People • Science • Regulation

PDA Letter

Volume XLVII • Issue #5 www.pda.org/pdaletter May 2011

Supply Chain Solutions

22

The Parenteral Drug Association presents the...

PDA Single Use Systems Workshop

June 22-23, 2011

Hyatt Regency Bethesda | Bethesda, Maryland

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, lead times and the number of connections to enhance sterility assurance.

If you can attend only one conference this year, PDA's Single Use Systems Workshop is clearly the meeting to be at. And here's why:

- This workshop will be structured around the PDA Technical Report Document on SUS. The Technical Report will be unique among the competing organizations hosting conferences on SUS showcasing the concepts and themes in the report.
- The SUS Taskforce was strategically designed as a partnership between end users, suppliers, industry enablers (BPSA, engineering companies) and regulators. This unique mix of skills and expertise will showcase a balanced, well vetted, consensus viewpoint that will ensure the educational value of the conference.
- PDA is in a position to enable the conference attendees to have a dialog with FDA/EMA and this is often not possible at other SUS conferences.
- The PDA Taskforce's close relationship with Bio-process System Alliance (BPSA) and SUS suppliers offers PDA a unique opportunity to host a Hands-On Technology showcase at the conference. This would be more than the typical conference vendor room. At PDA's Technology Showcase participants will see hands on technology demonstrations for key SUS technologies; bioreactors, connectors, mixing, etc. These showcases will be unique where specific technologies are grouped and suppliers work together to present their technology, not products.

Register by May 19th and save up to $200!

www.pda.org/Singleuse2011

Photos courtesy of Sartorius Stedim Biotech

PDA
Parenteral Drug Association

Register by 2 May 2011 and SAVE!

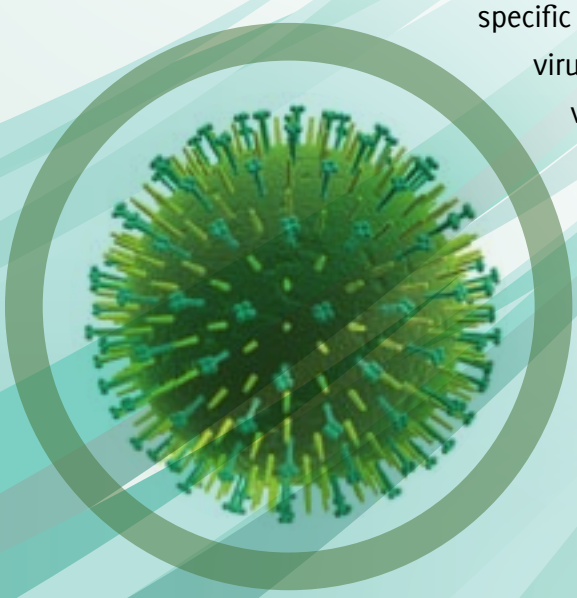
2011 PDA European

Virus & TSE Safety Forum

27-30 June 2011

Barcelona, Spain

The PDA Virus &TSE Safety Forum 2011 is organized in close collaboration with regulatory agencies in Europe and the U.S. It will focus on virus/TSE safety of cell derived or human plasma derived medicinal products. The conference will provide an overview on regulatory expectations, testing strategies (source and raw materials), QbD approach to demonstrate virus removal/inactivation by specific unit operations; a pre-conference workshop will focus on virus filtration methods. Worldwide occurrence of TSEs including vCJD and expected risk mitigation strategies will be discussed in the one day TSE part of the conference. As the previous conferences in this series (2001, 2003, 2005 and 2008), the 2011 event will provide a unique opportunity to exchange data, information and opinions with regulatory authorities.



PRE-CONFERENCE WORKSHOP 27 JUNE

CONFERENCE/EXHIBITION 28-30 JUNE

https://europe.pda.org/VirusTSE2011

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Cover Art Illustrated by Katja Yount

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Guangdong FDA Visits PDA, Impressed with What They See

A small group of the Guangdong FDA (GDFDA) visited PDA's headquarters in late February to learn more about parametric release implementation.

Five members of the Chinese GDFDA came to PDA to learn about parametric release of moist heat sterilized products in the United States and to become more familiar with PDA's platform.

Located on the southern coast of People's Republic of China, Guangdong is the most populous province in China with about 80 million people. In recent years there has been an upswing in pharmaceutical production; in 2010, there was a 25% increase of the pharmaceutical industry and Guangdong's pharmaceutical production was the third in China. The medical device industry in Guangdong is the highest in China.

With a little over 3,000 staff members, the main responsibilities of the GDFDA are what you'd expect for any regulatory body. They are accountable for implementing and drafting laws and regulations on drugs, medical devices, food and cosmetics.

However, the GDFDA is continually trying to make its regulatory process more efficient by enhancing its manner of operation to be more responsive to the needs of the local government as well as the State Food and Drug Administration. In the last few years, the GDFDA has also actively promoted practices for quality improvement for China's pharmaceutical production methods. For example, in 2005 it approved a limited number of companies to carry out parametric release trials. The new Chinese GMP's issued in March 2011 recognize parametric release and also include an increased emphasis on quality risk management and process control. The focus will now be on the development of formal regulation for parametric release of moist heat sterilized products. Both technical and supervisory staff will need to acquire new knowledge and understanding on the essential elements of parametric release.

In addition to learning about parametric release from **Terry Munson,** Technical Vice President, Strategic Compliance, Parexel Consulting; Officials were given presentations on general PDA activities and a tour and presentation of the Training and Research Institute by **Rich Levy,** Sr. VP, Scientific & Regulatory Affairs, PDA and **Bob Dana,** Sr. VP, Regulatory Affairs & TRI, PDA, respectively.

Levy noted that a PDA task force has just completed the final draft of the PDA Technical Report No. 30, (revised) *Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat,* which will serve as a baseline for good practices in the application of parametric release. "The high level of interest in parametric release as the preferred moist heat sterility assurance program from global regulatory authorities such as the GDFDA is encouraging," Levy said. "The content of TR-30 was developed to strengthen moist heat sterility assurance programs by promoting a harmonization of best sterilization practice to expand the use of parametric release."

According to Dana, the GDFDA Officials were very impressed with what they learned on their tour. The meeting finished on a high-note, and when they left, the GDFDA Officials agreed to devote some time on the agenda for PDA at the GDFDA-sponsored conference for injectables that will be held later this year.

We would like to thank the delegation team for coming.

The GDFDA is continually trying to make its regulatory process more efficient

GFDA Participants

Yongcai Ye, Deputy Section Chief/Section of Drug Safety Supervision, GDFDA

Kunbin Huang, Staff, ADR Monitor Center, GDFDA

Jianghao Zhang, Deputy Director/Center of Drug Certification, GDFDA

Yi Liu, Associate Research, Inspection Bureau

Han Minghui, Section Chief, Section training, GDFDA

GDFDA Officials learn more about parametric release at PDA's Headquarters

Annual Meeting Banquet Honors PDA's Dedicated Members

At the *2011 Annual Meeting* in San Antonio, Tex., PDA recognized the dedicated contributors who have shaped the Association in recent years at the Annual Meeting banquet. Held the night before the Annual Meeting commenced, the banquet was a joyous occasion.

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

Look for future coverage on each award winner throughout the year leading up to the 2012 Annual Meeting in Phoenix, Ariz.

Honorary Membership

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

Nikki Mehringer, Eli Lilly

Frederick J. Carleton Award

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

Bob Dana, PDA

Distinguished Service Award

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

Stephen Brown, PhD, Vivalis

Ursula Busse, PhD, Novartis

Lee Kirsch, PhD, University of Iowa

David Matsuhiro, Cleanroom Compliance

Kevin Trupp, Hospira

Service Appreciation Award

This award is given in recognition of special services performed on behalf of PDA. This year's recipients are:

Raphael Bar, PhD, BR Consulting

Gerard Boudreault, Drug Development Resources

Colman Casey, PhD, University College Cork

Michele Creech, Talecris Biotherapeutics

Véronique Davoust, PhD, Pfizer

Lothar Hartmann, PhD, F. Hoffmann-La Roche

Manuel Melendez, Amgen

Lara Soltis, ITW Texwipe

Laura Thoma, University of Tennessee

PDA/DHI Editor/Author Award

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

Jeanne Moldenhauer, Excellent Pharma Consulting

President's Award

This award recognizes PDA staff members, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year. This year's recipients are:

Leon Lewis, PDA
Dirk Stelling, PDA

James P. Agalloco Award

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

Arthur Vellutato Jr., Veltek Associates

Frederick D. Simon Award

This award is presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology* and is named in honor of the late Fred Simon, a previous PDA Director of Scientific Affairs. The winning article is "Root Cause Analysis of Tungsten-Induced Protein Aggregation in Pre-Filled Syringes," *PDA Journal of Pharmaceutical Science and Technology,* January/February 2010, pages 11-19. This year's recipients are:

Janice Davis, WindRose Analytica

Erwin Freund, Amgen

Yijia Jiang, Amgen

Wei Liu, Amgen

Anthony Mire-Sluis, Amgen

Linda Narhi, Amgen

Yasser Nashed-Samuel, Amgen

Zai-Qing Wen, Amgen

Rob Swift, Amgen

Gianni Torraca, Amgen

Aylin Vance, Amgen

Kirby Farrington Leaves Big Shoes to Fill at PDA's TRI

Stephanie Ko, PDA

PDA sadly announces the death of **Joseph Kirby Farrington** on March 26 from a heart attack.

Widely known as Kirby, he was actively involved with PDA's Training and Research Institute and was among the first instructors to be interviewed in the "Eye on TRI" section in the January 2011 *PDA Letter*.

Kirby was a joy to have in the training facility, and he has been described by those who knew him best as a "fun-loving" individual that was loved by students and faculty alike.

Recognized as an expert in water sterility, antimicrobial preservatives and regulatory compliance, he taught lecture courses that played to his strengths. Most recently he taught courses such as:

- "Use of HACCP for Microbiological Control in Pharmaceutical Manufacturing"
- "Investigating Microbiological Failures"
- "Microbiological Issues in Non-Sterile Manufacturing"

Kirby has had an extensive career in the pharmaceutical industry at Plough Laboratories; Schering-Plough; the Pharmaceutical Development Center; and, Eli Lilly, to name a few. He most recently worked at Auburn University as a Coordinator in the Microbiology Teaching Labs.

As an integral part of PDA's TRI, Kirby will be greatly missed.

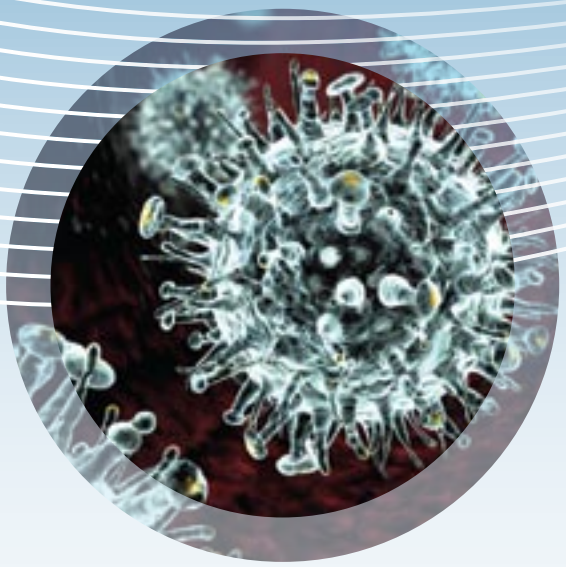
Honoring Kirby

Memorial contributions may be made in memory of Kirby to:

Dr. J. Kirby Farrington Endowment
Children's Home Society Foundation
1485 South Semoran Blvd., Suite 1448
Winter Park, FL 32792

From The Heart Rescue, Inc.
POB 659
Westfield, IN 46074

Auburn University
Microbiology Department
101 Rouse Building
Auburn, AL 36849



The Parenteral Drug Association Presents...

PDA/FDA
Adventitious Viruses and Novel Cell Substrates Conference

November 2-4, 2011
Rockville, Maryland

Be the first to know!

Sign up for the *PDA/FDA Adventitious Viruses in Biologics/Cell Substrate Workshop* Advanced Notice Alert, and be the first to know when information has been published on this event! Simply fill out the form at www.pda.org/adventitiousnotice and you'll automatically receive an e-mail once the website is available.

Volunteer

Edward H. Trappler, President, Lyophilization Technology

PDA Join Date: 1984

Interesting fact about yourself: Life has taught me what is really important, sometimes in the simplest of things. For example, it was always a dreaded task to dress up for Halloween when I was young. Now, I am reminded it's a wonderful life and find there is no greater reward than the expressions of enjoyment I see in the faces of the kids when I dress up as Sponge Bob or Woody at a Variety Club event for challenged or autistic children.

Why did you join PDA? Early on, I recognized PDA was an extraordinary organization. With the focus of my responsibility of developing parenteral products, I recognized it was the premier organization to join for staying up-to-date on the latest in science and technology. Starting my career as a Technician, I would read the *PDA Letter* and the [then called] *Journal of the Parenteral Drug Association* which the department manager circulated through the department.

I felt excited and enthused when I attended my first PDA meeting in Philadelphia, because I realized that it was a great opportunity to network with others in the field where I, too, had a strong interest. The great payoff has been getting to speak with and come to know industry leaders; those who have made a significant contribution and impact on the industry. Though I would like to name and thank them all individually, I don't think I would have enough room here. I do wish them to know they have each been a great influence on me; I have learned a lot from them, and I value their perspectives shared in our discussions when we meet at the PDA events.

