Packaging“

13-15 March 2012

Berlin Marriott Hotel
Berlin | Germany




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CONFERENCE 13-14 March | EXHIBITION 13-14 March | TRAINING COURSES 14-15 March

<https://europe.pda.org/ParPack2012>

Conclusions

The results from this survey were used to benchmark the current situation in our industry and to assess areas in which more guidance could be provided to industry in managing complaints and mitigating risk with TBA/TCA odors and taints through the publication of a PDA technical report, entitled "Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries." This technical report is scheduled to be published in or around the first quarter of 2012. To date, the primary focus in industry has been on the use of Heat Treated pallets made from TBP/TCP-free lumber to prevent risks of TBA/TCA odors and taints from entering into the supply chain. Other potential sources through which TBP or TCP can enter into the supply chain should also be considered and will be addressed in this technical report. Fungi perform the biomethylation of TBP (or TCP) to TBA (or TCA). Thus, moisture controls to minimize fungal growth on pallets is another risk mitigation step to consider. The complete survey has been published for purchase via the PDA Bookstore. 

Journal Preview continued from page 29

Barry Cherney, "Application of Quality by Design in the Control of Adventitious Viruses: Gaps in Current Processes in the Prevention of Virus Contaminants"

Robert Kiss and Roman Drews, "Breakout Session A: Elimination or Treatment of High-risk Raw Materials"

Rangarajan Sampath, "Advanced Techniques for Detection and Identification of Viral Contaminants Using the Ibis PLEX-ID Universal Biosensor"

David Munroe, "A Microarray Platform for Virus Detection and Identification"

Michael Morrow and John Donaldson, "Nanostring's nCounter—A True Digital Target Profiling Technology"

Amy S. Rosenberg et al., "Risk Mitigation Strategies for Viral Contamination of Biotechnology Products: Consideration of Best Practices"

Johannes Blümel, "Current European Regulations for Control of Adventitious Virus Safety"

Nathan Jones, "Identification and Remediation of a Cell Culture Virus Contamination"

Linda C. Hendricks and Dominick A. Vacante, "Case Study of Apparent Virus Contamination in Biopharmaceutical Product at Centocor"

Isabelle Pierard, "Contamination by Porcine Circovirus Type 1: Findings, Investigations, and Learnings"

Laurie Norwood and Kalavati Suvarna, "Summary of Breakout Session F: Facility and Equipment Decontamination Strategies"

David Onions, "Overview of Emerging Technologies To Detect Adventitious Agents"

J. L. Kolman, "Massively Parallel Sequencing for the Detection of Adventitious Viruses"

Houman Dehghani, et al., "Evaluation of a Single-Platform, Rapid, Nucleic Acid-Based Technology for Detection of Adventitious

continued at middle of page 47

WORKSHOP 6-7 March
EXHIBITION 6-7 March



The Parenteral Drug Association presents...

2012 PDA Europe Workshop

Quality by Design

*The Role of Analytical Science
in Implementing QbD
– Technical and Regulatory Aspects*

See the Highlights:

- Setting the Scene – Goals & Introduction
- Regulatory Positions (EMA/FDA) – two presentations
 - Differences between agencies, challenges, common views, etc.
 - EMA and FDA representatives should work together on presentations in order to make them complementary not repetitive
- Pharmacopoeial Positions (EDQM, USP)
 - EDQM and USP representatives should work together on presentations in order to make them complementary not repetitive
- Industry Position

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Hilton Hotel Liverpool
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<https://europe.pda.org/QbD2012>

2011-2012 PDA UPCOMING EVENTS

DECEMBER 2011



5-9 Quality Systems for Aseptic Processing – *New Course*

Bethesda, Maryland **SOLD OUT**
www.pda.org/qualitysystems

6-7 Modern Biopharmaceutical Manufacturing

Bordeaux, France
<https://europe.pda.org/Biopharma2011>

8 PDA Technical Report: Single Use Technologies

Bordeaux, France
<https://europe.pda.org/TCSingleUse2011>

8 PDA Technical Report: Biotechnology Cleaning Validation

Bordeaux, France
<https://europe.pda.org/TCCleaningValid2011>



JANUARY 2012

9-13 Aseptic Processing Training Program – Session 1 Week 1 (Week 2: February 6-10)

Bethesda, Maryland
www.pda.org/2012aseptic

FEBRUARY 2012

7-8 Clinical Trial Materials

Basel, Switzerland
<https://europe.pda.org/ClinicalTrial2012>

27 Pre-Conference Workshop Microbiology/Endotoxins/RMM

Berlin, Germany
<https://europe.pda.org/WSMicrobio2012>

28-29 Microbiology/Endotoxins/RMM

Berlin, Germany
<https://europe.pda.org/Microbio2012>

www.pda.org

For an updated PDA calendar of events please visit
www.pda.org/calendar.



Save these dates!

MARCH 2012

1-2
**Microbiology – Rapid
Microbiological Methods**
Berlin, Germany
<https://europe.pda.org/TCRMM2012>

2
**Environmental Control
and Monitoring for Regulatory
Compliance – *New Course***
Berlin, Germany
<https://europe.pda.org/TCEnviro2012>

5-9
**Aseptic Processing Training
Program – Session 2 Week 1
(Week 2: March 26-30)**
Bethesda, Maryland
www.pda.org/2012aseptic

6-7
**Workshop Quality by Design:
The Role of Analytical
Science in Implementing
QbD – Technical and
Regulatory Aspects**
Liverpool, United Kingdom
<https://europe.pda.org/QbD2012>

13-14
Parenteral Packaging
Berlin, Germany
<https://europe.pda.org/ParPack2012>

15
Container Closure Development
Berlin, Germany
<https://europe.pda.org/TCCCD2012>

15
**Selection and Utilization
of Glass Containers
in Pharmaceutical Packaging**
Berlin, Germany
<https://europe.pda.org/TCGlassContain2012>

20
IG Meeting Visual Inspection
Berlin, Germany
<https://europe.pda.org/IGVisual2012>

21
IG Meeting Freeze Drying
Berlin, Germany
<https://europe.pda.org/IGFreezeDry2012>

27
IG Meeting Pre-filled Syringes
Berlin, Germany
<https://europe.pda.org/IGPrefilled2012>

APRIL 2012

16-20
**2012 PDA Annual Meeting
and Course Series**
Phoenix, Arizona
www.pda.org/annual2012

18-19
**PDA Single Use Systems
Workshop**
Phoenix, Arizona
www.pda.org/singleuse2012

MAY 2012

14-18
**Aseptic Processing Training
Program – Session 3 Week 1
(Week 2: June 4-8)**
Bethesda, Maryland
www.pda.org/2012aseptic

14-18
**The 6th PDA Virus
and TSE Safety Conference
and Course Series**
Bethesda, Maryland
www.pda.org/virustse2012

Tech Trends continued from page 29

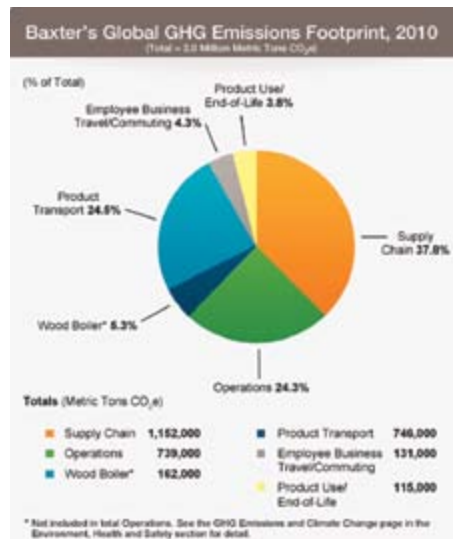
Baxter established its first formal environmental program and policy in 1977. Since then, milestones have included:

- Establishing The Baxter International Foundation in 1986
- Publishing the company's first formal ethics manual in 1989
- Introducing Baxter's first work/life benefit program in 1991
- Establishing the Corporate Responsibility Office to oversee the company's ethics and compliance practices in 1993
- Taking steps to reduce use of packaging materials, decrease water consumption and waste generation, and conserve energy since 1988

ability program worldwide. The Council meets quarterly to encourage employee engagement and address obstacles in implementing the program locally. Since 2009, Baxter has incorporated 20 green criteria into its purchasing procedures to provide its procurement organization a framework to evaluate suppliers' sustainability initiatives. Baxter structured these criteria to fall into four categories that align with Baxter's own sustainability efforts. In 2010, Baxter added a fifth category to evaluate suppliers' protection of human rights, since Baxter

considers this an important component of suppliers' sustainability commitments.

Baxter is driving continual performance improvement through ongoing programs and projects in energy conservation, installing cogeneration systems at select locations, sourcing renewable energy and purchasing select emissions credits and offsets. The firm is committed to driving reductions in its carbon footprint and use of natural resources with several related 2015 goals. For example, building from the 29% indexed



In 2010, Baxter's greenhouse gas emissions from operations equaled 739,000 metric tons of carbon dioxide equivalent

to revenue decrease in net greenhouse gas emissions from operations through 2010, Baxter will focus on meeting its 2015 goal to reduce greenhouse gas emissions by 45% indexed to revenue from a 2005 baseline. 🌱

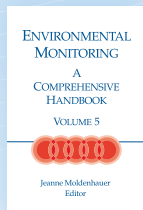
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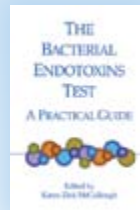
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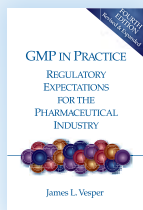
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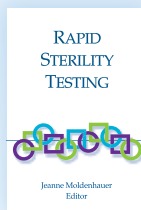
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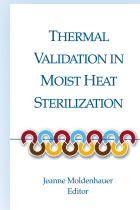
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PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment

Anastasia Lolos, Visionary Pharma Consulting



The third and last day of the *2011 PDA/FDA Joint Regulatory Conference* held in Washington, D.C. included traditional sessions wherein officials from the U.S. FDA provided updates on compliance matters and FDA Center initiatives. The following centers appeared:

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Veterinary Medicine (CVM)
- Office of Regulatory Affairs (ORA)

Mary Malarkey, Director of CBER's Office of Compliance started first the session providing compliance updates. Her dynamic presentation style captured the audience's interest, even though it was early morning. CBER's greatest accomplishment for the year is the ISO/IEC 17025 standard accreditation of its laboratories for 13 test methods by the American Association for Laboratory Accreditation. This is a long awaited endeavor, and CBER is pursuing accreditation for additional methods. Certainly, an accomplishment to be proud of as evidenced in the presentation. These test methods are used to support significant regulatory decisions with huge public health impact. Other updates from CBER include the Electronic Gateway for submission of H1N1 lot release protocols. The pilot was expanded to conduct randomized sampling of all biological product manufacturers subject to lot release. The first phase of the pilot has been completed, and results are being reviewed. The PREDICT method (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting) is in use and expanding. In her presentation, Malarkey emphasized that manufacturers must use the correct product codes and ensure data quality for faster entry into the United States without delays.