Of your PDA volunteer experiences, which have you enjoyed the most? Being part of the PDA educational activities has been the most rewarding experience. Having the opportunity to be involved in the early Education Committee activities of the eighties, through the growth in the nineties and watching the educational program grow from the nucleus of volunteer activity to the professional management of the PDA-TRI has been great. Seeing TRI become a significant and successful part of the PDA has been extraordinary.

From the early days of the Education Committee with Fred Carleton and Jim Agalloco, the first course I presented in Philadelphia when the PDA was under the direction of Sol Pflag, to the formation of the PDA-TRI, there was always a sense you were contributing to something significant: the success in the growth and continued fulfillment of PDA's educational mission.

How has volunteering in PDA benefited you professionally? Beginning my career in a science-focused product development group and eventually leading a group of well-educated and highly capable people as president of a company, there is no better way to educate and prepare yourself to achieve a higher level of professional growth, become more rounded, be more worldly and be so well-connected than collaborating with others in the industry on a volunteer project such as a committee, program or task force. It's a great way to grow professionally and make a significant difference in the industry.

Which PDA conference/training course is your favorite? The PDA/FDA has been the one meeting for which I walk away feeling I have my finger on the pulse and direction of the industry. This is a setting where you are able to catch up with colleagues, make new acquaintances and develop new contacts as well as hearing the latest from industry and the Agency.

More recently, my favorite conference has been the inaugural Lyophilization Workshop in San Diego last October; I feel that it is the best event PDA has put on for lyophilized products. The agenda was well-rounded and made possible by a really good group of speakers, with a great number of topics on the applied science as well as practical aspects. The program committee and speakers were great to work with and did an excellent job. Sharon Thoma, ORA National Expert Pharmaceutical Inspections and David Doleski, CBER DMPQ Team Leader were two of the best speakers I have heard on inspections and submissions for lyophilized products.

What would you say to somebody considering PDA membership? Don't miss out on the access and opportunities offered by being a member. The meetings keep you updated on scientific, quality and regulatory trends as well as insight into what is on the horizon. At meetings, the podium presentations are informative and insightful, the interest groups are a forum for discussions on specific areas, and the special events, such as the breakfast sessions, focus on key aspects of parenteral technology. The *PDA Letter* is a must-read, an invaluable resource and a great benefit of membership.

If you are a member of PDA, becoming involved in meeting committees, a task force or an interest group puts you into the mainstream of a prominent and influential professional association. The opportunities to associate with others working in a unique part of the health care industry are available for anyone to capitalize on. All you need to do is contact **Iris Rice** (rice@pda.org) for more information.

"The Gold Sheet"

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Bulletproof guidance for the QA/QC professional.

In 2010, were you...

- **Ready for every single new development in FDA and other regulatory enforcement?**
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- **100% prepared for every inspection?**
- **Fully briefed on every promising new manufacturing, supply chain and documentation practice?**

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GET ALL THIS FROM *"The Gold Sheet"*

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  It looks like chaos, and it might as well be for QA/QC pros: FDA's twists, turns and complex logic makes staying ahead of inspectors a nightmare. But ***"The Gold Sheet's"*** experienced analysts are trained to make sense of it all and deliver it to you in concise, plain language.

- **State-of-the-art production and quality techniques**

  You can't be everywhere around the globe, but ***"The Gold Sheet"*** can. You get reports straight from manufacturing facilities worldwide on successes and failures, so your own processes stay current and error-free.

- **Trends in quality control practices**

  It's easy to deliver headlines and soundbites. ***"The Gold Sheet"*** goes above and beyond that to uncover the trends and big picture guidance that help you be pro-active in keeping your operations fully compliant.

- **Best practices in supply chain integrity**

  With the global economy making mincemeat of supply chains, many a formerly clean operation has fallen drastically foul of FDA standards. Make sure it doesn't happen to you by reading ***"The Gold Sheet's"*** detailed reports on these issues and guidance in avoiding disaster.

- **In-depth reports on a vast range of GMP issues**

  Micro issues such as sterility, microbial controls, validation, laboratory data integrity, cross-contamination, out-of-spec (OOS) results and stability testing can be create macro problems. Let ***"The Gold Sheet"*** drill into the data and on-the-ground realities to keep these details from escaping you.

- **Drug recall and warning letter data**

  Count on ***"The Gold Sheet"*** to deliver exactly what QA/QC professionals need to know, not just general news reports aimed at executives with no quality responsibilities.

- **Early warning of new directions in FDA enforcement policy**

  "The Gold Sheet" has its ear to the ground and a large staff of reporters in the trenches around the industry who keep you one step ahead of an evolving FDA.

- **Insights from peers on ensuring quality from contract suppliers and service providers**

  Thanks to ***"The Gold Sheet's"*** global contacts, you get bulletproof guidance from the most experienced QA/QC pros in the business, making you look like a hero to your supervisor and shareholders.

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Faces and Places: PDA Cold Chain Management Conference

Introduction and Regulatory Update

(l-r) Rafik Bishara, Pharmaceutical Cold Chain Interest Group; Anthony DeStefano, USP; Denise Odenkirk, OM HealthCare Logistics

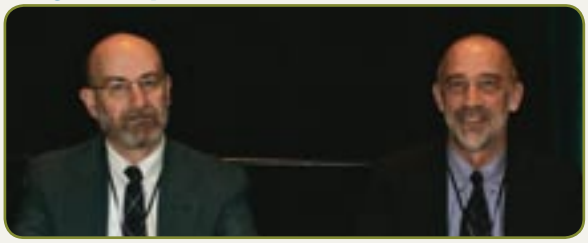
Case Study–Compliance with Cold Chain Importation/Nationalization/Distribution of Product Requirements in Latin American Countries

(l-r) Karl Kussow, FedEx Custom Critical; Elaine Araujo Menezes, Abbott; Emily Pereira, Abbott; Rebecca Gentile, Merck; Michael English, Merck; Rafik Bishara, Pharmaceutical Cold Chain Interest Group; Arminda Montero, Abbott; Bob Seevers, Eli Lilly

Global Comparison of Cold Chain/GDP Regulations

David Ulrich, Abbott

A Stability Budget as a Means of Protecting Drug Quality in the Distribution Environment

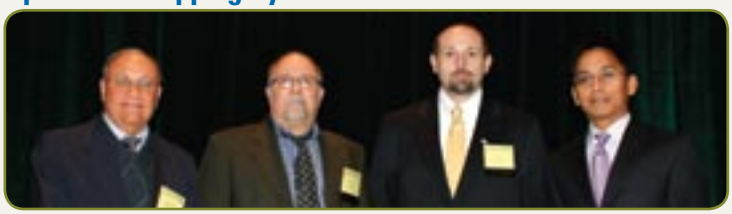


(l-r) Bob Seevers, Eli Lilly; Paul Harber, Eli Lilly

Compliance with GDP, GIP and Labeling Requirements

(l-r) John Howells, HDMA; Bob Celeste, GS1 US; Doug Bailey, AMS

Update on Shipping System Qualification and Process



(l-r) Edward J. Smith, Packaging Science Resources; John Bratz, Sensitech; Todd DeVore, AcuTemp Thermal Systems; Gerry Marasigan, SNC Lavalin Pharma

Exhibitors Hall

Faces and Places: PDA/FDA Atypical Actives Workshop

Liability

(l-r) Susan Schniepp, BioPharmaceuticals; Theodore M. Sullivan, Buchanan Ingersoll & Rooney PC

Impact on Industry

(l-r) Maria Guazzaroni Jacobs, Pfizer; Paul Weninger, Perrigo; Iain Moore, Croda

Case Studies

(l-r) Jeffrey Medwid, U.S. FDA; Joseph Giertych, Baxter Healthcare; Alexa Smith, Colorcon; Steven Wolfgang, U.S. FDA

Report Out

(l-r) Bob Dana, PDA; David Schoneker, Colorcon; Janeen Skutnik-Wilkinson, Pfizer

Technical Considerations

(l-r) Janeen Skutnik-Wilkinson, Pfizer; Jeffrey Medwid, U.S. FDA

Regulatory Considerations

(l-r) David Schoneker, Colorcon; Maria Guazzaroni Jacobs, Pfizer

Overview of Volunteer Opportunities Given at Virtual Orientation

PDA's Board of Director Immediate Past Chair **John Shabushnig,** PhD, Sr. Manager/Team Leader Quality Systems & Technical Services, Pfizer, will host the 2nd Virtual Volunteer Orientation on June 2 at 11:00 a.m.–12:00 p.m. EST.

The orientation will give members a detailed overview of volunteer opportunities.

To RSVP for this complimentary web seminar, please email **Hassana Howe** at howe@pda.org by May 30.

Please Welcome the Following Industry Leaders to the PDA Community

Vincent Adamo, B. Braun
Joseph Alentado, Merck
Adriansjah Azhari, PT. Bio Farma
Lefevre Benoit, GlaxoSmithKline
Carrie Bickle, Hollister-Stier Laboratories
Donna Blankenship, Merck
Mayumi Bowen, Genentech
Sandra Boyd, Biogen Idec
Charles Brawley, Bionostics
Peter Calcott, Calcott Consulting
Lee Carpe, Carpe Consulting
Hilary Chan, Pfizer
Kishor Chavda, Merck
Shok Chen Chee, Pharmaniaga Lifescience Sdn. Bhd.
Michael Christensen, Novo Nordisk
Christine Comerci, F. Hoffmann-La Roche
Veronica Cruz, McNeil Consumer Healthcare
Samit Deb, Pharmaceutics International
Laurent Delaunay, GlaxoSmithKline
Andrew Dick, Johnson & Johnson
Chase Duclos-Orsello, EMD Millipore
Kristina Eriksson, Tetra Pak Packaging Solutions
Suzanne Fetzer, Roche Molecular Diagnostics
Michael Fischer, Gerresheimer Glass
Heidi Foley, Biomet
Jean-Pierre Fonta, Merck Serono
Lynn Gallagher, Pfizer
Lisa Grigg, Lyophilization Services of New England
Michael Growney, Merck Sharp & Dohme
Katharina Guenther, Nordion
Sandrine Guerin, B. Braun
Sangeeta Gupte, Takeda
Kathrin Haberstroh, F. Hoffmann-La Roche
Geoff Habiger, Oso BioPharmaceuticals Manufacturing
Ofra Hacham-Levy, Sol-Gel Technologies
Birgit Halbgewachs, Fresenius Kabi
Fauad Hasan, Allergan
Robert Hayes, Gerresheimer Glass
John Hegg, Abraxis Bioscience
Vincent Hondebrink, Klinische Farmacie
Stanley Howell, Merc
Saddam Huq, GlaxoSmithKline
Katrin Husmann, Abbott
Tjut Vina Irviyanti, PT Bio Farma
Lis Jahanshahi, ALK-Abelló
Karen Kanyok, Gerresheimer Glass
Yeliz Kasapoglu, Mustafa Nevzat
Tracy Killingsworth, Alcon Laboratories
Miho Kimata, Mitsubishi Tanabe Pharma
Anna Kleine, Novo Nordisk
Antje Knoell, F. Hoffmann-La Roche
Catharina Koch, F.Hoffmann-La Roche
Heike Kofler, West Pharmaceutical Services
Atsushi Kosugi, Nichi-iko Pharmaceutical
Vijai Kumar, Pharmaceutics International
Frances Lacombe, Cubist Pharmaceuticals
Susan Li, UPS Healthcare Logistics
Nan Lin, Sigma-Tau Pharmasource
Traci Jo Lindow Sullivan, Paddock Laboratories
Nils Mueller, GlaxoSmithKline
Stanford Ma, MedImmune,
Rick Majszak, CSL Behring
Elise McCarthy, Shire HGT
Peter Mehring, Intelleflex
Lee Menszak, Lee Menszak Consulting
Nao Nakamura, CellSeed
Rachael Nelsen, Covidien
Niamh O´Dwyer, Pfizer
Kazuhiko Ozaki, Mitsubishi Tanabe Pharma
Ash Patel, Biogen Idec
Richard Patrick, Merck
Milena Pelusi, Patheon
John Peoples, Merck
Mark Perez, NNE Pharmaplan
Gregory Pitt, Eli Lilly
Marcin Placzek, Department of Pharmaceutical Technology
Abraham Polk, Seattle Genetics
Robert Posluszny, Judge
Matt Ream, Blue Spark Technologies
Stella Reed, Merck
Susan Ritter, Tolmar
Sandra Roque Reveron, Noven Pharmacuetical
Tony Rowland, SeerPharma
Wayland Rushing, ABC Laboratories
Gilbert Salud, Genentech
Yurie Sawada
Sara Sevillano, Crystal Pharma
Kendral Smith, Pfizer
Irina Sperling, Crucell
Karmen Starks, Novartis
Lauren Streb, Genentech
Julie Sundgaard, Microbiologics
Bill Tafuri, Lifecore Biomedical
Gabriel Tambunga, Laureate Biopharma
Mark Thomas, Laureate Biopharma
Alexander Tracy, Novartis
Boris Vaisman, HealOr
Guy Washinger, Lundbeck
James Webb, Catalent Pharma Solutions
Henrik Westerlin, Novo Nordisk
Thomas Willimann, ViforPharma
Melissa Willoughby, Alkermes
Lance Wong, Bavarian Nordic
Adam Young, 888 Online Media
Kerri Zawadzki, Amylin Pharmaceuticals

Results of PDA's West Coast Chapter Board Elections

On Thursday, March 24, PDA's West Coast Chapter held its Board Elections.

PDA would like to congratulate the following people:

President **Elizabeth Leininger,** E Leininger Consulting
President Elect **Elaine Eborall,** Genentech-Roche
Treasurer **Greg Meyer,** Compliance Media
Secretary **Beth Keij,** Novartis

PDA Tools For Success

Brought to you by the PDA Career Center.
Go to www.pda.org/careers for the latest opportunities.

How to Get a Job in a Recovering Economy

Maureen Crawford Hentz

As if it's not hard enough to find a job normally, an economy like the one following the 2008 meltdown complicates matters significantly. Yes, it's bad, but despite what your brother-in-law, your barber, your neighbor and the guy you pass while walking Fido all tell you, there are jobs to be found. The key is to be informed and work strategically.

Stimulus package jokes abound, and yet the stimulus package is pumping money into the economy. Even though you may not be a multimillion-dollar bank on the brink of collapse, you still can access your piece of the pie.

Go to the Source

The USAjobs.gov website is a good resource, but it lists limited jobs, including federal jobs. You'll also find a link on the front page to search for American Recovery and Reinvestment jobs. It's a fine source of jobs, but you can do even better with a little know-how.

On the other hand, Recovery.gov is the official U.S. government stimulus package website. This is where the pie is kept. Recovery.gov isn't a job site, so you will have to do some digging for what you really seek–specific open jobs created from the stimulus package. On Recovery.gov, you can find the names of new projects funded by the Recovery Act, including the company names and the projects funded.

Additional resources include:

- USAspending.gov
- Fed Biz Opps.gov
- Grants.gov

In addition, look for a recovery site for your own state. And, as an article in the *ExecuNet* newsletter points out, a hidden workforce of 10.5 million people employed as contractors and subcontractors to the federal government will continue to turn over, providing additional opportunities.

This is how to use these sites to power up your job search:

1. Check out all the resources on the site. One of the best gold mines of information is a section called "Where is the Money Going?" At this part of the website, you can easily query for contracts awarded in your state.
2. After you've honed in on your state, take a look at the kinds of projects that are funded. A quick look at my home state's funding, for example, showed projects in health,
3. Make a list of 10 or so companies and projects for which you can anticipate extra people power will be required.
4. Head over to the websites of the companies awarded contracts and apply on the company site. Indicate in your cover letter that you found out about the company by doing research at the Recovery Act grants page. This extra work alone might be impressive enough to get you the interview.

You can also set up a Google alert with these search terms: "your city (or state)" and "awarded" and "Recovery Act." Google will email you hot-off-the presses information every time a company in your area issues a press release announcing a stimulus award.

Get in the Pool

When you've identified a company that's been awarded stimulus money, applying on its corporate website as soon as possible is key. Even if you don't see jobs specific to the stimulus project or specific to what you want to do, apply to the general pool or general application. In this way, your resume will be in the system and available for searching.

When a job opens up at our company, for example, the very first step for our recruiters is called Tier One recruiting, which means recruiters are required to search in the database of current applicants for all jobs to see if they contain anyone who should be invited to apply for the new jobs.

You can also apply to general pools of jobs by going to the USAjobs.gov site. When you click on the recovery jobs site and query for jobs in your state, you are likely to see requisitions for "standing registers" of applicants. Here, you can apply for categories of jobs like "project

manager" and "engineer/architect."

Keep your resume fresh. When company recruiters look in their applicant tracking systems, they can usually see the date on which the candidate last updated the profile. Update your profile at least once every two weeks, even if updating is merely adding a period one week and deleting it the next.

Automate the Search

In addition to applying to a company's general database, set up a job alert in the company's careers section. You will be emailed when new jobs are listed. As an added bonus, some company recruiters think more highly of candidates who have expressed continued interest in the company by setting up a job alert. A caveat, though: don't apply for every job that is emailed to you. Doing so may have a negative effect on your candidacy. You can't genuinely be interested in and qualified for a PhD-level scientist job and a lower-level accounting clerk and 20 other jobs. We have a couple of people who have job alerts set for our careers page who seem to apply for every job regardless of the job's requirements. Needless to say, these folks probably aren't being considered as seriously for jobs for which they are qualified because they are enacting the job-seeker's version of the boy who cried wolf.

Think all this sounds like too much work? Think about it; you aren't sending cold resumes out into the world, but rather to companies who are actually hiring right now. Even when you send a resume to a position listed on one of The Big Three job boards (Monster, CareerBuilder and Yahoo Hotjobs), you can't be entirely sure those companies have open positions. They could be pipeline recruiting, meaning that although they don't have jobs now, they want to keep fresh candidates flowing into their applicant tracking system for when things get better. I don't know about you, but I'd rather spend my time applying to a company with jobs, rather than just a pipeline.

There are jobs and you can get one. Good luck.

About the Author

Regular *QuintZine* contributor **Maureen Crawford** Hentz is the manager of talent acquisition, development and compliance for Osramsylvania, a Siemens company. She is a nationally recognized expert on social networking and new media recruiting. With more than 15 years of experience in the recruiting, consulting and employment areas, her interests include college student recruiting, disabilities in the workplace, business etiquette and GLBT issues. In addition to her work for *QuintZine,* she is a contributor to the Boston.com HR blog. She conducts workshops, keynotes and conference sessions nationally.

Questions about some of the terminology used in this article?

Questions about some of the terminology used in this article? Get more information (definitions and links) on key college, career, and job-search terms by going to our Job-Seeker's Glossary of Job-Hunting Terms.

Latest Hot-Job Postings

For a complete list of all job postings, please visit www.pda.org/careers.

New jobs posted daily to PDA's Career Center!

Abbott, Chicago, Ill.
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GlaxoSmithKline, Conshohocken, Pa.
Senior QA Specialist

Eli Lilly, Indianapolis, Ind.
Consultant Packaging Development Engineer/Scientist

Interested in posting a job? Take advantage of all our career job postings and packages.

Tell Us What You Think!

We want to know what you think of the Tools for Success Section and how it is helping you. If you have a favorite article, tip or story you want to share, contact **Emily Hough** (hough@pda.org)!

snapshot

Task Force *Corner*

Striking the Right Balance: Single Use TF Ensures Equal Voice among Membership

Emily Hough, PDA

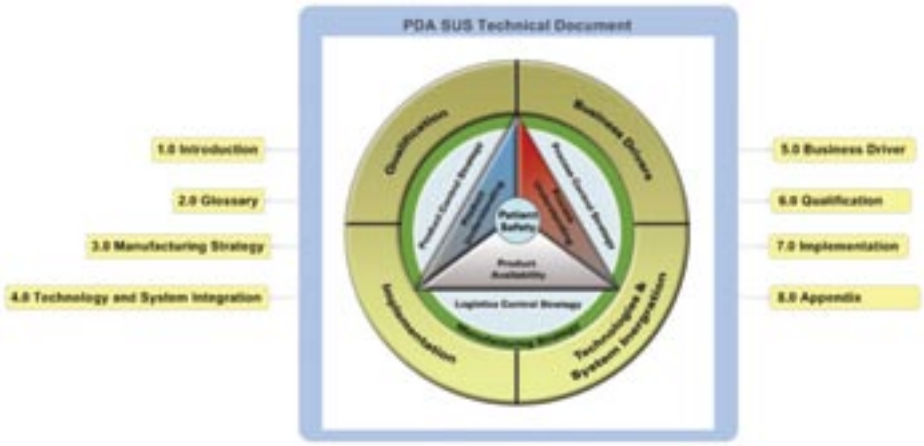
Co-chair of the Single Use Task Force, **Robert Repetto,** External Affairs & Strategy, Bio-Therapeutics Pharmaceutical Sciences, Pfizer, has made an effort to balance the Task Force with membership from industry end-users, regulators, enablers and single-use suppliers from the United States and Europe.

In fact, to make sure that Europe was represented fairly and to "facilitate communication and participation within the Task Force," Denmark's **Morten Munk,** Vice President, CMC Biologics, was recruited to become co-chair.

The Single Use Task Force has challenged itself to be supplier neutral and focus on technology, quality aspects, science and best practices. According to Repetto, in order to achieve this balance, the Task Force has worked hard to ensure that one sub-team isn't dominating the discussion. Risk assessment tools have even been utilized to evaluate how well they are achieving this.

To prepare for meetings and to interest new members, Munk and Repetto often meet with **Robin Alonso,** Project Manager, Genentech in advance of the monthly Task Force meeting to work out the agenda and identify topics for discussion. According to Repetto, "The Task Force is very fortune she is a part of the group and that Genentech has allowed her to participate." She often gets 20 people from four or five time zones to join and participate in two hour conference calls, a feat for any global company, but even more so when the participants are all volunteers.

The Task Force is organized into six sub-teams based on the structure of the technical document that is being prepared.



The Section Leaders Are

Morten Munk: Manufacturing Strategy (section 3)

Jeff Carter: Technology and System Integration (section 4)

Niels Guldager: Business Driver (section 5)

Duncan Low and **Ingrid Markovic:** Qualification (section 6)

Steve Brown: Implementation (section 7)

"Chairing an industry task force like PDA's has all the challenges you would face leading any large initiative in a global organization with one real difference," Repetto said. "On a PDA task force, everyone is a volunteer and has very real responsibilities in the organization for which they work. Task force members need to find time to call into monthly task force meetings and sub-team meetings as well as writing or researching topics to contribute content."

From the start, in order to make sure the discussions were effective, Repetto took it upon himself to take a QbD approach to guide the task force by focusing on what was critical to the final product, the technical report. It is on track to be published this summer. The technical report will focus on a thorough understanding of product and process risks that face single-use systems end-users. The goal is to offer a flexible approach to developing a well-designed manufacturing strategy, so end-users can customize their approach based on their needs and capabilities, developing a robust process that includes process and logistic controls supporting the desired states of patient safety and product availability.

To ensure that it addresses PDA members concerns, the Task Force is also developing a tool for the PDA website to collect questions and concerns about single-use systems for the Task Force to consider in the final document and during the PDA Workshop on single use systems in Bethesda Md. on June 22-23.

The Task Force would like to thank Genentech for not only allowing Alonso to participate, but also for the services of **Hillary Russak,** Technical Writing.

continued at top of page 20

Interest Group *Corner*

Packaging Science IG Doesn't Shy Away from "Hot-Topics"

Emily Hough, PDA

The Packaging Science Interest Group (PSIG) has been in operation for about a decade. For as long, **Ed Smith,** Principal Consultant, Packaging Science Resources, has been drawing on his passion for knowledge to lead the Interest Group. One of the activities he enjoys most is answering any questions from his group relating to packaging and diss-eminating information about opportunities that may exist in the field and about new packaging technologies.

Ed's responsibilities as Interest Group leader include sending members periodic announcements about PSIG activities and upcoming meetings and preparing for his group's twice-a-year meetings, at the PDA Annual and PDA/FDA Meeting. To choose topics that will engage the 250-member Interest Group, Ed sends a notice several months ahead of the meetings asking for feedback. At this year's Annual meeting in San Antonio, Tex., the Interest Group held a joint meeting with the Pre-Filled Syringe Interest Group on glass defects—a preview of the upcoming PDA/FDA Glass Quality Conference meeting to be held in May.

"We try to pick issues that are on everyone's mind at the moment and these issues change month-by-month, so it is hard to pick topics long in advance. New topics come up quite suddenly. I think this year we've picked a good topic. The last meeting we had dealt with package integrity/container closure integrity."

According to Smith, package integrity/container closure integrity is always a hot topic. Extractables and leachables and glass defects are also high on the list, currently.

Spearheading an effort to build an online presence for the PSIG, Smith is working on establishing an online forum that would help the group keep in contact on a regular, consistent basis. He would also like to have the PSIG create a glossary for rubber component defects, similar to the current *PDA Technical Report No. 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing,* as there is currently nothing like it available for rubber defects.

If you would like to join the PSIG, or have any questions, please contact Ed Smith at esmithpkg@msn.com.

About the Expert

For the last three years, Ed has served as Principal at Packaging Science Resources (PSR) and as Senior Advisor at Genesis Technical Advisors. PSR is a consulting and training company that provides the pharmaceutical, biotechnology, and medical device industries with packaging expertise. At Genesis Technical Advisors, he consults about packaging technologies. Prior to these positions, he worked for Wyeth and West Pharmaceutical Services previously.

continued at bottom of page 20

Journal *Preview*

Risky Business in May/June Issue

Risk and risk management are recurring themes in this month's *PDA Journal of Pharmaceutical Science and Technology.* One article outlines a "simple, workable" approach to risk analysis of sterile product manufacturing facilities; another looks at risk analysis for laboratory notebooks used in small pilot facilities; and the third examines just how risky pinhole leaks in isolator gloves really are. The issue includes four engaging review articles, and more!

Editorial

Maik Jornitz and Govind Rao, "Wish You Were Here!"