CBER is evaluating rapid microbial methods for testing biological products for sterility in its laboratories. This can offer great insights into alternative microbiological methods from regulators who are studying these methods themselves. Such tasks enhance more informed regulatory decisions. Regarding the sterility test, amendments have been proposed to 21 CFR 610.12. The proposed rule was published in June 2011 and updates a very outdated section of the CFR for sterility testing of biologics. This

proposed rule was many years in the making, and many are glad to see it published.

Malarkey also provided an update on what CBER has found through its inspectional activities:

- One establishment sold semen without adequate protection against disease
- A firm owner sold unapproved stem cell vials
- A physician implanted allogeneic amnion tissue without an investigational drug application (without screening and testing donors)

In addition, there were two separate disqualifications and restrictions of two physicians.

Eric Nelson, Division Director of Compliance, CVM, provided the number of inspections from 2009 to present, emphasizing the significant increase in surveillance inspections for veterinary drugs. For cause inspections were directed towards compounders or were in response to incidents. CVM is receiving more requests for medically necessary veterinary products (MNVP) and recognizes the need to prevent drug shortages. However, the conferred MNVP status is not a substitute for GMPs. His division is supporting the Unapproved Drug Initiative through the drug approval process and coordinated enforcement events. Product can be moved to legal status while unsafe products are removed from the market.

Ann Ferriter, Acting Director, CDRH's Division of Risk Management Operations, Office of Compliance, presented current CDRH issues. She presented graphics that showed the major reasons for delayed recalls. But, significant efforts are being made to improve the recall process, including corrections and removals of products; metrics are being implemented to streamline recall processing and recall classification through data analysis.

A draft guidance on distinguishing medical device enhancements from product recalls and plans for improvement are underway. Those plans include:

- Improved collaboration between CDRH and ORA
- Increased training for CDRH staff
- Effective outreach to industry through guidance
- Improved communication with patients and health professionals

Ferriter mentioned that the FDA recall website has been improved to help in these efforts.

Steve Lynn, Acting Director, Office of Compliance, presented for **Ilisa Bernstein**, CDER's Director of the Office of Compliance. Lynn outlined the new structure of the Super Office and, in particular, the Office of Drug Security, Integrity and Recalls and the Office of Manufacturing and Product Quality.

CDER's compliance accomplishments have been:

- The membership acceptance into the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- The Joint Australia, EMA and U.S. CGMP Inspection Pi-

lot Program

- The GCP U.S./EMA Pilot Program
- The GCP Inspection risk model pilot program
- The completed preliminary review of counterfeit/diversion case information
- The development of track and trace standards

Lynn, however, did not elaborate much on the status and success of these pilot programs. In the future, it would be useful to see metrics and results presented, along with a discussion on how these programs will lead to pharmaceutical excellence and regulatory innovation.

The second part of CDER's presentation included certain notable warning/untitled letter and actions. There were two consent decrees, a STD joint initiative with the Federal Trade Commission, and an enforcement action against marketed unapproved cough, cold, and allergy products. A warning letter to Cetero was also mentioned regarding bioequivalence studies conducted at a contract laboratory and questionable practices revealed during inspection. Applicants who employed the contractor to support ANDAs were notified.

CDER's compliance priorities are globalization, pharmaceutical supply chain issues, multisite/corporate global issues, marketed unapproved drugs, quality of compounded drugs, quality management systems and prevention/mitigation of drug shortages. ➤

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It was not clear from the presentation which metrics will be used to monitor how these priorities will be addressed or how to gauge its effectiveness. Success of several will not be easy to determine.

Armando Zamora, Acting Director, Office of Enforcement, ORA, presented the FDA initiatives that are affecting enforcement actions. Current focus is on improving the enforcement process and making it more transparent, effective and timely. A slide outlined Commissioner Hamburg's six initial steps to achieve this feat. Enforcement cases must be processed more quickly and eliminate redundancy without sacrificing quality and objectivity. Zamora referred to FDA's Transparency Initiative, launched in June 2009, though it would have been useful for him to present metrics and results associated with it. Equally important would be a discussion about what is an appropriate time frame to evaluate initiative results.

All presenters were available to answer questions in a panel at the end of the first plenary session on compliance updates. Following a break, the conference continued with the last session, Center Initiatives.

Steve Silverman, Director, Office of Compliance, CDRH, presented the business case for compliance. All units should support and own quality, not just the quality and compliance units, in order to have a culture of compliance with collaboration, risk prevention, lower costs, fewer complaints, fewer investigations per batch and enhanced productivity. The U.S. device industry has been growing rapidly, but quality incidents are growing faster than the market. More than half of all device recalls are due to design and manufacturing process control failures. Silverman presented several graphs to demonstrate these facts and emphasize that risks are concentrated to certain device types. Device recalls have also increased with gaps in product design, manufacturing process controls and supplier management. FDA will attempt

to address quality gaps through reshaping its compliance focus. A slide of interest is the one depicting the level of regulatory focus and a question in a box. The question asks whether there is a mismatch between where industry perceives risk and FDA's regulatory focus. The next steps are to gather input from constituents, publish findings and assess what needs to change for improved device quality.

CBER initiatives were described by **Chris Joneckis**, Senior Advisor for CMC Issues. Joneckis presented CBER's six strategic goals for 2012-2016, which

All presenters were available to answer questions in a panel at the end of the first plenary session on compliance updates

are to 1) increase national preparedness for addressing global threats, 2) improve global public health through international collaboration, 3) enhance ability of science and technology for the development of safe and effective biological products, 4) ensure product safety, 5) advance regulatory science and research, and 6) manage for organizational excellence and accountability. The last goal is extremely important for successful realization of the other goals.

CBER will employ science and regulation to advance product development through public meetings, workshops, collaboration with other government agencies, patient advocacy groups, scientific societies and international organizations. Active and early engagement of all stakeholders by FDA is of the utmost importance for stem cell-derived medical products to translate biomedical innovations into new safe and effective products. Specific examples were provided regarding these products and CBER interactions with CDRH, NIH and other stakeholders. Regarding global public health, FDA has frequent interactions with EMA and formal cooperation and confidentiality arrangements. Joneckis referred to placental/cord blood for he-

matopoietic reconstitution and efforts made to develop standards and guidance for their approval. Methods are developed to address the availability of influenza vaccines and increase their production. The regulatory approach is a pyramid that starts with laws followed by regulations, guidance and external standards, and finally, policies and precedents. Risk should be evaluated based on science. Laws are created based on risk and should support science.

Joneckis summarized a list of guidance and rule actions in 2011 performed by CBER. He ended his presentation emphasizing health informatics needs and scientific computing. These have a major role to play in detecting adverse events

and access healthcare resources so as to anticipate public health outcomes. In addition, there are initiatives for submitting electronic applications to CBER in the future. His last slide outlined CBER's vision to use innovative technology for the advancement of public health.

Bernadette Dunham, Director of CVM, provided an overview of her center and the products it regulates. CVM has been tasked to transform food safety practices as part of the 2011 Food and Safety Modernization Act. Other priorities are animal biotechnology, unapproved animal drugs, the Animal Drug User Fee Act and Animal Generic Drug User Fee Act, approval of drugs for minor use/minor species, bovine spongiform encephalopathy (BSE), illegal drug residues in animal derived foods, antimicrobial resistance, international activities, turtles (due to *Salmonella* species), and outreach to consumers and stakeholders to increase animal health literacy. The Food Safety Modernization Act encompasses prevention through enhanced partnerships, inspections, compliance and response and import safety. Dunham presented additional detail on each center priority. She provided a list of recent actions and sum-

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Reasons for Missing the Mark of First Cycle Approvals

Bob Darius, GSK Vaccines

Regulators have between four to ten months to determine whether a new drug product or major manufacturing change is safe, efficacious and acceptable for approval. However, industry has between five to seven years to prepare and process, then submit the application or supplemental application to regulators. With the mounting pressures on both the industry and regulators, increasing challenges and expectations around the approval of new products, including costly financial investments in new infrastructure or manufacturing technologies, the need to get it right the first time for regulatory reviews is needed now more than ever before. The U.S. FDA has taken note of this need and shared their top ten findings leading to delays in approvals at the 2011 PDA/FDA Joint Regulatory Meeting in Washington, D.C. this September.

Carol Rehkopf, Consumer Safety Officer, CBER, presented her talk, entitled, “First Cycle Review—Top Ten Reasons for Missing the Mark of First Cycle Approval for BLAs, NDA, NADAs and their Supplements.” These findings were

obtained from an analysis of FDA Complete Review letters for applications submitted during the past four years (from 2008–2011), which did not receive first cycle approval. This analysis includes findings from FDA’s drug, biologics and vet centers (CDER, CBER and CVM).