Research

Mohan Guguloth, Ramesh Bomma, and Kishan Veerabrahma, "Development of Sustained Release Floating Drug Delivery System for Norfloxacin: In Vitro and In Vivo Evaluation"

Anna Fàbregas-Fernàndez, et al., "Quality and Integrity of Data in Research, Development and Innovation. A Risk Analysis Method Applied to Laboratory Notebooks in a University Pilot Plant"

Guenther Gapp, Peter Holzknecht, "Risk Analysis of Sterile Production Plants: a New and Simple, Workable Approach"

Technology/Application:

Angela Gessler, et al., "How Risky are Pinholes in Gloves? A Rational Appeal to Integrity of Gloves for Isolators"

Review

Praful Balavant Deshpande, et al., "Supercritical Fluid Technology: Concepts and Pharmaceutical Applications"

Luis Jimenez, "Molecular Applications to Pharmaceutical Processes and Clean Room Environments"

Beth Junker, et al., "Design-for-Six-Sigma for Development of a Bioprocess Quality-By-Design Framework"

Sandeep Nema and Ronald J. Brendel, "Excipients and Their Role in Approved Injectable Products: Current Usage and Future Direction"

Journal *Update*

Journal Archive Expanded by 18 Years

The *PDA Journal of Pharmaceutical Science and Technology* now boasts an archive that extends back to 1980. In order to launch the new Journal website in 2009 in a timely and cost-effective manner, we only included archival issues back to 1998 (volume 52). Now readers can access all articles published between 1980 and 1997 (volumes 34-51). Our plan is to expand the archive all the way back to Volume I over the next few years.

continued at top of page 21

Task Force Corner continued from page 18

"Of all the professional development efforts that people can make, I believe that active participation in an industry task force is one of the most rewarding." Repetto said. "It's a chance to step outside the framework of your individual experiences and have though provoking discussions with colleagues you might never have even met otherwise. Morten and I would like to thank the Task Force members for their dedication and insightful discussions; the technical report is one step closer to the desired state because of their efforts."

Task Force Members

Chair **Robert Repetto,** Pfizer

Co-chair **Morten Munk,** CMC Biologics

Robin Alonso, Genentech

Stephen Brown, PhD, Vivalis

Jeff Carter, PhD, GE Healthcare

Niels Guldager, NNE Pharmaplan

Bill Hartzel, Arkema

Eric Isberg, Computype

Christian Julien, Meissner Filtration

Michael Kraich, PhD, Boehringer Ingelheim

Rich Levy, PhD, PDA

Duncan Low, PhD, Amgen

Ingrid Markovic, PhD, U.S. FDA

Jerold Martin, Pall Life Sciences

Paul Priebe, Sartorius Stedim Biotech

James Robinson, Lachman Consultant Services

Hillary Russak, Genentech

Robert Shaw, Ark Therapeutics

Chris Smalley, PhD, Merck

Russell Wong, Bayer Healthcare

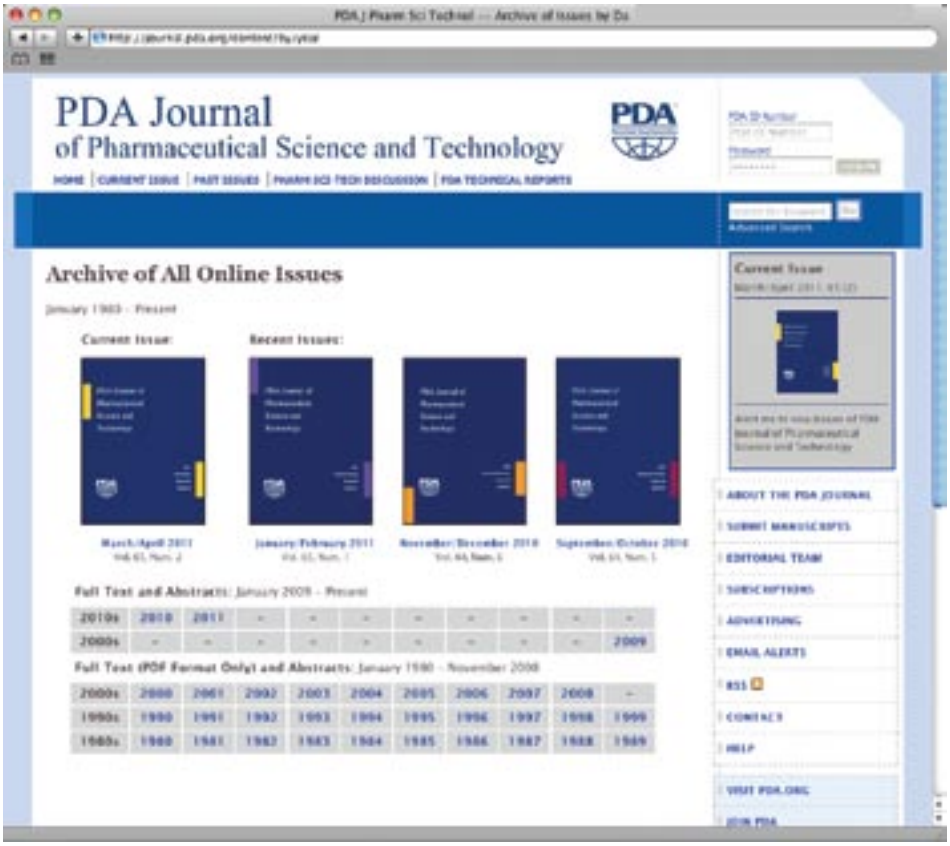
About the Expert

Robert Repetto is a Research Fellow, External Affairs Technical Advocacy, Pharmaceutical Sciences at Pfizer BioTherapeutics. He focuses on industry and regulatory trends that enable the BioTherapeutics and Vaccine portfolio. Robert has over 20 years of process development, manufacturing and clinical production experience. Prior to this position, he was the Director of Technology and Innovation for Wyeth Biotech, where he was responsible for development of strategies focused on new technologies, innovation, risk management, process technology, and real time process monitoring.

Interest Group Corner continued from page 19

Since Smith joined PDA in the late-1970's, he has been involved as an instructor with PDA's Training and Research Institute, a member of the recently formed TBA Task Force, a steering committee member of the Pharmaceutical Cold Chain Interest Group, and is the leader of the Packaging Science Interest Group. Smith explained that he has been so involved with PDA because "the quickest way to learn is to get involved. To really find out what is going on, you need to go to meetings and get involved in committees, that is where you pick up most of the information." He said that when he first started at West Pharmaceutical Services, he was brand new to the industry, and PDA was his way into the pharmaceutical world. When he joined Wyeth almost 24 years later, he said he still felt the same way about learning. "If you wait for publications, you are a month behind the times. PDA is a great source of information."

Journal Update continued from page 19



Also, by the time this issue of the Letter hits your desk, readers of the PDA Journal will have the ability to provide feedback electronically on each and every article. The online feedback tool, called "E-Letters," is in the queue for launch as this issue goes to press. The Journal editors will monitor the postings, but all appropriate reader comments are welcomed! By the end of June, authors will be able to use the online submission tool to submit their manuscripts to the Journal.

To view our progress and to see past and present Journal articles by year, please visit journal.pda.org/content/by/year. Don't forget to sign up for e-Alerts and RSS feeds at the website for the *PDA Journal of Pharmaceutical Science and Technology* to stay on top of the latest content.

PAST ISSUES now includes Volume Years 1980-1997

8 Solutions for Controlling Supply Chain Risk

The pharmaceutical supply chain is particularly at risk in the zones outside of the direct control of manufacturers: ingredient supply and final product distribution. In this issue of the *PDA Letter,* we present articles that offer a number of solutions to lower risks throughout the chain. Below is a list of the top eight. The page number for the article containing more information on the solution is indicated in parentheses.

1. **On-Demand Visibility** (p. 26)
2. **On-Site Auditing of Whole Ingredient Chain** (p. 32)
3. **Audit Sharing** (p. 24 & 32)
4. **Tamper Evident Seals** (p. 24)

5. **Photographic Libraries** (p. 24)
6. **Include R&D in Supply Chain Decisions** (p. 26)

7. **Learn from Law Enforcement** (p. 24)
8. **Use Global Product ID Numbers** (p. 34)

Undoubtedly, our suggestions are not the only solutions, as many good ones are being developed. Through conferences and articles, PDA and its members have been at the forefront of facilitating dialogue to develop solutions (read more about our upcoming workshop, co-sponsored with the U.S. FDA, on page 40) and articles.

The Parenteral Drug Association presents the...

2011 PDA/FDA Pharmaceutical Supply Chain Conference & TRI Course

June 6-8, 2011 | Bethesda North Marriott | Bethesda, Maryland

The *2011 PDA/FDA Pharmaceutical Supply Chain Conference & TRI Course* will expound upon how **high quality, safe and effective drug products and drug ingredients depend upon a consistent supply of high quality ingredients and starting materials.**

The challenge of securing and protecting the integrity of the vast, global pharmaceutical supply chain can be met through a variety of science- and risk-based approaches. New laws, regulations and guidance continue to evolve helping to stimulate innovation toward enhancing good manufacturing, distribution, and importation practices. Building on earlier PDA co-sponsored conferences and workshops on pharmaceutical supply chains, this meeting will provide a forum to further implementation of innovative approaches aiming to prevent illicit acts such as counterfeiting, diversion, and economic adulteration from threatening the safety of the drug supply.

Supply chain security is evolving into a global initiative as well as a cross-departmental initiative. Global regulators must partner, just as industry must partner to promote patient safety. By attending the *2011 PDA/FDA Pharmaceutical Supply Chain Conference & TRI Course* you will hear from US and EU regulators as well as industry experts.

The conference, in addition to plenary sessions, will consist of a series of concurrent sessions ranging from topics on applying risk models, exploring innovative security solutions, tracking finished products in the supply chain, finding solutions on how to authenticate products, and more. Since the conference covers the entire supply chain, one track will focus on materials security and the other will focus on finished product security.

The PDA Training and Research Institute (PDA TRI) will host a training course immediately following the workshop on June 8th on *Developing a Robust Supplier Management Process.*

www.pda.org/supplychain2011

CONFERENCE June 6-7 | **EXHIBITION** June 6-7 | **COURSE** June 8

Multi-Pronged Strategy Needed to Combat Counterfeiters

Martin VanTrieste, Amgen

Globalization is impacting most industries, and the pharmaceutical industry is no exception. On the positive side, it has enabled our industry to enter markets all over the world and provide life-giving medicines to millions of patients.

With the benefits of globalization, however, comes significant challenges and responsibilities. One of those challenges is ensuring the authenticity and quality of materials moving through the supply chain. I recently had the opportunity to present on supply chain security, and as I was doing my research for the presentation, I became increasingly unsettled and overwhelmed by the magnitude of this problem.

I quickly realized that the challenges presented by a very complex, global supply chain, which spans numerous regions of the world and many regulatory jurisdictions, are too vast to take on at one time or with one solution. It was clear to me that there is no magic solution for this. I decided to break down the problem to make it more manageable, and using my knowledge of cGMP and security practices, I developed a layered strategy.

First, I had to accept that the GMPs are important, but alone, they could not protect the supply chain from unethical players and criminals who see the potential to make staggering amounts of money. They are playing by different rules, so the industry requires a different approach. We must learn from law enforcement and security professionals about solutions to implement, so we can thwart counterfeiters efforts and actions.

I have previously compared the profitability of different types of counterfeit products: A criminal can take $1,000 and convert it into $10,000 of profit counterfeiting a consumer product, like a DVD, watch or purse. That same $1,000 can be converted into $100,000 dealing in illicit drugs like cocaine. But, a criminal can take $1,000 and make $1,000,000 counterfeiting pharmaceuticals. These numbers are rough estimates, but they illustrate in a very real way the severity of the issue. It costs $60/kg to buy Viagra API in China or India, which can be converted into 25 mg tablets that would sell in the United States for up to $200,000. **(1)**

As professionals within the pharmaceutical industry, we do not have to wait for another attack—we can take action now

When speaking with law enforcement professionals, they tell us that crime prevention requires a three-pronged defense that involves deterring, detecting and disrupting criminal activity. As professionals within the pharmaceutical industry, we do not have to wait for another attack—we can take action now. We can improve systems and techniques to deter, detect and disrupt criminal activity that threatens our supply chain.

With all of this in mind, I developed the following strategy:

- Use common sense
- Embrace new ideas/Adopt advanced technologies
- Always collaborate and communicate with other stakeholders

Common Sense

Common sense dictates that you understand your supply chain in detail. You should be able to answer the following questions honestly:

- Who is the real manufacturer of the material? (Not the broker or distributor)
- Where is the real manufacturer of the material located?
- How many different organizations or links are in your supply chain?
- Is your supplier transparent?
- How is the material transported and stored from the manufacturer to your site?

It is critical to remember that every step in the supply chain represents an opportunity for risk. As such, common sense dictates that we work with trusted partners in the supply chain to mitigate that risk. To find those trusted partners we must perform thorough due diligence by understanding the supply chain and the players involved; building and maintaining a relationship with suppliers as well as staying in constant contact with them; and, by all means, providing routine oversight of suppliers and the supply chain.

When a trusted partner is not available, however, common sense dictates that you apply a robust risk management process that identifies and aggressively mitigates unacceptable risk. For example, one can qualify a new supplier; work with them to improve their performance; or implement measures designed to deter and detect problematic activities. Options for the latter include a person-in-the-plant and extensive sampling and testing schemes upon receipt.