Inadequate or missing manufacturing process validation data are another major area of concern

The top ten reasons for missing first cycle approval are discussed further below, but include:

- Inaccuracies in cross-referenced Master Files in CMC applications
- Inadequate/missing assay validations or data
- Inadequate/missing manufacturing process validations
- Discrepancies in clinical data or additional clinical analyses requested
- Unclear clinical data presentations
- Incomplete statistical evaluations or statistical methods used not justifiable
- Insufficient detail for acceptance data and CMC information
- Disagreement on in-process and final product testing criteria or methods
- Quality of reference standards unclear

- Inspection issues

Challenges noted with cross referenced Master Files in CMC sections include submission of incorrect file numbers; missing authorization for review letters and obsolete listings of authorized users. In some instances, the Master Files had not been updated or did not include appropriate information to support the application.

Compliance issues (or GMP concerns noted on inspections) of the facilities referenced in the Master Files were not always communicated to the sponsor, but were known by the regulators at the time of review.

Inadequate assay (method) validations, missing validations or incomplete information submitted in the CMC and clinical assay sections have also been noted.

Inadequate or missing manufacturing process validation data are another major area of concern. In an earlier session at this conference, **Lisa Skeens**, Vice President Global Regulatory Affairs, Pharmaceuticals, Global Regulatory Affairs, Baxter, recommended starting early in order to plan for a high quality submission. This can be done by having sound scientific positions for decisions made during the



Carol Rehkopf



Laurie Norwood



Lisa Skeens

development of production processes.

Additional recommendations included:

- Generating data of appropriate quality and quantity to meet regulatory expectations
- Focusing on study designs and executing them with accuracy

The importance of gaining approval from the regulators on the study designs prior to execution was also stressed.

Discrepancies have been noted in clinical data provided in submissions. Additional analyses of clinical data have been requested to support the risk benefit assessments for some products after submission of the application. Several speakers at this session stressed the importance of developing and maintaining clear communication with regulators. The need to listen and understand their concerns and gain agreement on the studies needed to appropriately identify and understand risks is a critical skill which could be more fully utilized.

Unclear clinical data presentations for controls, definitions and timing of events were other contributing factors leading to lengthy delays. The submission of additional clinical data to an application or submission will add significant delays to review timelines since these are typically considered major amendments.

A sound body of evidence and data are the cornerstone of any good application. However, Rehkopf noted that there have been examples where the analytical statistical methods used may not have been justified or the evaluations submitted were obviously incomplete. Therefore, the need for rigorous statistical evaluations using different methods and approaches is important to allow for a more robust understanding of what the data exhibits.

Additional results of nonoptimized communication with regulators include insufficient details provided for acceptance criteria or specifications and CMC information. Disagreements between the sponsor and regulators on in-process and final product testing criteria, specifications or methods may also cre-

ate situations resulting in delays due to the need of repeat testing. These areas should be discussed in detail prior to producing conformance lots. Additionally, if a sponsor chooses not to follow a regulation directly, it is critical to notify regulators early to seek clarification on what data would be needed to support the equivalency of an alternative process.

An unclear history, pedigree or quality level of reference standards are other unfortunate reasons for potentially extensive delays in approval after the first review cycle.

Lastly, inspectional issues noted during pre-approval inspections of sponsors, suppliers, or contract manufacturing organizations (CMOs) highlighting significant

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Practical Recall Lessons Given at PDA/FDA

Emily Hough, PDA

No matter how hard companies work and spend on ensuring product quality, recalls happen, so companies are advised to have plans in place to manage product recalls. A session at the *2011 PDA/FDA Joint Regulatory Conference* on drug product recalls offered both the regulatory and industry perspectives on this critical quality procedure. U.S. FDA's **Israel Santiago**, Acting Branch Chief, CDER's Office of Compliance, reviewed the regulatory expectations for reporting recalls; MedImmune's **Raymond Godlewski**, Sr. Vice President, Quality and Compliance, provided tips on managing the process internally.

Santiago discussed a company's responsibility to notify the public about product recalls. He admitted that there are challenges with communicating with the Agency while going through a company's specific chain of command. However, he said, "the earlier FDA knows about [the recall], and we can start working with you in addressing this, the easier it will be for everybody."

Developing effective communication to the public can be a challenging area when a company is initiating a recall

He also mentioned that it is the firm's responsibility to identify the root cause, not just the reason for a recall. Providing a true root cause to FDA enables the regulators to convey meaningful feedback to the industry and helps the manufacturer to implement effective corrective actions, he said.

Developing effective public communication can be a challenging area when a company is initiating a recall, he said. The information that is conveyed to the public must be specific and provide timely information via a Recall Letter and/or Press



Israel Santiago



Raymond Godlewski

Release, depending on what class of recall is being implemented.

Santiago also mentioned that in August CDER initiated a pilot program to post recalls to the Enforcement Report before they have been classified as a type I, II or III recalls. This program will be reevaluated within six months.

Once the information is received, the Agency is immediately interested in the company's history, GMP status, product recalls of the same or similar products (even if it was recalled by another company), and why that product has been recalled in the past. This gives the Agency the ability to view past behavior with a specific product in order to determine the cause of the recall. While root cause information is not always available when a recall is submitted, Santiago advised companies to "definitely identify it at an early stage, as the root cause will help not only you, but also the Agency. It will help

everybody contain the problem more effectively, know the scope of the problem and how widespread it may be."

When Handling Recalls Think Out of the Box

Godlewski gave the audience some "out of the box" tips on dealing with recalls. He said that good science doesn't lie, and it is important to analyze the data in a multiple of ways; if it indicates a recall situation, you must accept it.

He told members of the audience that they must really think about the words "voluntary recall" and how others could interpret them. For example, some healthcare providers have interpreted the words to mean that they can choose whether to send the product back or not.

Godlewski also pointed out that non-traditional methods of communication like social media could be used to share with the public that a recall is occurring. He said since there is "no central pharma anymore" a different way is needed to get the word out to user groups that are using the products.

He ended his presentation saying, "Patient safety first. There isn't a right away to do the wrong thing." ➤



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Practical Tips for Handling Recalls

Raymond Godlewski, Sr. Vice President, Quality and Compliance, MedImmune, gave some practical tips on how to avoid the traps and pitfalls of a recall situation at the PDA/FDA Joint Regulatory Conference.

Godlewski said it was important to make appropriate Agency contacts to discuss this situation before any outside communications are made, especially in situations where there are complex supply chains. He clarified, "You may have a third party that you are manufacturing for that has a district on the west coast, you may be in Texas and have another group headquartered [elsewhere] and you have a manufacturing plant in another jurisdiction. The key is to have all of those Agency offices informed at roughly the same time and with roughly the same information, or you will get a bevy of phone calls at varying points. Make sure you know who your contacts are."

He said it was important not to assume that a situation does or does not require recall information. He discussed a situation involving a drug product that even the FDA New Jersey District Office director used. "He brought a unique perspective to the decision-making process and what we were about to do." Those types of discussions, he said, led to a continued supply of the product in the marketplace, especially for those who critically needed the medicine.

It is important, Godlewski continued, for firms to describe the NDC packaging level in recall letters in order to ensure that different user groups know what to pull and don't mistakenly leave a product on the market that should have been pulled.

About the Experts

Raymond P. Godlewski is currently the Sr. Vice President, Quality and Compliance, MedImmune, where he is responsible for global quality and compliance for research and development activities and commercial operations. Prior to joining MedImmune in April of 2011, Godlewski held positions of increasing responsibility in manufacturing, quality assurance and quality control at Ayerst, Abbott Laboratories, Wyeth and Baxter Healthcare. Godlewski was a

contributor in the development of PDA Technical Report No. 43, has served on the Rx-360 Board of Directors and has spent the majority of his 29 year industry career in the area of aseptic processing.

Israel Santiago accepted a position in CDER Office of Compliance in the Recalls Branch in 2007. There he helped develop standardized business processes and further foster the responsibilities of the branch to assure an Office of Compliance-wide

coordinated approach to events to ensure the containment of drug products that posed a risk to consumers. In this role he became the focal point of contact coordinating Office of Compliance' response to the Heparin Crisis in 2008; and in that same year, he was selected as a Team Leader in the Recalls Branch. He has actively accepted the role of Branch Chief by representing and leading the Recalls Branch in developing policy, procedures and precedent setting events. 🍷

PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment, continued from page 38

marized international activities in which the Center participates. As one of FDA's smallest centers, CVM is involved in an impressively wide array of activities and has broad responsibilities.

Elaine Morefield, Deputy Director, Office of New Drug Quality Assessment, CDER, presented CDER's goals and initiatives. These are very familiar to the PDA community, and include: 21st Century Review Initiative, Computation Science Center, Critical Path Initiative, Pharmaceutical Quality for the 21st Century, Safety First Initiative, Safe Use Initiative, Sentinel Initiative, Transparency Initiative and Unapproved Drugs Initiative.

Zamora presented ORA's initiatives; he expanded on a number of the topics he discussed in the previous session.

Conclusion

It is a credit to the Agency that high-level officials make time to appear at the PDA/FDA conference each year to discuss their regulatory initiatives.

Several of the CDER initiatives began many years ago. While there have been interim and final reports published, it would be valuable to see how the Center is measuring their overall impact, including a discussion of the metrics used. For example, what are the initiatives' impact on public health? Have they fostered innovation? Are pharmaceutical products

safer? What if the initiatives are not successful? Does the FDA have backup plans to enhance regulatory innovation?

It is equally important for industry and consumers to provide feedback for innovation to occur. Industry is accountable to FDA's regulations, but FDA is also accountable to the public and patients in fulfilling its role of safeguarding public health and using its resources efficiently and wisely to accomplish this tremendous feat. The *PDA/FDA Joint Regulatory Conference* is an ideal forum, at least for industry, to provide FDA with feedback.