It makes sense to require suppliers to utilize good tamper evident seals. I can best describe what a good tamper evident seal is

by first explaining what is unacceptable.

A tamper evident seal is not:

- A piece of tape
- A piece of string
- A rubber band
- A knotted plastic bag
- A common electrical zip tie

A good tamper evident seal has a unique serial number, is applied to every container and is tracked throughout the supply chain. When tampered with, it is easy to spot. The integrity of the seal is verified upon receipt, and tamper evident seals, and if, something does not match, investigate! Most discrepancies can be easily resolved with a quick phone call to the supplier.

Most importantly, when in doubt about the integrity of your supply chain, act quickly. Far too often I have come across problems that have been encountered and solved before, but due to organizational malaise they were not promptly implemented until after negative consequences were experienced. How many times have you heard "I don't have enough resources to work on that"; yet, an army of people are ready to swarm a problem when it arises?

New Ideas for a Secured Supply Chain

There are many new ideas that can be adopted to secure the supply chain. Right-size testing, photographic libraries and pedigree systems, for example, can make it easier to detect security problems.

Right-size testing is a concept that requires developing a raw material sampling and testing scheme using risk assessments that consider supply chain security and final product requirements. Under this approach, raw materials would be accepted based not just on identification testing and compendial testing, but also on special testing based on supply chain security risks or other special parameters to protect the final product's performance.

Pedigree systems are processes that allow materials to be tracked from the point of manufacturer, through any distributors, re-packagers, etc., to the point of receipt at the pharmaceutical manufacturer.

To learn more about photographic libraries, go to bit.ly/eSUfUB

A photographic library is a simple tool that allows multiple individuals throughout the organization to detect potential product tampering. The goal is to have an early detection system that is quick, easy and effective for identifying tampering of incoming materials as early as possible. A photographic library basically compares a trusted photograph of the container, closure, tamper-evident seal, labeling and packaging and compares it to the actual item being received.

Technology can be adopted to prevent and detect problems within the supply chain, and new technologies are becoming available every year. The use of sensors, tracking systems, taggants and hand held analytical instruments will deter and detect security problems.

Collaboration and Communication

It is also important for all of us to collaborate by sharing knowledge, best practices and resources so that we can attack this global complex set of challenges in a coordinated and more effective manner. If 100 different companies, 50 different countries and 10 different trade organizations develop independent solutions and approaches, the unintended consequences of this disorder could be disastrous. The only individuals that will benefit from this havoc are the unethical players and criminals who will exploit the chaos for their own personal financial enrichment.

In order to facilitate the level of collaboration required to address the complex challenges of the supply chain, an international nonprofit consortium was formed called Rx-360. Its mission is to create and monitor a global quality system that meets the expectations of industry and regulators and assures patient safety by enhancing product quality and authenticity throughout the supply chain.

Rx-360 will achieve their mission by detecting, deterring and disrupting negligent, unethical, or criminal behavior while improving quality by:

- Sharing information on the supply chain
- Developing and sharing new technologies
- Setting standards and adopting best practices such as excipient guidances published by IPEC
- Sharing audits and the burden of conducting audits

continued at bottom of page 33

More on Rx-360

Currently Rx-360 has over 55 members, including PDA. To be eligible for membership in Rx-360, an organization must fall into one of the following categories:

- Manufacturers of pharmaceutical products
- Suppliers of ingredients and components of pharmaceutical or biotechnology products, along with their suppliers
- Suppliers of services relating to the quality or safety of the pharmaceutical or biotechnology supply chain

In addition, the following groups can be observers in Rx-360:

- Governmental units or quasi-governmental units
- Non-profit trade or professional associations representing the pharmaceutical or biotechnology industries
- cGMP auditing firms

Go to www.Rx-360.org for more information.

Achieving Visibility On-Demand

An interview with Daniel R. Matlis, Axendia

Walter Morris, PDA

There are no easy answers to the question of how to reduce risks in the pharmaceutical supply chain, particularly with respect to ingredients purchased from an expanding and complex international market. In recent years, PDA has worked with industry and regulators to sponsor meetings, an industry consortium has formed, new regulations/guidances have passed and/or are being considered, yet it seems there continues to be more questions than answers.

To help cut through the fog of information on this topic, a group of quality, regulatory and supply chain officials from leading pharmaceutical companies worked with the consulting firm Axendia to find answers by surveying their industry peers. The results, published in the report *Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences,* are enlightening. I had a chance to read the report and hear the firm's president, **Daniel R. Matlis,** discuss the findings at a recent industry trade show. He agreed to discuss the report with me for the *PDA Letter*.

The first question I had for Dan was how his company got involved with the survey. Part of Axendia's business, he explained, is to prepare research reports for industry. Axendia is an analyst and strategy consulting firm he helped found to serve high-level executives in the life-science and healthcare industry to address business issues in a highly regulated environment with enabling technologies.

The firm does not promote any specific technology, but does seek support from service and technology enablers to underwrite their reports. In the case of the supply chain report, Axendia signed three underwriters. Dan noted that their role was similar to an underwriter of a National Public Television/Radio program, and that there is a "firewall between the underwriter and the content."

In fact, Dan said, the industry officials who approached Axendia about the survey, a group that included PDA Director **Martin VanTrieste,** Amgen, formed an Executive Advisory Council that helped write the survey. "What we did," Dan explained, "is have conversations with them to identify the key issues. That is how our questionnaire was developed. Next, we validated the data that we receive with the Executive Advisory Council to make sure that our interpretation was reasonable based on what they are living day-to-day."

The following is our discussion of two major elements of the report presented in Q&A format. First we talked about the concept of "On-Demand Visibility," a key recommendation in the report. Next, we address a finding in the survey that suggests there needs to be a bigger role for R&D in making supply chain decisions.

PDA Letter: The survey and the report are very interesting. There is a lot we could talk about. One aspect I found intriguing is this concept of "On-Demand Visibility." It is something that I never heard described the way you did in the report. I like your analogy of the air traffic controller looking at the blips on the radar. Why don't you tell us a little bit about it and a little more information on the systems that would need to be in place to have on-demand visibility?

Dan: Initially, visibility was fairly straightforward to achieve within the four walls. You need information from within your corporate four walls, you call somebody, you get that information, they email it to you and you have it. Now that you are dealing with suppliers, the challenge is how to get that information. And not all suppliers are created equal and not all contracts and agreements are created equal. So the challenge becomes how do you get the visibility that you need from your supplier in order to be able to manage your process once that raw material or active pharmaceutical ingredient comes into your plant, so that you can properly manage your process.

The current process is: You do an audit of that supplier and that gives you a snapshot in time that says, they had the policies, procedures and methodologies that they needed at that point in time. And then, perhaps every time you get a shipment, you get some kind of quality certificate with that batch of product that tells you it has met your quality requirements. Now the challenge is that those quality requirements might not be all of the data points that are needed to actively manage the process. So if you are getting lactose USP, and it meets the USP standard for lactose, what is the particle size density? That could make a huge difference downstream in your process as to what the output of our manufacturing process will be down the line.

So what we call for is what we termed "on-demand visibility." And the reason we call it this is because, as opposed to real-time visibility, when you have the data streaming to you all of the time, we are suggesting that companies employ this on-demand visibility that gives you the ability to gain that relevant information that you are supplied with at the appropriate time. This is done so you can make the best decision you can based on the analysis of the data that supplier is providing you. So what that means is, instead of just sharing or giving you this quality certificate, it involves having them share their process manufacturing data for you to know what went on when they made that batch, just like you ➤

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had when you were making that batch in-house. Before you outsourced, you had all of that process data and knowledge and you used it to feed and control downstream processes. What we are suggesting is that that same approach be used with contract manufacturers or outsourcers, so that you can tightly control that next step, whether it is done in-house or on another link in the chain.

That's why we like to use the analogy of the air traffic controller. The air traffic controller has on-demand visibility. Yes, all of the information is streaming, but they are not just seeing one airplane at a time. They are looking at all of the airspace that they are responsible for and they are making decisions not just according to what one particular plane is doing, but they are making decisions based on the overall airspace and not just on the information that is provided to them on each one of the planes, but also based on other important parameters such as weather. If pharmaceutical companies would look at the supply network in a similar way that air traffic controllers look at all of the parameters in the airspace, we believe it would give them the opportunity to better and more tightly control those products that are being delivered to them by third parties.

PDA Letter: Maybe we can distill this down to an example. You are talking about going beyond just a regular certificate of analysis. How would this work?

Dan: Let's say you don't typically check for moisture in a binder ingredient, but as a result of moisture in the manufacturing process, you are getting a different particle size density. Maybe you are getting caking. So that is one piece of data that would be helpful. Now, take it through the supply chain. Is it being shipped on a container ship across many, many miles. Let's assume it is something you do not typically ship in a temperature-controlled container because it is an inactive chemical and it is not really going to make a big difference in general. But the ship could go through tropical waters and the temperature and humidity is higher than normal and this could cause problems.

We are managing an outsourced environment still with the organizational structures of internal manufacturing

PDA Letter: So what is the visibility here? What do companies need to get on top of the COA?

Dan: What they should be getting is all the critical to quality parameters that are associated with that product. For each product it might be different. Maybe this product doesn't need to be temperature-controlled during shipping, but you may need to get a temperature sensor that records what the temperature exposure was for that particular product, because the product is still good. But, based on the temperature exposure profile, you might adjust your manufacturing parameters for blending or for drying.

The things that most people will measure are temperature, pressure and relative humidity. The question is, are those critical to quality parameters? Are there other parameters based on your process understanding—and that's where it starts. You need to understand your process and what are those critical to quality parameters—and then you need to get visibility into those parameters across the entire chain, from manufacturer to the point that it makes it into you facility.

PDA Letter: This is an interesting discussion, and there is a lot more information in the report about on-demand visibility. Another part of the report I liked was the data on the internal groups involved in supply chain decisions. The usual suspects were listed by the companies as those groups currently involved: Purchasing, supply chain management, quality groups, manufacturing groups, auditing. But then you asked the interesting question, "Who do you think should be involved?" The answers were product development, product testing, and even marketing. In your opinion, why are certain functions out of the loop?

Dan: I think the biggest issue we are dealing with is history. We are managing an outsourced environment still with the organizational structures of internal manufacturing. Pharmaceutical companies are notorious for not just having silos, but having silos with moats around them and crocodiles swimming in them, so nobody could jump over from one silo to the other. Sometimes that is due to regulatory requirements or confidentiality, and there is very little communication between the silos until you need it. When it is time to start manufacturing the product for the clinical trials, then we'll get the right small team involved in clinical manufacturing. Once we know we are ready for phase 3 and it looks good, then we will get the people in scale-up involved. In the meantime, we are still building a whole facility. We are building a brand new facility with all brand new equipment, because we have ➤

a high degree of confidence that this product is going to make it to market.

Once you move to an outsourced environment, you cannot manage it with a silo approach. You need to bring the right team of people together so you can make the right decisions. From an outsourcing standpoint, the people who used to deal with outsourcing or with contracts were in procurement, because historically you bought stuff from suppliers, and you bought it based on a spec that somebody at a functional area or department gave you. They even sometimes suggested who to buy it from. But then what happened was that the purchasing folks or the supply chain folks became the central point for managing outsourcers. And then they started bringing in the people down the chain that they needed. So that is why you have very often manufacturing, engineering and production people involved, because they are the ones involved when you are making the product.

PDA Letter: I see, but in the in-house model you described, information about the properties of the ingredients must have been communicated. So what is happening now that adds to the risk—because things generally are working and we only have had a few instances of problems, severe as they are—in the process of handing off the process from development to the other side? In other words, what can be gained adding development into the purchasing loop?

Dan: Well, as you say, you can lower risk. But also, you can minimize some of the redundancies and some of the scale-up issues that are often associated with new products and some of the variability that is associated with externally supplied products. So I think the value and the benefit is better when you can characterize the product early on, gain more knowledge throughout the process, and then use that process knowledge and characterization that you have learned to communicate with your suppliers. Tying back to the on-demand visibility, if I can write into the contract that in addition to the quality certificate that lists all of these characteristics and all these data points, I also want to be able to get from the supplier these additional data points and the history. You can write the contracts to require that. You can actually help your supplier by telling them what is important to you, so that when they provide you with that raw material or ingredient, it is exactly what you expect, as opposed to mostly what you expect.

You can actually help your supplier by telling them what is important to you

PDA Letter: So like our example of the binder, it might include all of the temperature and humidity data?

Dan: And frankly, if you don't write that into the contract, then legally you have no right to it. You might have a good relationship with your supplier and they might send it to you, but things go well until there is a problem. That is why we have contracts. So if you can write that into agreements that you require that information to be provided. One of the other challenges and issues here is, what if your supplier goes out of business? The more you have that process understanding and characterization early on, the more you know about the process, the easier it is to manage it.

PDA Letter: So we are not necessarily saying that someone from product development/testing is there all of the time, but what you mean is that they are providing more information downstream to help the purchasing?

Dan: It should be a team approach as opposed to an individual decision, and it should always be based on the facts. The facts should be gathered as early on as possible in the process and the learning should be done early on.

Maybe the whole product is going to be outsourced. If you don't get the information from each one of those suppliers along the way, then everybody is reinventing the wheel when they get to their part of the process. So what we are talking about here in a global outsourced environment is that some of these folks that need to participate might not even work for you. If they work for a third party, you need to make sure they are available and contractually obligated to collaborate with somebody downstream from perhaps a different outsourcer who does something else or maybe their direct competitor.