In the end, we all must work together to find common ground. 🍷

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FDA PIC/S Its Friends

Emily Hough, PDA

Since it became a member of PIC/S in 2010, the U.S. FDA has taken advantage of opportunities to gain regulatory support from its counterparts in other countries. **Brenda Holman, Stephan Rönninger, PhD, and Katrin Nodop, PhD,** spoke about those opportunities at the *2011 PDA/FDA Joint Regulatory Conference* in the Tuesday session, “FDA Accession to PIC/S.”

Holman, Executive Director, Strategic Initiatives, Office of Regulatory Affairs, U.S. FDA, said PIC/S’ international training forum, jointly run by regulatory authorities, for new inspectors who wish to improve their oversight skills in a specific field. This program involves teaming up junior inspectors with experienced inspectors during routine inspections. Holman said that the training allows for personal contact with regulators from different countries, which often simplifies contacts and exchange-related information. “PIC/S is one of the few international GMP groups for networking and confidence-building amongst regulatory inspectorates and inspectors where experts can meet, discuss issues of mutual concern, and share experiences and information.”

Nodop, Principal Scientific Administrator, Inspections Sector, European Medicines Agency, concurred with Holman. “I think the most important collaboration with PIC/S is the networking and the training aspect. I think for that, PIC/S is really excellent. I think part of why it works so well is that it is not mandatory. These authorities work together because they want to work together. There is no regulatory framework with legislation coming down from the top telling them what to do.”

Rönninger, Head, External Relations Europe/Japan, F. Hoffmann-La Roche, stated that PIC/S provides the ability for informal alliances and joint understanding and trust with other agencies.

While inspections by participating authorities do not have to be accepted by other members automatically, PIC/S provides an opportunity for regulatory authorities to better understand the processes performed by other inspectorates.

There is also an endeavor to expand and offer electronic learning opportunities through the PIC/S website for inspectors only.

Another benefit of PIC/S membership of inspectorates is that regulatory authorities automatically benefit from being a part of the a rapid alert recall system. The system notifies participating regulatory authorities of pharmaceutical product recalls that have been distributed. Nodop said that PIC/S members are part of the distribution list of the European Rapid Alert system for quality defects.

By facilitating cooperation and networking among regulatory authorities and regional and international organizations, PIC/S has attracted 39 participating authorities. Additionally there are some major economies and international regulatory authorities that have shown an interest in joining the organization, including those in China, Japan, Russia, South Korea, Turkey and Hong Kong.

By taking part in the meetings of the PIC/S committee, participating authorities were involved with the development and harmonization of international GMP guides and guidelines. The main document referred to was the PIC/S GMP guide. Holman said this has been revised over time to accommodate stringent manufacturing requirements and to cover newer areas in scientific development, such as biological and biotech products. In addition to the GMP guide, PIC/S has pioneered the development of a number of guidance documents on topics like site master files, quality systems requirements for pharmaceutical inspectorates, and the first guideline for the manufacture of

APIs which was used as the basis for a draft ICH Q7. She mentioned that there is a potential to expand PIC/S activities for APIs, good clinical practices and good distribution practices.

Some new challenges for PIC/S are that globalization has changed the way the industry does business. According to Holman, “We see an increasing amount of imported products; we are approximately at 80% of APIs and 40% of finished products being imported to the United States. Many regulators are struggling with imports coming from countries with less developed regulatory systems.”

Holman said that many countries are concerned that globalization increases the complexity of the supply chain and could also increase the broad scope of potential threats including counterfeits, diversion, intentional adulteration, cargo thefts, substandard products and even threats of bioterrorism.

PIC/S has and is presenting new opportunities for FDA by engaging in regulatory cooperation which will increase confidence among PIC/S partners, make better use of shared information, avoiding duplication of work, and make improved and more informed regulatory decisions.

In just one year, it was clear that FDA has greatly benefitted from PIC/S membership. One can only wonder how the U.S. watchdog much greater the benefits will be in the future.

About the Experts

Brenda Holman has been with FDA twenty-three years. She currently is the Executive Director of Strategic Initiatives for Office of Regulatory Affairs. In this capacity she oversees the implementation of an all inclusive Quality Management System in ORA. In August 2009 and August 2010, Holman was actively involved



in the PIC/S assessment of FDA as part of the Agency's application for membership to PIC/S. FDA was officially accepted into PIC/S January 1, 2011 as a full Participating Authority.

Katrin Nodop, PhD, joined the Inspection Sector at the European Medicines Agency in 1997. She was responsible for the implementation and operational aspects of Mutual Recognition



Agreements between the European Union and Third Countries including related activities; Sampling and Testing of Centrally Authorized Products; and she provided the secretariat for the EEA Joint Audit Programme of GMP

inspectorates until very recently. Now Katrin focuses on the coordination of the implementation of the new European legislation on falsified medicines within the Agency and with the EU member states. She holds the chair of the EU GDP drafting group revising the EU GDP guideline and related procedures and the chair of the falsified medicines taskforce at the Agency. She also supports the Agency's GMDP Inspectors Working Group in regulatory GMP and GDP topics.

Stephan Rönninger, PhD, is the Head of External Relations Europe/Japan of F. Hoffmann-La Roche based in Basel, Switzerland and is responsible for collaboration, information management and commenting regarding Quality Management, Good Manufacturing

and Distribution Practice (GMDP) topics. He represents, on behalf of Roche in the European industry association, EFPIA. He acts as moderator of the network on "Better Regulations" including foreign regulatory GMP/GDP inspections and represents EFPIA in the ICH Quality Implementation Working Group (Q-IWG), Quality Risk Management (ICH Q9) and as a GMP expert in the discussions regarding GMP-certificates for Turkey. For PDA, he is the European Regional Leader for the Regulatory Affairs and Quality Advisory Board (RAQAB) and one of the founders and co-chair of the Paradigm Change in Manufacturing Operations initiative.



Journal Preview continued from page 31

Contaminants of Cell Culture"

Richard L. Friedman, "FDA Post-Approval Expectations for Adventitious Virus Contamination Prevention"

Mahmood Farshid, "Viral Safety of Plasma-derived Products"

Sridhar Pennathur, "Application of Risk Assessments in the Design of the Overall Viral Control Strategy Used during the Manufacture and Testing of Live Virus Vaccines"

Anthony S. Lubiniecki, "Evolution of Approaches to Viral Safety Issues for Biological Products"

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PDA Chats with James Vesper About New Book

Walter Morris, PDA

The following is an interview with **James Vesper** about his book, *In Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition*. Vesper, President, Learningplus, has had more than 30 years experience in the pharmaceutical industry and has co-developing a series of web-based training programs covering basic, intermediate, and advanced GMP, GCP and other U.S. FDA/industry-critical topics.

PDA: How did this book come about?

Vesper: The first edition was a by-product of an e-learning course I helped develop in 1999. We were trying to give an overview of the GMPs that apply to making pharma products and examples of specific requirements.

PDA: The book's third edition had about 20 chapters; this new edition has 33. Why such a large increase?

Vesper: When I wrote the first edition, the concept of an integrated quality system was just starting. In fact, what I refer to now as "quality system elements" I called "GMP tasks." The elements presented in the new edition reflect what you see in many companies and also the

themes found in the ICH Q10—Pharmaceutical Quality System guideline.

PDA: You talk about "expectations." What exactly are they? Are expectations the same as "regulations"?

Vesper: I started using the term "expectations" in the early 1990s when doing training programs. Participants would ask for "proof"—for example, where in the GMPs does it call for internal audits or for a specific way to correct errors? You can't find those things in the U.S. cGMPs. (You do see those requirements now in the Canadian and European GMPs.)

A key to understanding what makes an expectation is from a warning letter FDA sent out in 1998. In it, FDA says that what makes for a manufacturing practice to be current and good is if it is "feasible"—you can do it or others are doing it—and "valuable"—you'll have more control over your product or process or information used to make a decision about your product or process. In other words, these are the things that investigators, inspectors and compliance auditors want to see.

PDA: So expectations change?

Vesper: Absolutely. We're seeing this now with quality risk management. While FDA cannot cite a pharma firm for not doing a risk assessment (because it isn't a regulation), you see FDA wanting firms to try to justify their practices like preventing cross contamination through a risk assessment. In a way, the firms are being challenged to show that they know what the risks are and that they have adequately controlled them by doing a risk assessment. The term may be new, but at the core, its GMP.

PDA: In what other ways is the new edition different?

Vesper: Because of my interest in risk assessment, I added some risk questions that are relevant to each quality system element. Also included are citations from the World Health Organization (WHO) GMPs and ICH Q8, Q9 and Q10.



PDA: This new edition is 600 pages. How long did it take to write all of that?

Vesper: Much longer than I had planned. As I started on revising the chapters from the last edition, I saw that a lot of the underlying GMP philosophy had evolved—more systems and risk-based thinking. Because of that, I realized I needed rewrite most everything. I began over the winter holidays in 2010 and finished it in late July 2011. It probably took about 1200 hours.

PDA: Who is the book written for? GMP experts?

Vesper: The intended audience includes those who are relatively new to GMPs and pharma manufacturing, and those who are wanting a broader, more integrated international perspective on what "good practice" is. I think trainers and auditors will also find it quite useful. It makes a great holiday gift for your boss.

Question: You've written five books and a number of book chapters on topics like risk management, training, auditing and GMPs. What are you working on now?

Vesper: I'm half way through a PhD in education. It's a project I'm doing with WHO on developing expertise of those involved in cold chain. So, that takes a lot of time. I'm finding the whole area of ex-

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James L. Vesper

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pertise and knowledge management pretty interesting. Maybe in the future there will be something publishable on that.

PDA: Why do you write? What rewards or satisfaction does it give you?

Vesper: The best way to learn about a particular topic is to try and teach it back to someone else. To do that, you

need to construct a mental model—a picture in your mind—of how all the elements in that topic fit together. Unless you have that, you won't be able to explain the topic to someone else. For me, writing forces me to develop that model and understanding.

Probably the biggest reward I get is

when an email comes in or I meet someone at a conference who says that a book or chapter was useful to them and that they used it in developing a system or it helped them get some practical insights. Because we in our industry develop and produce products that improve health and save lives, so having a small part contributing to that is very fulfilling. 🍷

First Cycle Approvals continued from page 41

GMP gaps sometimes result in a final blow to an already challenging and costly process of attempting to attain approval of drug products. This is an area where the sponsor should be in close coordination with the manufacturing sites or CMOs to establish a good working relationship. Thorough evaluation of the manufacturing and testing facilities, equipment, procedures, validation/qualification documents and quality systems as they apply to the particular product or manufacturing process should be done well before the manufacturing agreements are completed.

An additional recommendation to help assure timely reviews was made by **Laurie Norwood**, Deputy Director, CBER, U.S. FDA. She recommended notifying the appropriate regulatory teams within FDA to confirm when any new applications or supplements are scheduled to be submitted. This allows adequate resource planning to assure that appropriate reviewer expertise is available, as well as allowing for planning of workload management.

About the Author

Bob Darius is currently Head of the Quality

Units for the GSK Vaccines manufacturing sites located in Germany and North America. Previously, he worked in the FDA Center for Biologics Evaluation and Research for 15 years. After leaving FDA in 2005, he worked for Biologics Consulting Group, and then started Radius Biotechnology, LLC (a biotechnology consulting company). Bob is a Microbiologist by training and attended George Mason and Johns Hopkins Universities. 🍷



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- Aseptic Processing/Parametric Release/Aseptic Process Simulation
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Interest Abounds During Process Validation Session

Karen Ginsbury, PCI Pharmaceutical Consulting Israel

[Editor's Note: The following article expresses the opinions and ideas of the writer.]

The breakfast session on Process Validation aroused sufficient interest to get delegates out of bed at 7:30 a.m. in the morning and fill the room to capacity. No one wanted to miss the current take on regulations/expectations versus guidance/recommendations.

Moderated by U.S. FDA's CDER's Consumer Safety Officer **Doug Campbell**, the session included brief presentations from **Scott Bozzone**, PhD, Senior Manager, Global QO Validation, Pfizer, and **Shawn Gould**, Consumer Safety Officer, CDER. A panel discussion which included **Steven Hertz**, Consumer Safety Officer, CDER, followed.

There was discussion on interpretation of retrospective validation within the lifecycle scheme. One of the take-home messages was that the use of quality risk management needs to focus validation effort on high-risk process parameters. This will only work where there is a robust predictive small scale model. If "surprises" are encountered during scale-up, then the model clearly is less robust than anticipated. Modifications may be necessary before launching the commercial process and/or additional full scale batches. In any case, it is not realistic or responsible to base the whole commercial manufacturing experience on a single full scale batch at the time of product launch and process performance qualification. The company should have a documented rationale to support the decisions that they make moving away from the classic "three batches and I'm done" approach.

A company must also develop a product control strategy identifying which process parameters need control and monitoring. When the submission is made, the reviewers will determine if the submitted data are adequate and appropriate to support the conclusions and the

proposed model. Modification of parameters and adjustments to the process should be based on predictive statistical models and some situations will always warrant a red flag. For example, replacing a lot of resin in a protein purification process is going to need a change control of some kind. Closer scrutiny will be needed. It will probably involve an enhanced sampling and testing plan as well as close monitoring of the process for the first few batches produced after the change. Companies will also need to be prepared to take diversionary action where data trends indicate that an out of control situation is developing or "less than desired" results are obtained. This includes notification of senior management in a timely manner which is a regulatory requirement.

In answer to a query regarding transfer of processes and performance of a process performance qualification (PPQ) by a Contract Manufacturing Organizations (CMO), one of the FDA panelists said that there would be knowledge transfer and sharing of negative outcomes during the development process to enhance control and process understanding at the CMO. They noted that this should be a formal process. Generally, it would be expected that the Design of Experiment would be conducted during process development. The outcomes should be formally communicated when legacy products are transferred from site-to-site. Common cause of variation must be

understood to allow deviations and non-conformities to be assigned as a common cause as opposed to a special cause.

The Q&A also included a discussion on the role of CMOs in process validation in the quality agreement with roles and responsibilities assigned between the sponsor/contract giver and the CMO (Contract Acceptor). It is important to clarify this relationship early before any development and manufacturing take place. When development is performed by one party and commercial manufacturing is done by another, there needs to be documentation of technology transfer and an agreement on who will do the first stage of validation.

Another question addressed the issue of retrospective validation. FDA emphasized that their position is that this is no longer considered appropriate; in fact, the option has been removed from the new document.

A participant asked what would happen if a company had been manufacturing for other markets and then wanted to register a product in the United States, would it be appropriate to use retrospective data. The answer was that previous full-scale manufacturing data would certainly be a useful starting point for the formal PPQ, but that data needs to be collected after a formal sampling plan and acceptance criteria have been established and some level of formal prospective validation would be expected. ☺



Scott Bozzone



Doug Campbell



Shawn Gould

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PDA Supports Timing/Content of FDA Bio Product Amendments, Offers No Revisions

For the comments grid, visit www.pda.org/regulatorycomments



Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Amendments to Sterility Test Requirements for Biologic Products
Docket No. FDA-2011-N-0080 (Comments due, Sept 19, 2011)

Dear Sir/Madam,

PDA is pleased to support FDA's Amendments to Sterility Test Requirements for Biologic Products. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in drug substance and drug product sterility testing, including members representing our Biotechnology, Regulatory Affairs and Quality, and Science Advisory Boards.

PDA has no suggested revisions on this proposed amendment of the regulations. We support both the timing and content of your proposals which are intended to provide manufacturers of biological products with greater flexibility and encourage the use of state-of-the-art test methods.

For your information, in a letter to FDA dated June 27, 2011, in response to the *Periodic Review of Existing Regulations* (Docket No. FDA-2011-N-0259), PDA has already identified 21 CFR 610.12 as a regulation that is outdated and possibly causing harm. This regulation can cause unnecessary risks to drug product sterility by requiring that manufacturers conduct a bulk sterility test just prior to filling. A copy of that letter is attached, and reference to it will show in detail why and how this regulation should be modified.

PDA supports FDA's expedited review and implementation period for these amendments to the Sterility Requirements for Biologic Products.

Sincerely,

Richard Johnson
President, PDA

CC: R. Dana, PDA, R. Levy, PhD, PDA, J. Lyda, PDA

PDA Commenting Task Force

Michael S. VanDerWerf , GlaxoSmithKline Biologicals (Co-chair)	Amy Giertych , Baxter Healthcare Corporation
James C. Lyda , PDA (Co-chair)	Barbara J. Potts , PhD, Potts and Nelson Consultants
Steven Mendivil , Amgen	Norbert Hentschel , Boehringer Ingelheim Pharma
E.J. Brandreth , Althea Technologies	Susan J. Schniepp , OSO Biopharmaceuticals Manufacturing
Robert L. Dana , PDA	Carol Lampe , J.M Hansen & Associates

The Parenteral Drug Association presents...



2012 PDA Europe Clinical Trial Materials

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The Conference

Key Notes:

- Current Regulatory Trends
- Clinical Manufacturing of IMPs
- Primary Packaging for Parenterals
- Devices in Clinical Trials
- Usability Studies

7-8 February 2012
Basel | Switzerland

Two Tracks: Biologicals and Small Molecules

- Early Stage Formulations and Supply Strategies
- The API and the Requirements for Formulation Development
- Formulation Challenges and Solutions

Plenary Presentations

Extractable and Leachable Testing for Clinical Trial Materials

New Developments of Excipients: Suppliers Report

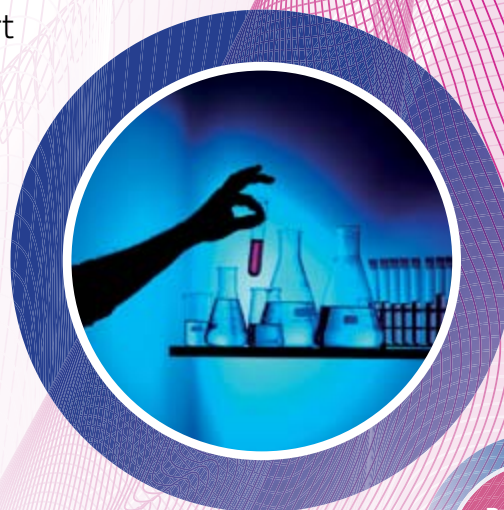
QbD, Technical and Business Considerations

- QbD - a Reality Check
- Case Studies

Panel Discussion about Current Trends in
Clinical Trial Manufacturing

The Site Visit at Roche

Clinical Trial Manufacturing
Plant B97 in Basel



Register by
12 Dec 2011
and SAVE!

Scientific Planning Committee

Chair: Hanns-Christian Mahler, *Roche*
Karoline Bechtold-Peters, *Roche*
Gerrit Hauck, *Sanofi*
Hans Lindner, *Bayer Healthcare*

Ingo Presser, *Boehringer Ingelheim*
Siegfried Schmitt, *Parexel*
Ailyn Kandora, *PDA Europe*
Georg Roessling, *PDA Europe*

<https://europe.pda.org/ClinicalTrial2012>

Regulatory Briefs

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

International Harmonization

Anticipated Progress of Q3D and Q11 at ICH Meeting in Spain Outlined at U.S. FDA Public Meeting

The U.S. FDA held a public meeting on Oct. 25 to solicit public input prior to the Nov. meeting of the ICH Steering Committee in Seville, Spain.

FDA told participants that Q11 was on track and is expected to reach step 4 by the end of the ICH meeting. FDA also stated that a pre-Step 2 draft of Q3D should be completed by the end of the Seville meeting.