PDA Letter: Sounds like this can get very complicated.

Dan: It could, and it is going to get more complicated as time goes on, because we are talking about globalization and outsourcing and the combination of the two. And each company might do it slightly differently. What we are suggesting here is, get everybody together, figure out not just within your company but across the industry and figure out for these particular products, excipients, what is important to us.

PDA Letter: Dan, I appreciate the time you spent with us today. Thanks so much.

Questions for Dan can be sent to dmatlis@axendia.com. To request a copy of report, *Achieving Global Supply Chain Visibility, Control and Collaboration in Life Sciences,* visit www.axendia.com/2010_LS_GSC.html.

About the Expert

Daniel R. Matlis is Founder and President of Axendia, which works with life-science and healthcare executives on business, technology and regulatory issues. He is also the chief contributor and editor of Life Science Panorama, and is a frequent lecturer at industry events and has published numerous articles on key issues facing the Life Sciences and Healthcare industries.

Dan has over 20 years of experience in the Industry. He began his career at Johnson & Johnson where he provided leadership in the areas of technology, compliance and business. Dan managed the development and implementation of automation and technology systems. Most recently, he was General Manager and Vice-President at Stelex.

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IPEC Contributions Mitigate Risk in Excipient Supply Chain

IPEC-Americas GMP Committee Vice-Chair Juanita Garofalo, Avantor™ Performance Materials

The supply chain for drug components has become an area of strong focus for drug manufacturers and regulators around the world in recent years, due to several unfortunate events that affected the health of hundreds of patients around the world. These events revealed once more that patient safety cannot only depend on the drug itself and its manufacturing conditions, but on each step of the supply chain, from the starting material to the end-user.

The supply chain of an excipient is generally considered to start with the suppliers of the raw materials that will be used to produce the excipient. Next manufacture of the excipient may require one or more additional processing steps, such as milling or micronization, that may be performed by separate entities from the original manufacturer. The excipient will be sold to one or more distributors, who will then deliver the excipient to the drug manufacturer.

A deep knowledge of the suppliers and distributors that carry the excipient along the supply chain is of paramount importance to ensuring the safety of the final excipient to be used in the drug product. Visits to the plant sites where the excipient is manufactured or handled, and reviews of their quality systems and documentation utilized to identify the product, such as certificates of analysis and labels, need to be considered. Back in 2008, although auditing of the heparin manufacturer in China took place, it lacked sufficient detail to uncover the underlying risk of product contamination that occurred.

IPEC Americas works on different fronts to develop tools for auditing different parties associated with the excipient supply chain and provide guidance in the area of excipient pedigree.

Auditing Tools

During the April 2010 *PDA/FDA Pharmaceutical Supply Chain Workshop,* the U.S. FDA made very clear to the drug manufacturing industry the importance of knowing their suppliers thoroughly and the need to perform physical audits of manufacturers and distributors in addition to paper audits.

In January of 2011, IPEC published *Good Distribution Practices Audit Guide for North American Distribution of Pharmaceutical Excipients.* This guide offers a framework for the auditing entity to develop an audit checklist depending on the type of activity that the target of the audit performs. In addition, the guide provides questions related to Good Manufacturing Practices that are applicable to those distributors performing manufacturing activities, such as repackaging. In these cases, the questions address procedures related to receiving and handling, retaining samples, labeling and other activities where there is a risk of contamination or mishandling of the excipient.

A deep knowledge of the suppliers and distributors that carry the excipient along the supply chain is of paramount importance

While these guides can help a company hone its auditing practices, the resources required to perform these periodic audits are in many cases not adequate due to the large number of suppliers and distributors for active pharmaceutical ingredients and excipients with which each company conducts business. Third-party auditing may be an option. An example of a third-party auditing resource is IPEA, which is an independent subsidiary of IPEC-Americas, and provides third-party audits of excipient manufacturers using IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and USP chapter <1078>.

Pedigrees

In addition to the auditing, documentation is another aspect that is necessary to help mitigate the risks like contamination and economically motivated adulteration of the excipient in the supply chain.

Part of the responsibility that FDA has emphasized to the pharmaceutical industry is the need of an excipient pedigree or system that allows verifying the completeness and validity of the data being transferred each time an excipient moves from link-to-link in the supply chain. The excipient pedigree does not have to be a separate system. Companies can use their current operational and/or quality systems to draw on the data required by the pedigree system.

In 2008, IPEC issued a position paper "to describe a process and its elements to establish the pedigree of an excipient with a high degree of confidence using existing documentation to the greatest extent possible."**(1)** The position paper included the expectations and documentation for each of the main players in the supply chain: manufacturer, distributor and end-user. Documentation, such as Certificate of Analysis (COA) and bill of lading with the shipment, for each link is required.

Most importantly, documents such as

the COA need to be verified on a periodic basis for authenticity. IPEC worked during 2010 to update its Certificate of Analysis Guide and reinforced some of the elements that the COA should contain, such as the excipient characteristics, test description and source of manufacturing and testing to assure the proper information is included.

Agreements

Establishing strong relationships among the supply chain parties helps them to better understand each other's needs and more effectively manage change. Quality agreements foster understanding of each party's expectations and the systems that are in place to achieve them.

IPEC developed a quality agreement guide and two templates: one for excipient manufacturers and one for distributors. This tool facilitates the task of defining the type of quality responsibilities that need to be part of the agreement to meet the needs of the supplier, distributor and end-user.

One new initiative that IPEC is undertaking is the update of the Excipient Information Package (EIP), initially developed in 2005 to provide guidance to drug manufacturers when qualifying an excipient. Although the package provides information regarding regulatory, quality and site security, drug manufacturers are raising the bar to go deeper into these topics, so more details will be added to the EIP to better comply with the tighter excipient qualification process.

Cooperation and willingness to share information and records is crucial in order to mitigate the risk of long excipient supply chains. As described above, each party plays a significant role in the supply chain and is responsible for the documentation trail that it provides. With manufacturers, distributors and users as members, IPEC is in a unique position to receive input from each of these industry players and develop appropriate tools and guides that help address issues and that strive for strengthening the excipient supply chain with the ultimate goal of assuring patient safety.

IPEC welcomes companies to join and participate in the process. Go to www.ipecamericas.org for more information. Questions about article can be sent to juanita.garofalo@avantormaterials.com.

References

1. TriPEC Excipient Pedigree Position Paper, 2008, ipecamericas.org/content/excipient-pedigree-white-paper

About the Author

Juanita Garofalo is the Director of Regulatory Affairs for Avantor Performance Materials. Part of her duties include managing the Supplier Quality Program. She has worked for Avantor for 18 years. For the last four years she has been involved in several IPEC committees.

Multi-Pronged Strategy Needed to Combat Counterfeiters continued from page 25

I am convinced that, by developing simple, robust, sustainable solutions in a collaborative manner, we will fortify our defenses, make it more difficult for unethical players and criminals to succeed and better serve patients.

History will be our judge and in the words of Horace Mann, "Let us not be content to wait and see what will happen, but give us the determination to make the right things happen." Questions about the article can be sent to mvantrie@amgen.com.

References

1. Roger Bate, *Fake Drugs: Causes, Consequences, and Possible Solutions,* Speech at American Enterprise Institute, March 3, 2010, www.aei.org/speech/100125

About the Author

Martin Van Trieste is the Sr. VP of Quality at Amgen, member of the PDA Board of Directors, and Co-Founder, Past Chair and member of Rx-360 Board of Directors. Prior to joining Amgen, he was with Bayer HealthCare's Biological Products Division as the VP of Worldwide Quality and Abbott Laboratories as the VP of Quality Assurance for the Hospital Products Division (now known as Hospira).

New Product Tracking Systems Soon Required

Emily Hough, PDA

Working to ensure that safe and effective drugs are available to consumers, industry and regulators are looking to authenticate and identify achievable features of a track and trace system.

Doug Bailey and **Bob Celeste** spoke at PDA's *2011 Pharmaceutical Cold Chain Management Conference* about efforts in the United States and by the standards-setting organization GS1 to encourage the use of global standard product characterization and identify codes.

Celeste, Director of Healthcare, GS1 US, told audience members that his organization has been working with the healthcare community to universally adopt standardized identifiers for products, locations, returnable assets, etc., through Global Trade Item Numbers (GTIN) and Global Location Numbers (GLN). Celeste said these numbers will be "very helpful" and allow for a more efficient supply chain and tracking area.

"The regulators have said they would like to walk into someone's facility, pick up a bottle and have you explain where that bottle has been in its lifetime. That would be nice if we could chuck bottles onto trucks as we drove them around and delivered bottles by themselves, but in order to do that, we would need to track the things that the bottles have been in," he said. In a repackaging operation, where bottles are emptied, individual pills would have to be tracked almost through the whole operation. As they go into the hoppers, for instance, they would need to be associated with the bottles that went in and the bottles that came out."

Recently in the United States, there has been a lot of activity towards implementing standardized identifiers. In September 2007, Congressional passage of the Food and Drug Administration Amendments Act required the Secretary of Health and Human Services "to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded or expired drugs." **(1)** In September 2008, the state of California passed a track and trace statue to "protect consumers from counterfeit, diverted or adulterated drugs."**(2)**

The Californian State Board of Pharmacy within the Department of Consumer Affairs passed a measure that 50% of all pharmaceuticals in California must be identified with a unique serial number associated with them by 2015. By 2016, the other 50% must be identified. Wholesalers and repackagers must accept and forward products with the e-pedigree by July 1, 2016. Pharmacies and pharmacy warehouses must accept and pass e-pedigrees by July 1, 2017.

In March 2010, the U.S. FDA released the guidance, *Standards for Securing the Drug Supply Chain–Standardized Numerical Identification* (SNI) for Prescription Drug Packages. By addressing serialized National Drug Codes (NDC), provides recommendations for package-level identification. However, the guidance says, "it does not address how to link a repackager SNI to a manufacturer SNI, nor does it address standards for prescription drug SNI at levels other than the package-level."

The FDA believes that by creating a serial number of up to 20 characters with the NDC, the serialized national drug code should be sufficiently robust to support billions of units of marketed products without duplication. This, it feels, will "allow manufacturers and repackagers to

assign serial numbers to combine with the NDC for unique identification of individual product packages. The SNI can also be linked to databases containing product attributes like lot or batch number, expiration date, distribution/transaction history information, and other identifier related to a product."

In February 2011, the FDA held a two-day workshop on track and trace attributes for the drug supply chain. Areas of interoperability, authentication of the life of the product through the supply chain and through a data management perspective were reviewed. The meeting

A serialized NDC is composed of the NDC that corresponds to a specific drug product (including the particular package configuration) combined with a unique serial number, generated by the manufacturer or repackager for each individual package

was a follow-up to a 2008 conference where officials asked some questions around tracking and tracing of pharmaceuticals in the US supply chain.

In the United States, healthcare facilities and third-party audit organizations are asking pharmaceutical manufacturers to place global trade numbers and specific location numbers on vials, and hospitals are asking them to be identified in con-

tracts and in transactions by one number. According to Celeste, this is not a big issue for pharmaceuticals, as NDC's already are placed on bottles, but it is an issue for medical devices because a lot of items are identified by a part number and not a standardized number.

In 2012, hospitals are asking that healthcare products be identified using GTIN, used in business transactions, marked on appropriate packaging levels, and are scanned at points-of-delivery within the clinical areas.

To prepare for serialization and visibility within the US pharmaceutical supply chain, GS1 has formed a strategic leadership team with people from different areas of the supply chain and has started a program for 2015 readiness by developing toolkits and other educational and marketing collateral to engage companies in pilot frameworks. According to Celeste, this affects about 35,000 manufactures, 22,000 pharmacies, 7,500 hospitals and "a couple thousand wholesalers." Celeste said that his company hopes to publish a framework by the middle of the second quarter this year and to have a broad understanding of how the supply chain works.

Bailey, Chief Information Officer, USDA, AMS, spoke about solutions the US International Trade Data Systems (ITDS) Product Information Committee has come up with a way to deal with incoming product imports so government agencies can do their job more efficiently.

"We have a great opportunity to use electronic commerce data and global standards and business data to accomplish a breakthrough," he said. "First, industry is already using these standards for logistics management. Second, a global product identity number allows us to uniquely identify a single product from all others in the supply chain. Finally, it doesn't take special technology; these standards are in common use today."

We have a great opportunity to use electronic commerce data and global standards and business data to accomplish a breakthrough

The ITDS is looking to complete work on three existing product pilots and issue a business case report on their results, collaborate on new future pilot with interested parties, and support a phased approach to implementation. Through their efforts, importers and governments can use these global standards to save money, and move products through points of entry more quickly, while improving the effectiveness of the government admissions process.

Bailey described how GTINs can help make the product admission process at the borders more efficient and secure.

If an FDA official is responsible for shipments at the border, and the first shipment of ten different products enters the checkpoint, each identified by a GTIN, the official doesn't have the resources to look at all of them, but can check three of them. After looking at them, he knows that those three are okay and can be admitted all the time. The rest of the products pass through or don't pass through on the best judgment of the official.

A few days later, the same load comes in again. Now, the official remembers what he did for the first three, so he knows with confidence that those are admissible. So, he moves on to the next three. Now six products have been verified. Five days later, the same load comes in again. He now knows over 50% of the shipment is admissible. "There is no guessing, no wondering about what exact product it was or if it should have been looked at more closely because the global product identification number says that you previous admission decision can be reused with confidence."