North America

U.S. FDA Draft Docs Supporting eCTD Submissions Available

The U.S. FDA is announcing the availability of the following draft versions of documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications entitled “The eCTD Backbone Files Specification for Module 1, version 2.0” (which includes the U.S. regional document type definition, version 3.0) and “Comprehensive Table of Contents Headings and Hierarchy, version 2.0.” Supporting technical files are also being made available on the Agency website.

These draft documents represent FDA’s major updates to Module 1 of the eCTD, which contains regional information.

Submit comments on the draft documents by December 27.

U.S. FDA Draft Guidance Available on Aseptic Preparations for PET Drugs

A U.S. FDA draft guidance intended to help manufacturers of Positron Emission Tomography (PET) drugs meet the requirements for the Agency’s CGMP regulations for PET drugs is now available.

Comments on *Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs* should be

submitted by December 29.

U.S. FDA Guidance Available on Labeling Content and Format

A U.S. FDA guidance is available on the labeling content and format of human prescription drug and biological products.

The guidance is intended to assist applicants and reviewers in drafting the warnings and precautions, contraindications and boxed warning sections of labeling for human prescription drug and biological products. The recommendations in the guidance are intended to help ensure that the labeling is clear, useful, informative and, to the extent possible, consistent in content and format.

U.S. FDA Publishes Guidance on Anti-counterfeiting Physical-Chemical Identifiers

A U.S. FDA guidance, titled, *Incorporation of Physical-Chemical Identifiers Into Solid Oral Dosage Form Drug Products for Anti-counterfeiting* is available.

The guidance provides recommendations on:

- Design considerations for incorporating physical-chemical identifiers (PCIDs) into solid oral dosage forms (SODFs)
- Supporting documentation to be submitted in new drug applications or abbreviated new drug applications to address the proposed incorporation of PCIDs in SODFs
- Supporting documentation to be submitted in post approval submissions to report or request approval to incorporate PCIDs into SODFs
- Procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a post approval change

Retrospective Review of Bar Code Technologies for Drugs and Biological Products

The U.S. FDA has announced a review of the “Bar Code Final Rule,” under Ex-

Key Regulatory Dates

Comments Due:

December 27 — U.S. FDA Draft Docs Supporting eCTD submissions Available

December 29 — U.S. FDA Draft Guidance Available on Aseptic Preparations for PET Drugs

January 9 — Retrospective Review of Bar Code Technologies for Drugs and Biological Products

ecutive Order 13563, “Improving Regulation and Regulatory Review.”

The Bar Code Final Rule, which was published in 2004, requires certain human drug products and biological products to have a bar code. Information submitted can help FDA to reassess the costs and benefits of the rule and to identify any relevant changes in technology that have occurred since it went into effect.

Initial comments must be received on or before January 9, 2012.

Executive Order Instructs U.S. FDA to Get Better Advance Warning System

On October 31, in order to address the “escalating shortage of life-saving medicines,” President Barack Obama signed an executive order that instructed “the U.S. FDA to get better advance warning of impending supply problems and speed up its review of applications from companies that want to change or ramp up production to address shortages.” FDA Commissioner Margaret Hamburg said that FDA would not be able to prevent all future drug shortages, but by expanding early warnings, a difference could be made. ☺



2012 PDA North America Conferences

For latest info: www.pda.org | Subject to change

EVENT NAME	LOCATION	DATE
2012 PDA Annual Meeting	Phoenix, AZ	16-18 Apr
PDA Single Use Systems Workshop	Phoenix, AZ	18-19 Apr
PDA Chemistry Manufacturing & Controls (CMC) Workshop	Bethesda, MD	14 May
PDA/FDA Virus and TSE Safety Conference	Bethesda, MD	15-17 May
PDA/FDA Glass Quality Conference	Bethesda, MD	4-5 June
2012 PDA Innovation and Best Practices on Sterile Technology Conference	Chicago, IL	18-19 Jun
PDA/FDA Joint Regulatory Conference	Baltimore, MD	10-12 Sep
PDA Biennial Training Conference	Bethesda, MD	8-9 Oct
The Universe of Pre-filled Syringes & Injection Devices	Las Vegas, NV	15-17 Oct
PDA 7th Annual Global Conference on Pharmaceutical Microbiology	Bethesda, MD	22-24 Oct
PDA/FDA Pharmaceutical Supply Chain Conference	Bethesda, MD	13-14 Nov
2012 Pharmaceutical Cold Chain & Good Distribution Practice Conference	Bethesda, MD	15-16 Nov
PDA/FDA Vaccines Conference	Bethesda, MD	3-4 Dec



Conference Recordings & On-Demand Web Seminars
www.pda.org/WebSeminars

Single-Use Workshop Addresses Items Found in TR

Phoenix, Ariz. • April 18-19, 2012 • www.pda.org/singleuse2012

Co-chairs Morten Munk, CMC Biologics and Robert Repetto, Pfizer

Single-use (disposable) technology is a proven alternative solution for the biopharmaceutical industry offering several significant advantages over standard reusable stainless steel systems. This technology can help firms reduce risks of cross-contamination, save on cleaning and associated cleaning validation, lower capital investment, and potentially speed up facility start up time. However, this new technology also offers several chal-

lenges which must be overcome for a successful implementation. This workshop will guide participants through these challenges by helping them to ask the right questions when considering single-use system (SUS) implementation.

The PDA Single-Use Systems Task Force is completing a technical report on the implementation of single-use systems and would like to invite you to attend the *Single-Use Systems Workshop*

being held April 18-19, 2012 in Phoenix, Ariz., in conjunction with the *2012 PDA Annual Meeting*.

The workshop will showcase and encourage the philosophies championed in the technical report. This workshop will offer a different approach, presenting science and risk-based concepts which are flexible and can be applied in many different situations and organizations.

Single-use systems offer unique challenges for both Sr. Management and the shop floor technician. This workshop will help all organizational levels understand the right questions to ask to overcome SUS challenges and ensure the right decisions are made.

We look forward to continuing our conversation with the PDA community that we started at the June 2011 SUS Workshop. Please join us for critical discussion and “can’t miss” information crucial to professionals involved in SUS. 🍷

This workshop will be of significant value to:

- SUS Suppliers
- Plastic manufacturers
- End Users
- Suppliers
- Regulatory
- Anyone who is currently frustrated by the current state of SUS's

Specifically, pharmaceutical and biopharmaceutical professionals with the following responsibilities are encouraged to participate: Anyone in a position to influence or change the way their organization operates Procurement/Purchasing, Process Development, Senior Management, Regulatory, Quality, Operations.

2012 Annual Meeting to Highlight Manufacturing Innovation

Phoenix, Ariz. • April 16-18 • www.pda.org/annual2012

Co-chair Vince Anticetti, Keck Graduate Institute of Applied Life Sciences and PDA

The *2012 Annual Meeting* theme is “Harnessing Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology,” and it will highlight a number of the more exciting, daunting challenges before our industry today. Chief among these challenges are “right the first time” sterile dosage form production in the global environment, developing flexible and economic large scale cell culture production systems, and control strategies for emerging cellular therapies. These areas of biopharmaceutical manufacturing are at the forefront of the reliability

and economic improvements needed to help the increasingly complex medicines from biotechnology reach greater numbers of patients. The expertise of PDA’s global membership and their commitment to develop scientifically sound and practical solutions will make the Annual Meeting an important event for anyone involved in the areas of sterile or biopharmaceutical production.

Two distinguished leaders in the advancement of cancer therapy will address the plenary session. **David Shanahan**, President, Mary Crowley Institute and CEO, Gradalis, will provide an entrepre-

neurial vision for the transformation of cancer treatment through personalized medicine. Joining him will be, **Ted Love**, MD, Executive Vice President, R&D and Technical Operations, Onyx Pharmaceuticals, a pioneering physician/scientist working on developing cancer and cardiovascular biotechnology derived therapies. Love will use his perspectives as Head of R&D at Onyx Pharmaceuticals and a board member of the California Institute for Regenerative Medicine to present the exciting scientific opportunities ahead for innovative cellular therapies as well as the technical and regula-

tory challenges.

Manufacturing Innovation and Emerging Technologies

Two important areas of biotechnology highlighted in the 2012 meeting are manufacturing innovation and emerging technologies. Heading the biotechnology manufacturing innovation track will be advances in large-scale cell culture techniques. Innovations in high titer production systems and best practices in contract manufacturing are two of the many important topics that will be covered. Cellular therapies and combination products will lead the themes highlighted in the emerging biotechnology arena. Lessons learned in the manufacture and control of recently approved cell-based cancer therapies will be presented along with current regulatory viewpoints. Control strategies for biopharmaceuticals will comprise the

third focus track for the PDA Annual Meeting. Track highlights will include risk-based approaches to lifecycle management and cost efficient solutions in the quality control arena.

Personal Career Development Strategies

Lastly, personal career development strategies will be highlighted in a special breakfast panel discussion at the annual meeting. Three widely respected experts, **Cheri Spolin**, Human Resources, Genentech; **Roy Blitzer**, Executive Coach, RJB Consulting; and **Dave Fortier**, Managing Director/Executive Recruiter, ZRG Partners, will share their insights on career advancement and changing organizational roles, using your network and successful leadership traits of technical executives.

Students Submit an Abstract for Poster Presentation

For the first time, the Program Planning Committee is encouraging students to

submit an abstract for poster presentation. Abstracts must be noncommercial, describe developments, strategies or work and significantly contribute to the body of knowledge relating to pharmaceutical manufacturing, process knowledge, quality management and technology. Abstracts related to sterile or related product manufacture are preferable, but those addressing other technologies are welcome. All abstracts will be reviewed by the Program Planning Committee for consideration. To review submission guidelines and submit an abstract please visit pdaannualmeeting.org.

Don't miss the 2012 annual meeting. It will keep you abreast of the latest innovations in biopharmaceutical manufacturing and emerging cellular technologies to advance your firm and advance your career. 🌐

The Parenteral Drug Association presents...

PDA Single Use Systems Workshop

Knowledge Enables Implementation - A Consensus Approach

April 18-19, 2012 | JW Marriott Desert Ridge Resort | Phoenix, Arizona



Single-use (disposable) technology is a proven alternative solution for the biopharmaceutical industry offering several significant advantages over standard reusable stainless steel systems, by reducing cross contamination risk, cleaning and associated cleaning validation, capital investment, potentially reducing facility start up time. However this new technology also offers several challenges which must be overcome for a successful implementation.

This workshop will help guide participants through these challenges by helping them to ask the right questions when considering SUS implementation.

Plenary sessions at this workshop include:

- Technical Report (TR) Overview
- Section 6 Part 1 – Qualification
- Overcoming Technology Challenges
- Section 7 – Implementation
- Section 5 – Business Drivers
- Regulatory Issues Related to Single Use Systems

Agenda
now
online!

Visit www.pda.org/singleuse2012 for more information and to register!

Another Successful Year for TRI

Bob Dana, PDA

As I write this, it's mid-September, and I'm sitting in a hotel room in Beijing, China thinking about the year that is drawing to a close. I know, you're thinking, "If it's mid-September, why does he think it's the end of the year?" Well, actually I don't—I know there are still 3 ½ months to go—more than 25% of the year. No one wants to wish their life away, least of all me. Still, by the time you're reading this, the year is really coming to a close. So, here are my thoughts and reflections on 2011.

First of all, how in the world did I get to Beijing and why am I here? I got here by virtue of a very long day of plane travel—about 25 hours to be specific, including 12 hours nonstop from Seattle to Beijing. If you've never done it, it is quite the experience, although tiring, but as it turned out, very worthwhile. I spent two days in Shanghai (don't ask how I got there from Beijing) and two more in Beijing working with TRI instructor **Hal Baseman** to present courses on PDA *Technical Report No. 22, Process Simulation Testing for Aseptically Filled Products* and PDA *Technical Report No. 28 Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals* to about 65 people involved in sterile product manufacture in China. Following the TRI courses, Hal and I had the opportunity to speak at and represent PDA at the *2011 Parenteral Drug Industry Congress* in Beijing. This was really a great opportunity to provide education to representatives of the pharmaceutical industry in China, as well as spread the word about PDA and all that we offer to the industry.

To continue our global focus, we held two separate training events in Israel this year, working in partnership with PDA's Israel Chapter. **Jeanne Moldenhauer** taught a "Microbiology Update" course earlier in the year, and **Jason Orloff** will help bring down the curtain in November when he teaches a course entitled "Applied Statistics in Process Validation

and Ongoing Product/Process Performance Monitoring." This marks the third year we have been able to bring PDA's education programs to Israel.

These were just two of the nontraditional education opportunities TRI supported in 2011. We also presented a number of "in-house" courses in 2011 both within and outside the United States. In-house training is really a great opportunity for individual companies to save money while meeting their training needs in a customized fashion. If you have never thought about this as a cost-effective way to provide continuing education to your company's employees, I encourage you to consider it. We will be happy to work with you.

But I digress. Besides China, Israel and in-house training, what were some of our other highlights and successes in 2011?

This year marked our first venture into providing topic-focused, week-long training opportunities at our training center in Bethesda, Md. These provided students a chance to take more than one course focused on a specific topic, thus allowing them to reduce the travel costs associated with opportunities to learn new information about specific topics that they could take home and apply on the job.

Feedback from our students made us optimistic that this concept would be well received as we moved through the year. That turned out to be the case, though at first we weren't sure how this would work. But we were willing to give it a try. So how did it go? In a word—*Great!* We kicked the concept off with TRI's Prefilled Syringe Week in March. TRI instructors **Michael Gross, Tibor Hlobik, Wenzel Novak, Markus Lankers** and **Patty Kiang** presented the following three courses to over 40 students:

- "Development of Prefilled Syringes"
- "Solving Strategic Quality, Regulatory and Technical Issues During

the Development of Prefilled Syringes, Autoinjectors and Injection Pens"

- "Syringes and Elastomers: Understanding the Effects on Quality and Demonstrating the Production Process, Influences and Needs"

Other focused weeks and their courses were Lyophilization Week which included:

- "Fundamentals of Lyophilization"
- "Economical Design of Lyophilization Experiments"
- "Validation of Lyophilization"

Risk Management Week which included the following courses:

- "A Risk Based Approach to Technology Transfer"
- "Practical Applications of Risk Management"

Filtration Week included basic and advanced courses on "Filters and Filtration in the Biopharmaceutical Industry."

Look for more focused weeks from TRI in 2012!

2011 also marked the first of our courses built around PDA's technical reports.

Our members tell us that the technical reports are the most valued benefit PDA provides them, so we thought we would find a way to make them even more valuable. Having task force members who wrote the technical reports as instructors added more value for the students.

So far this year we have offered a course on Steam Sterilizers based on PDA *Technical Report No. 48, Moist Heat Sterilizer Systems* at the Annual Meeting and a course on Glass Defects based on PDA *Technical Report No. 43, Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing* at the Glass Quality Conference.

Next year we plan to offer courses on Validation of Biotechnology-related



PDA Web Seminars – Interactive Online Learning

PDA Web Seminars allow you to affordably hear from today's top presenters in the bio/pharmaceutical industry with no traveling!

Recordings from PDA's Spring conferences are now available for purchase. The events include:

2011 PDA Annual Meeting | www.pda.org/annualaudio

Individual sessions are available for purchase for \$75/each.

Sessions include:

- Manufacturing Protein Therapeutics
- Change as a Key to Continuous Improvement
- Single-Use-Systems
- Advances in Single-Use-Systems
- Opening Plenary Session
- Closing Plenary Session
- Analytical Methods in QC – Applications and Life Cycle Management

2011 PDA/FDA Glass Quality Conference | www.pda.org/glassaudio

Recordings from the entire conference are available for purchase for \$199. Purchase includes:

- Recordings of all nine plenary sessions from this conference
- PDA handouts of every presentation
- Unlimited access to all session recordings for 60 days.

2011 PDA/FDA Pharmaceutical Supply Chain Conference

www.pda.org/supplychainaudio

Individual sessions are available for purchase for \$75/each.

Sessions include:

- Supply Chain Security – Global Initiative
- Solutions That You Can Use Today
- Ensuring Secure Distribution of Finished Products
- Risk Model: Materials

PDA 2011 Analytical Methods Development & Validation Workshop | www.pda.org/analyticalmethodsaudio

Individual sessions are available for purchase for \$75/each.

Sessions include:

- Qualifications and Compendial Methods Verifications
- Method Development – Applying Principles of QbD for Analytical Methods
- The Methods Life Cycle – The Overview
- Complete Life Cycle Case Study and Ask the Experts Panel Discussion
- Post-Qualification and Post-Validation Activities
- Method Validation: Validation Strategies and Acceptance Criteria
- Reference Standards and Method Transfers

PDA Single Use Systems Workshop | www.pda.org/singleuseaudio

Individual sessions are available for purchase for \$75/each.

Sessions include:

- Technology Showcase
- Section 4 – Technologies and System Integration
- Section 5 – Business Drivers
- Section 6 Part 2 – Goals of Implementing Single Use Systems (SUS)
- Section 6 Part 1 – Qualification
- Technical Report (TR) Overview
- Single Use Systems Knowledge Management
- Implementation

**For more information on PDA Web Seminars
please visit www.pda.org/webseminars**

Cleaning Processes; Preparation of Virus Spikes Used for Virus Clearance Studies; Parametric Release of Pharmaceutical Products and Medical Devices Terminally Sterilized by Moist Heat; and Steam in Place—to name just a few.

Of course, we continued to offer our courses in conjunction with PDA Conferences in 2011. We presented successful course series at the Cold Chain Conference, the *2011 PDA Annual Meeting*, the Glass Quality, Supply Chain, Visual Inspection and the Global Conference on Pharmaceutical Microbiology, as well as at the PDA/FDA Joint Regulatory Conference.

Our laboratory courses, led by the flagship *Aseptic Processing Training Program*, continued to *rock* in 2011. Literally. On August 23rd, in the midst of one of the *Aseptic Processing Training Program* sessions, PDA's office and labs were rocked by a significant earthquake. This represented a first for TRI and most of the students in the course, although one or two students from California were pretty much unfazed by the event.

So, as 2011 comes to an end, I need to recognize again, as I do every year, the contributions, dedication and hard work of the TRI staff. Without the dedication and unceasing efforts of **Stephanie Ko** and **James Wamsley** to ensure a quality education experience for our students, we could not have had the successful year we did. Thank you Stephanie and James.

And, of course, I want to express my appreciation and gratitude to all our instructors. They take time away from their day jobs to prepare and deliver the courses for us. Thanks to each and every one of them. And lastly, once again this year, we trained almost 1000 students and helped them fulfill their commitment to career long learning. We thank them all and appreciate their choosing PDA to help further their learning. Without all these people, there would be no TRI,

In closing, I want to extend my personal wishes to each of you for an enjoyable Holiday Season, and a happy, healthy and prosperous New Year! I hope to see many of you in attendance at a TRI course in 2012.

PDA's Who's Who:

Hal Baseman, CEO, Valsource

Michael Gross, PhD, Chimera Consulting

Tibor Hlobik, Associate Director Marketing, Marketing, West Pharmaceutical Services

Markus Lankers, PhD, CEO, rap. ID Particle Systems


Jeanne Moldenhauer, Vice President, Excellent Pharma Consulting

Wenzel Novak, PhD, Director, Pharmaceutical R&D, Groninger & Co.