Bailey said that if officials look up the GTIN and data indicates it is a low-risk product, the government can release it without inspection, if they choose. But if it appears to be a high-risk product, inspections can take place.

Reasons to Use Global Identifiers, According to Bailey

1. The identifiers would allow for globally unique product identification
2. Product can be identified in each entry line. That would tell what company is behind the product and the product model that is moving in the supply chain
3. Context, such as risk profiles, can be added to the products by adding global classification codes

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1. Standards for Securing the Drug Supply Chain–Standardized Numerical Identification for Prescription Drug Packages, U.S. FDA, www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm
2. California Board of Pharmacy, The Script, February 2009, www.pharmacy.ca.gov/publications/09_feb_script.pdf

About the Authors

Bob Celeste is a Director of GS1 Healthcare US. He has more than 25 years of experience in business process and supply chain management in the healthcare, pharmaceutical and a variety of other industries. GS1 Healthcare US focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry to improve patient safety and supply chain efficiency.

Douglas C. Bailey serves as the Chief Information Officer for the Agricultural Marketing Service, an agency of the United States Department of Agriculture. He provides technology services and guidance to all agency business units including grading programs for beef, poultry, and fruits and vegetables; market news services for agricultural producers; and commodity purchase programs for school lunch and international feeding programs.

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.

North America

Agency Postmarketing Guidance Available

A guidance on Postmarketing Studies and Clinical Trials that focuses on the implementation of section 505(o)(3) of the Federal Food, Drug and Cosmetic Act is now available.

The guidance, *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act,* provides information on implementation of the new requirements for certain postmarketing studies and clinical trials for prescription drugs approved under the FD and C Act and biological products approved under the Public Health Service Act. It also provides a description of the types of postmarketing studies and clinical trials that will generally be required under the new legislation.

Guidance Available on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products

An Agency guidance on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products is now available.

The guidance encourages manufacturers of medically necessary drug products and components to develop production plans in the event of an emergency that results in high absenteeism at one or more production facilities. The purpose of the guidance is to provide to industry considerations for developing plans for those types of emergencies, as well as to discuss CDER's intended approach to assist in avoiding drug product shortages that may have a negative impact on the national public health during such emergencies.

Collection of Information Available for Sponsors of NDAs/ANDAs

A proposed collection of information is available relating to the requirements imposed on sponsors, by the regulations under part 21 CFR Part 314, who apply for approval of an NDA or ANDA in order to market or continue to market a drug.

Comments should be submitted by May 13.

Non-Penicillin Beta-Lactam Risk Assessment Draft Guidance Available for Comment

A draft guidance on Non-Penicillin Beta-Lactam Risk Assessment is now available.

The draft guidance describes the importance of implementing appropriate steps during the manufacturing process to prevent cross-contamination of finished pharmaceuticals and active pharmaceutical ingredients with non-penicillin beta-lactam antibiotics. It is intended to assist manufacturers in assessing whether separate facilities should be used based on the relative health risk of cross-reactivity.

Comments on the draft guidance should be submitted by May 16.

ICH Preparation Meeting to Be Held May 19

A public meeting for the preparation of the ICH Steering Committee and Expert Working Group Meetings in Cincinnati, Ohio will be held May 19 from 2 p.m. to 4 p.m. at Hilton Washington DC/Rockville Hotel & Executive Meeting Center. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings scheduled on June 11-17.

Agency Soliciting Comments on NDA Holder Requirements

The U.S. FDA is soliciting comments about the requirements for an NDA holder to notify the Agency if an authorized generic drug is marketed by clearly including this information in an easily accessible place in an annual report and by sending a copy of the relevant portion of the annual report to a central contact point in the Agency.

Comments on this information collection should be submitted by June 13.

Key Regulatory Dates

Comments Due:

May 13 — Collection of Information Available for Sponsors of NDAs/ANDAs

May 16 — Non-Penicillin Beta-Lactam Risk Assessment Draft Guidance Available for Comment

May 19 — ICH Preparation Meeting

June 13 — Agency Soliciting Comments on NDA Holder Requirements

July 12 — Safety Labeling Changes Draft Guidance Available

Safety Labeling Changes Draft Guidance Available

A U.S. FDA draft guidance is available on safety labeling changes. The draft guidance, Safety Labeling Changes – Implementation of Section 505(o)(4) of the Federal Food, Drug and Cosmetic Act, includes a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how the Agency plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes.

Comments should be submitted by July 12.

Asia-Pacific

Agency to Monitor Pharmaceuticals Made in Japan for Elevated Radiation Levels

The U.S. FDA has announced that it will monitor any pharmaceuticals made in Japan for any signs of elevated radiation levels, though Japanese pharmaceuticals make up only a small fraction of prescription drugs imported into the United States.

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Engage in Analytical Method Development and Validation Dialogue

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Committee member Sue Schniepp, OSO BioPharmaceuticals Manufacturing

PDA is pleased to host the *2011 Analytical Methods Development & Validation Workshop* on June 20-21 at the Hyatt Regency in Bethesda, Md. The purpose of this workshop is to offer conference attendees an in-depth view from the beginning to the end of analytical method development and validation. The conference will begin with a plenary session that will discuss and educate the audience on the various stages of the analytical methods lifecycle using the guidance developed by the PDA Analytical Task Force as a basis for the presentations.

The workshop will feature a variety of industry speakers knowledgeable on the details of method development and validations. Featured speakers include:

- **Gregory Martin,** PhD, Vice Chair, USP General Chapters Expert Committee
- **Stephan Krause,** PhD, Principal Scientist, MedImmune and author of *Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies* and chair of the workshop planning committee
- **Rajesh Gupta,** PhD, Deputy Director, Division of Product Quality, CBER, U.S. FDA

The workshop will also feature some of the foremost scientists from leading pharmaceutical companies including Merck, MedImmune, Sanofi-Pasteur and Genentech who will speak on the various aspects involved in method development and validation including robustness and design of experiments, method selection process, applying the principle of QbD to analytical methods, and method qualification.

Each one of the main topics will be followed with a case study demonstrating the practical application of the theory presented.

The workshop will end with a presentation, titled, "A Case Study Illustrating the Complete Bioassay Lifecycle" given by **Jonathan Zmuda,** PhD, Scientist II, Analytical Biochemistry, MedImmune. After this case study, participants will be able to interact with the workshop speakers in a unique hour-long "Ask the Experts Panel Discussion."

If your job is to develop, validate, verify or just understand the details of analytical methods and how they apply to the product lifecycle, you need to come to this workshop to hear the most up-to-date discussions and case studies from a renowned panel of experts who are shaping the way in which analytical methods are viewed. Visit www.pda.org/analyticalmethods2011 for more information or to register.

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PDA 2011 Analytical Methods Development and Validation Workshop will bring together all levels of industry professionals to network and benefit from a program that will provide an update on recent regulatory expectations when developing and validating analytical methods. The workshop will provide participants with a comprehensive review of the laboratory and documentation standards expected during the development, qualification, and validation of analytical methods. Case studies will also be discussed.

Here's a look at highlighted sessions and speakers:

- **The Methods Life Cycle – The Overview**
  - Mapping Out the Development and Qualification, **Earl Zablackis**, PhD, Director Analytical Processes and Technology, *Sanofi Pasteur*
  - Mapping Out the Validation Process, **Stephan Krause**, PhD, Principal Scientist, Development, *MedImmune, LLC.*
- **Method Development: Robustness and D.O.E**
  - Method Selection Process, **Philip Ramsey**, Director, QC/AD, *SAIC-Frederick, Inc.*
- **Method Development: Applying Principles of QbD for Analytical Methods**
  - Principles of a QbD, **Anu Bansal**, Senior Scientist, Analytical Development, *Genentech, Inc.*
- **Qualifications and Compendial Methods Verifications**
  - Method Qualification Process and Models, **Melissa Smith**, Senior Consultant, Quality and Analytical, *MJ Quality Solutions*
  - USP Visions of Verification of Compendial Methods: USP ‹1226›, **Gregory Martin**, Vice Chair, USP General Chapters Expert Committee, *U.S. Pharmacopeia*
- **Reference Standards and Method Transfers**
  - Analytical Reference Standard Lifecycle: Modern Preparation Technology, **Dorian Zoumplis**, Associate Scientist II, Development, *MedImmune, LLC.*
- **Method Validation: Validation Strategies and Acceptance Criteria**
  - Regulatory Expectations for Method Life Cycle and Validation, **Rajesh Gupta**, PhD, Deputy Director of the Division of Product Quality, CBER, *FDA*
- **Post-Qualification and Post-Validation Activities**
  - Maintenance of Qualification Status, **Dwayne Neal**, Assay Validation Manager, Quality Control, VRC/VPP, *SAIC-Frederick, Inc.*
  - Replacement of Old Assay with New Ones for Legacy Products, **Robert D. Sitrin**, PhD, Executive Director, VMSC-Bioanalytics, Merck Manufacturing Division, *Merck Sharp and Dohme Corporation*
- **Complete Life Cycle Case Study**
  - Analytical Methods Development & Validation – A Case Study Illustrating the Complete Bioassay Lifecycle, **Jonathan Zmuda**, PhD, Scientist II, Development, *MedImmune, LLC.*

www.pda.org/analyticalmethods2011

CONFERENCE June 20-21 **EXHIBITION** June 20-21

Learn Best Practices at Supply Chain Conference

Bethesda, Md. • June 6-8 • www.pda.org/supplychain2011

Committee member Londa Ritchey, Pfizer

Counterfeiting, product diversion and economic adulteration are on the rise. We are all aware that these illicit acts can occur at any point in the extended pharmaceutical supply chain. The weakest link is where the perpetrators focus. It is time to stop considering each part of the supply chain as an independent function and instead take a holistic end-to-end product integrity approach. Functional organizations, regulatory agencies and industry must band together in an open and collaborative manner for the sake of patient safety.

The *2011 PDA/FDA Pharmaceutical Supply Chain Conference & TRI Course,* offers presentations and plenary sessions demonstrating the necessity and value of collaboration in an end-to-end approach to product integrity. This conference offers examples and potential solutions from subject matter experts representing material suppliers, pharma industry and regulators. Solutions and discussions relate to big and small, branded and generic pharma and material suppliers alike.

This end-to-end supply chain security conference includes topics which will appeal to all functions associated with product integrity, including, but not limited to:

Security	**Quality**
Logistics	**Business Development**
Packaging Technology	**External Supply**
Procurement	**Supplier Management**

Professionals in all areas impacting product integrity should attend. Function- specific learning sessions allow professionals responsible for different areas of the supply chain to acquire information on best practices and potential solutions for immediate use. Plenary sessions increase awareness on where the regulations are headed and how companies are taking the comprehensive approach to product integrity. Whether it is a need to better understand the best practices within your functional area, or a need to better understand how your function fits into the overall plan for product integrity, this conference will meet your needs.

PDA's Training and Research Institute will offer a training course, entitled, "Developing a Robust Supplier Management Process." Taught by **Lisa Hornback,** Hornback Consulting, this workshop will discuss best methods for determining appropriate level of control for suppliers based on risk and developing assessment methods and continuous monitoring tools. Through discussion of best practices and current regulatory expectations, participants will develop a better understanding of supplier selection, evaluation and monitoring processes. Course participants will receive examples of assessment tools which will assist them in applying the concepts learned within their own company's supplier management process.

Visual Inspection Forum to Focus on Inspection Requirements

Bethesda, Md. • October 3-6 • www.pda.org/visual2011

Forum co-chairs John Shabushnig, PhD, Pfizer and Markus Lankers, PhD, rap.ID GmbH

Visual inspection continues to be an important element of the manufacturing process and the quality assurance of injectable products. Product inspection provides necessary information for lot release and coupled with defect identification contributes to a strategy of continuous process improvement.

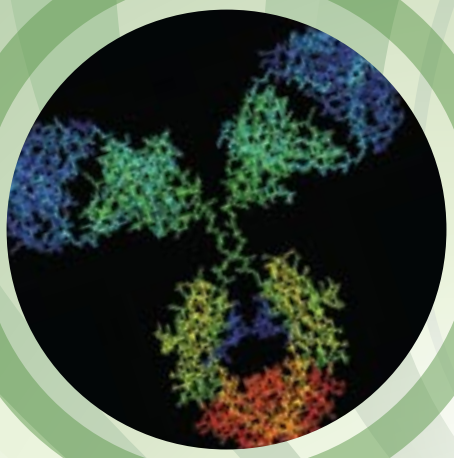
Since 2000, PDA has organized the Visual Inspection Forum to discuss new technical and regulatory developments in this field. It has grown into the leading event for those working in visual inspection.

This meeting alternates between the United States and Europe; this year's *2011 PDA Visual Inspection Forum & Training Course* will be held October 3-6 in Bethesda, Md. The meeting will provide a forum to discuss new developments in the field of visual inspection, including:

- Contributions to a basic understanding of the sampling and inspection process
- Practical aspects of manual and automated methods
- Leak detection
- Critical container and closure quality attributes
- Regulatory and compendial requirements that govern the inspection process

A special focus of this conference will be the unique inspection requirements of biopharmaceuticals.