Jason Orloff, Statistical Engineering Consultant, J. Orloff & Associates

Patty Kiang, PhD, Kiang Consultant Services

Stephanie Ko, Sr. Manager, Lecture Education, TRI, PDA

James Wamsley, Sr. Manager, Laboratory Education, TRI, PDA 

TRI Staff Goes to China

Bob Dana, PDA

In September of this year, PDA Board member **Hal Baseman**, CEO, Val-Source, and I traveled to China to present PDA Training and Research Institute (PDA TRI) courses to members of the Chinese pharmaceutical industry. While in China, both Hal and I had the opportunity to address delegates attending the Parenteral Drug Industry Congress in Beijing. The trip was as a result of an invitation from JPT Consulting Beijing, whose staff coordinated the logistics and handled all course registrations.

On Sept. 2, Hal and I presented a course based on PDA *Technical Report No. 22: Process Simulation Testing for Aseptically Filled Products* to over 25 students in Shanghai. We taught a course on the next day on PDA *Technical Report No. 28, Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals*.

I also had the opportunity to give a brief presentation about PDA to the course attendees. I explained a bit about PDA, our vision, mission, focus, and our various activities. I also described our members' competencies and highlighted the benefits of PDA membership. The participants were very interested in the new, reduced-cost membership program for emerging

economies, which includes China.

After a day off to get a bit more acclimated to the time change, we repeated these two courses for students in Beijing. The courses were presented in English, and Hal and I were assisted by **Deng Haigen**, Senior Consultant, JPT Consulting, who provided translation services as necessary. His assistance was very helpful to us and contributed greatly to the interactive nature of the course and the break out sessions where the students had the opportunity to apply what they had learned to a case study.

Following the Beijing courses, we participated in the Parenteral Drug Industry Congress in Beijing, also sponsored by JPT Consulting. There were approximately 200 people in attendance from several countries in Asia, Europe and the United States. I had the opportunity to address the attendees, focusing on PDA and the global state of the pharmaceutical industry. Hal then presented a paper on Quality Risk Management for Aseptic Processes. He covered regulatory expectations and aseptic processing risk, then went on to discuss lessons learned in the development of PDA *Technical Report No. 44: Quality Risk Management*



Hal and Bob visit the Great Wall

for *Aseptic Processes*, with a focus on uncertainty, residual risk and the appropriate level of granularity.

PDA had a booth at the Exhibition held in conjunction with the PDI Conference, and a number of attendees stopped to visit and ask for more information about PDA. Many were especially interested in PDA's technical reports.

No trip to China and Beijing would be complete without a visit to some of the historical sites in the city and surrounding area. Hal and I had the opportunity to visit the Great Wall of China as well as the Forbidden City. We found it pretty amazing that construction of the Wall began in the 5th Century BC, although most of what is the now-existing wall was constructed during the Ming Dynasty in the 14th Century. Both the Great Wall and the Forbidden City were most impressive, and Hal and I enjoyed our visits there.

Overall, this was a good opportunity to convey some technical knowledge and information about PDA to a section of the world of increasing importance to the pharmaceutical and biopharmaceutical industry. 🍵



Students in Beijing listen to presentations on PDA TR No. 22 and 28



Parenteral Drug Association Training and Research Institute (PDA TRI)

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals



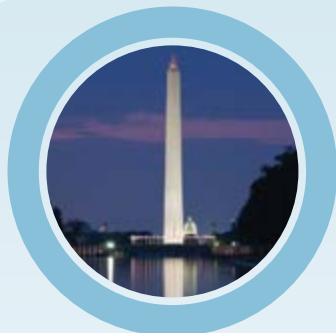
January 2012



2012 Aseptic Processing Training Program

Bethesda, Maryland | www.pda.org/2012aseptic

- Session 1: January 9-13 and February 6-10, 2012
- Session 2: March 5-9 and March 26-30, 2012
- Session 3: May 14-18 and June 4-8, 2012
- Session 4: August 20-24 and September 10-14, 2012
- Session 5: October 15-19 and November 5-9, 2012



April 2012

The 2012 PDA Annual Meeting Course Series

April 19-20, 2012 | Phoenix, Arizona | www.pdaannualmeeting.org/courses

- Reprocessing of Biopharmaceutical Products - *New Course* | April 19
- Manual Aseptic Processing - *New Course* | April 19
- Biotechnology: Overview of Principles, Tools, Processes and Products | April 19-20
- Sterile Pharmaceutical Dosage Forms: Basic Principles | April 19-20
- Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotech Manufacturing Operations - *New Course* | April 19-20
- Process Validation/Process Verification - *New Course* | April 19-20
- Process Simulation Testing for Aseptically Filled Products - *New Course* | April 20
- Microbial Data Deviations - *New Course* | April 20



Laboratory Courses



The PDA Training and Research Institute is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

For more information on these and other upcoming PDA TRI
courses please visit www.pda.org/courses

Editor's Message

Invigorate Your PDA Membership

PDA membership is very valuable on many levels. For one, it includes subscriptions to the *PDA Journal*, the *Letter* and Technical Reports, a triple play of value that is hard to beat. But another important, and perhaps the most significant, benefit is inclusion in a community of experts that is able and willing to share their knowledge across the industry.

Nowhere is this more evident than at the *PDA/FDA Joint Regulatory Conference*, which ranks at or near the top of PDA's largest events each year. And it includes the participation of more FDA officials than any other meeting in PDA's areas of interest. For that reason, we dedicate the Nov/Dec issue to covering the meeting.

One thing I'm not sure comes out each year in our coverage is just how invigorating it is as a PDA staff person to attend the conference. When I am at the meeting, I get exposed to expert presentations on a myriad of important regulatory topics. This gives me a sense of the variety of issues our members both in industry and in the regulatory bodies must deal with. It is a huge burden on both sides to ensure medicines are of the highest quality, yet cost effective. And, I'm always pleased to learn, our members do a fantastic job! I return to work following this, and all PDA events, motivated to continue working hard in support of our members. I hope our readers who haven't been to the *PDA/FDA Joint Regulatory Conference* benefit from our coverage of the meeting. I also hope the coverage prompts some to decide to finally attend!

I must recognize, yet again, the sad passing of a past PDA leader and current member of our *PDA Letter* Editorial Committee (PLEC). **Doris Conrad**, known to many, passed away in October. We are saddened by this news. In an issue where we are celebrating the proceedings of the *PDA/FDA Joint Regulatory Conference*, it is worth noting that Doris served as the Chair of the event's first planning committee back in 1990. Please see the In Memoriam article on page 8 for more information about this outstanding PDA Honorary Member.

It is that time of year when we are looking for new volunteers on the PLEC. With our rotation system, PLEC participants serve for two years. We then open up their spots to new members. I'd like to thank **Matt Schmidt**, **Miriam Estrano**, **Georgiann Keyport** and **Kamaal Anas** for their strong contributions to the committee. Their insights into submissions were always well regarded and influential. So, we are looking for active PDA members to provide ideas and to comment on articles for the *PDA Letter*. For more information about this two-year volunteer commitment, please contact **Emily Hough** at hough@pda.org by December 15.



Finally, PLEC member **Sandra Zoghbi-Gay** added a beautiful daughter to her family earlier this year and has shared a photo of Julie with us. Forgive us for going for the cheap "oh she's so cute" points, but hey, it is true! 🍷

PDA Letter

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PDA LETTER STAFF

Walter Morris
PDA Letter Editor,
Director of Publishing
+1 (301) 656-5900, ext. 148
[moris@pda.org](mailto:morris@pda.org)

Emily Hough
Assistant Editor
hough@pda.org

Katja Yount
Publication Design Specialist
yount@pda.org

PDA LETTER EDITORIAL COMMITTEE

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TO ADVERTISE, CONTACT

Dave Hall, Vice President, Sales
+1 (301) 656-5900 ext. 160
hall@pda.org

PDA GLOBAL HEADQUARTERS — BETHESDA TOWERS

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

PDA EUROPE — ADALBERTSTR. 9

16548 Glienicke/Berlin Germany
Tel: +49 33056 23 770 Fax: +49 33056 23 7777
petzholdt@pda.org

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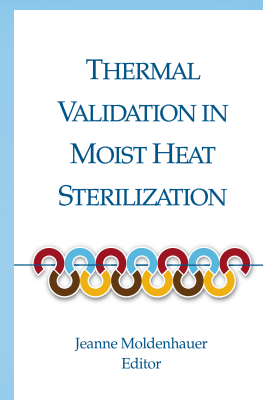
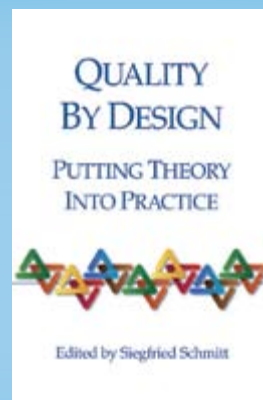
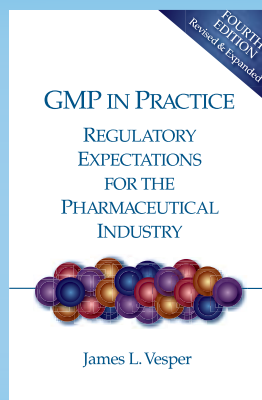
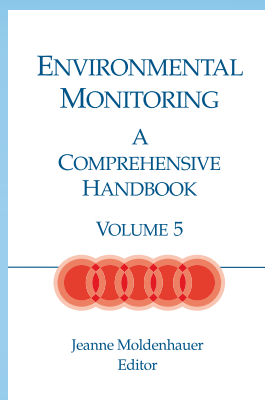
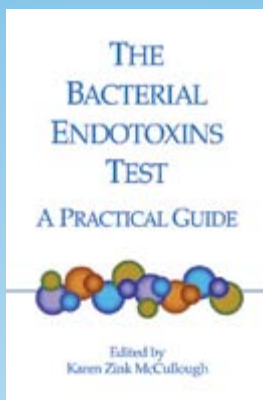
4350 East West Hwy., Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900 Fax: +1 (240) 482-1659
info-tri@pda.org



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