This is an excellent opportunity to learn more about visual inspection and to discuss inspection challenges with the experts. A further goal of this conference is to build a network of experts and interested professionals working in this important and specialized field. For this purpose, we have scheduled time for both



Register by 8 April 2011 and SAVE!

4th PDA Europe Workshop + Exhibition on

Monoclonal Antibodies

Life Cycle Management – CMC and Regulatory Considerations for Monoclonal Antibodies and Related Products

WORKSHOP, EXHIBITION

https://europe.pda.org/Monoclonal2011

7-8 June 2011

Basel, Switzerland

a formal and informal panel discussion.

As in past years, the meeting will feature an exhibition where attendees can see the latest in commercial inspection hardware and discuss production needs with key suppliers of inspection systems and services.

An optional two-day training course offered through PDA's Training and Research Institute will be held immediately following the Visual Inspection Forum on October 5-6 at the PDA TRI, located a short walk from the conference hotel. The course, "An Introduction to Visual Inspection," covers the basics of visual inspection, establishing and managing a visual inspection program, and qualification and validation of inspection processes as applied to injectable products. It will be a combination of lecture/discussion and hands-on laboratory exercises used to develop and practice practical inspection skills. The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

This is an excellent opportunity to learn more about visual inspection and to discuss inspection challenges with the experts

For more information on the Visual Inspection Forum and related TRI course, visit www.pda.org/visual2011. We look forward to seeing you at this exciting and informative meeting.

The Parenteral Drug Association presents the...

2011

PDA/FDA Joint Regulatory Conference & TRI Courses

Quality and Compliance in Today's Regulatory Enforcement Environment

September 19-23, 2011

Renaissance Hotel | Washington, D.C.

The *2011 PDA/FDA Joint Regulatory Conference & TRI Courses* offers the unique opportunity for you to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on the current state of efforts impacting the development of global regulatory strategies; while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

PDA is also offering an exhibition during the conference and a post conference workshop on Combination Products. The PDA Training and Research Institute (PDA TRI) will host seven courses immediately following the conference, September 22-23, to complement what you learn at this meeting.

PDA TRI courses include:

- Active Pharmaceutical Ingredients - Manufacture & Validation
- Documenting and Conducting OOS Investigations
- Effective Investigations and Corrective Actions
- GMPs for Manufacturers of Sterile and/or Biotechnology Products
- Preparing for Regulatory Inspections for the FDA and EMA
- Role of the Quality Professional in the 21st Century
- Quality by Design for Biopharmaceuticals: Concepts and Implementation

Advanced Notification
Sign up to receive an email notice when more information is available about this event!
www.pda.org/pdafda2011

CONFERENCE September 19-23 **EXHIBITION** September 19-20
COMBINATION PRODUCTS WORKSHOP September 21-22 **COURSES** September 22-23

www.pda.org/pdafda2011

Challenges Facing Pharma. Microbiology in the 21st Century

Bethesda, Md. • October 17-21 • www.pda.org/2011microbiology

Program Co-Chairs Lynne Ensor, PhD, U.S. FDA and Edward Tidswell, PhD, Baxter Healthcare

The program planning committee would like to invite you to attend *PDA's 6th Annual Global Conference on Pharmaceutical Microbiology & TRI Courses* in Bethesda, Md. The theme of this year's meeting is "Challenges Facing Pharmaceutical Microbiology in the 21st Century." This conference will offer an excellent opportunity to meet and interact with your fellow microbiologists, regulatory representatives, key product vendors and other global leaders in pharmaceutical microbiology from October 17-21.

- New technologies
- Microbiology and combination products
- Challenges and case studies in cleaning validation
- Container closure integrity
- Product and labeling attributes impacting sterility assurance
- Updates from the United States Pharmacopeia

The popular Urban Myths session will also return.

This conference will offer an excellent opportunity to meet and interact with global leaders in pharmaceutical microbiology

The conference will feature two keynote addresses. **Daniel Fung,** PhD, Professor, Food Science, Kansas State University, has been invited to speak on "Global Developments of Rapid Methods and Automation in Microbiology: A Thirty Year Review and Predictions into the Future." This talk should be of interest to anyone who currently utilizes or is considering the utilization of rapid methods for microbial detection. Our second speaker is **Dennis Guilfoyle,** PhD, Pharmaceutical Microbiologist, U.S. Food and Drug Administration, who has been invited to speak on "Challenges Facing Pharmaceutical Microbiologists to Define and Control Objectionable Microbes."

Other planned sessions include discussions on:

- Developing a meaningful environmental monitoring program for sterile ans non-sterile manufacturing, impact of objectionable organisms on the industry and patient safety

New panel discussions include "Ask the Regulators" and "The Microbiologist of the Future–Junior Industry Panel Discussion." Additional podium presentations and posters will be selected from submitted abstracts.

The PDA Training and Research Institute will also host four training courses from three industry experts from October 20-21. Courses include:

"Environmental Control and Monitoring for Regulatory Compliance" and "Auditing for Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing" by **Frank Kohn,** PhD, President, FSK Associates.

In "Environmental Control and Monitoring for Regulatory Compliance," he will teach students about facility design and validation, including personnel flow, equipment flow, baseline monitoring, media fills and quality control. The tracking and trending of the data will be reviewed, and a focus on the "best industry practices" to employ when performing environmental monitoring. Also, U.S. FDA and international standards related to microbiological issues will be covered with an emphasis on how to avoid quality problems.

In "Auditing for Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing," Kohn will focus on the various techniques, tools and methods for auditing manufacturing operations from a microbiological viewpoint. Current FDA and international boards of health GMP regulations will be reviewed.

"Microbiological Issues in Non-Sterile Manufacturing," will discuss various issues in non-sterile manufacturing including setting of specifications, process development, holding times, preservation, cleaning, sanitization and approaches to evaluating recovered organisms.

"Rapid Microbiological Methods: Overview of Technologies, Validation Strategies, Regulatory Opportunity and Return on Investment," taught by **Michael J. Miller,** PhD, President, Microbiology Consultants, will provide a comprehensive review of currently available RMM technologies, validation strategies, applications, regulatory expectations, financial justification models and implementation plans. Taught by one of the industry's leaders in rapid methods, attendees will be immersed in discussions that will provide a meaningful and understandable roadmap for how to evaluate RMMs and employ them in laboratory and manufacturing environments.

For information about the meeting, courses and how to register, visit www.pda.org/microbiology2011.

Highlights from PDA's 2011 European Microbiology Conference

Michael Miller, *PhD, President, Microbiology Consultants, manages a website on one of his areas of expertise—**rapidmicromethods.com.** As part of the site, Dr. Miller blogs about various topics of interest. This year, he covered PDA's 2011 Europe Conference on Pharmaceutical Microbiology/Mycoplasma and has graciously shared some of his posts for the* PDA Letter.

The recent PDA Europe conference on pharmaceutical microbiology was a tremendous success, with presentations ranging from Mycoplasma, statistical process control, viral safety testing, microbial data deviations and rapid microbiological methods (RMM).

Emmanuelle Charton, PhD, Deputy Head, EDQM, provided an overview of the history and objectives of Chapter 5.1.6 as well as other chapters within the Ph. Eur. that encourages the use of rapid or alternative microbiological methods. For example, Ph. Eur. 2.6.12 and 2.6.13 states that alternative microbiological procedures, including automated methods, may be used, provided that their equivalence to the pharmacopoeia method has been demonstrated. Chapter 2.6.7 states that nucleic acid amplification techniques may be used as an alternative to one or both of the other Mycoplasma methods after suitable validation. Chapter 2.6.27, Microbiological control of cellular products, also allows the procedure to be carried out manually or using an automated system.

Next, **Hans van Doorne,** Assistant Professor, Dept. Of Pharmaceutical Technology, University of Groningen, provided preliminary results from a questionnaire that was sent to the industry and to European Licensing Authorities (via National Pharmaceutical Authorities) with respect to the existing Chapter 5.1.6. The questionnaire asked if the current chapter is appropriate and whether a revision is necessary. Because the enquiry is ongoing, the European Pharmacopoeia Working Party Modern Microbiological Methods) has not finalized any decisions, and the Ph. Eur. Commission has not discussed the results, only preliminary information was provided during this presentation.

The following are some of the discussion points that were included in the questionnaire:

Which compendial and non-batch release methods have been replaced by alternative/rapid methods?

Response: RMMs are currently used in place of the compendial tests for sterility (2.6.1), microbial enumeration (2.6.12), specified microorganisms (2.6.13), Mycoplasma (2.6.7) and the standardization of suspensions. RMMs are also used for purposes other than batch release, including in-process control, real time release of pre-filtration bioburden, environmental monitoring, trouble shooting, microbial identification, antimicrobial assays and WFI testing.

What do you consider as the strengths of the chapter?

Response: In general, the chapter applies to any new method not described in the pharmacopoeia, it is easily understandable and applicable, and it provides a road map for approval of rapid methods in the EU.

What do you consider the weaknesses of the chapter?

Response: There is no global harmonization with other published documents (USP 1223 and PDA TR#33). It is also too prescriptive, and microbial identification methods should be separated from true rapid methods. There were also questions raised about the equivalence between the chapter and EN ISO methods.

Next, **Riccardo Luigetti,** PhD, Scientific Administrator, Compliance & Inspection, EMA, provided an overview of the EMA's current perspectives on RMMs. Ph. Eur. chapter 5.1.6, Alternative methods for control of microbiological quality, provides the regulatory basis for the introduction of RMMs in the EU. Not only do the various EU competent authorities support RMMs, but some of the elements of the new variations regulations (implemented in January 2010) can be used to support the introduction of RMMs.

Historically, RMM validation protocols and their associated data were submitted under a Type Variation (e.g., Type 2) and the competent authorities reviewed all of this information as a whole. However, a very recent change to the management of RMM reviews has just been introduced, which should make the validation and approval process much more predictable. The new process, which is very similar to FDA's comparability protocol, is called the Post Approval Change Management Protocol (PACMP). In this two-step process, a testing protocol is first submitted as a Type 2 Variation, and when the protocol is approved, the testing is executed as specified in the protocol. The second step of the PACMP process involves submitting the resulting data as either a Type 1A or 1B Variation. The introduction of the PACMP is a welcomed addition to the EMA's other recent policy changes, and will greatly simplify the validation and implementation of RMMs within the EU.

Finally, I presented industry perceptions that have prevented or delayed many companies from validating and implementing RMMs. Some of these perceptions include (a) little or no regulatory guidance, acceptance or understanding of RMMs, (b) we will see things we have never seen before and our products will be at risk, (c) we will have to change our acceptance levels or specifications, (d) there is no clear guidance on validation expectations, and (e) we will realize little or no return on investment. Each of these perceptions were thoroughly discussed and dismissed, and I provided guidance on how the current worldwide regulatory framework actually encourages the qualification and implementation of RMMs.

Next year's conference is already being planned and promises to be as exciting as this year's.

Emmanuelle and I will be co-chairing the 2012 meeting, and we both invite you to join us again in Europe!

SAVE THE DATE

Pharmaceutical Quality Systems (ICH Q10) Conference

A Practical Approach to Effective Lifecycle Implementation of Systems and Processes for Pharmaceutical Manufacturing

Co-sponsored by FDA and Supported by EMA

October 4-6, 2011

Crystal City, Virginia USA

PDA Parenteral Drug Association

ISPE Connecting a World of Pharmaceutical Knowledge

TRI to Offer Four Lecture Courses Over the Summer

Stephanie Ko, PDA

This summer, TRI will offer four lecture courses in supplier management, biotechnology, technology transfer and risk management.

The first course, "Developing a Robust Supplier Management Process," will be held June 8. Held after the *2011 PDA/FDA Pharmaceutical Supply Chain Workshop,* this course is a "must attend" as it will help support the industry in strengthening their supplier control program due to the U.S. FDA increasing their scrutiny of the regulated industry and their evaluation and control of suppliers.

Instructor **Lisa Hornback,** Principal Consultant, Hornback Consulting, will teach participants to primary steps, current regulatory expectations and "best practices" in the supplier management process. Participants will be able to reduce the risks associated with supplier management at their company by understanding the use of risk management tools and best methods for determining appropriate level of control for suppliers based on risk, assessment methods and continuous monitoring tools. Students will come back to their company with an action plan to enhance the supplier management process.

Next, a beginner course for individuals seeking a solid foundation and working knowledge of the biotechnology industry will be offered. "Biotechnology: Overview of Principles, Tools, Processes and Products," will take place July 11-12 at PDA's Training and Research Institute (PDA TRI) in Bethesda, Md. Taught by **Antonio Moreira,** PhD, Vice Provost, Academic Affairs, UMBC, who has nearly 30 years of experience in the biotechnology field, participants will be introduced to scientific principles, tools, biopharmaceutical product development, biomanufacturing strategies, and types of products and their applications in medicine.

What makes this course different than others which may be out there is that it links the scientific principles of biotechnology to their application in the field. Participants will learn the basic science within the context of how it's used in the real world. Moreira feels that participants who obtain an integrated understanding of the industry and its practices can better appreciate how what they do contributes to and possibly impacts the outcome of the processes in place in their companies

In July, we are pleased to present our Risk Course Series, consisting of two back-to-back courses, enabling participants to take one or both courses in a single trip. Both courses will be located at PDA TRI.

"A Risk Based Approach to Technology Transfer," will take place on July 25. **Frank Kohn,** PhD, President, FSK Associates, will focus on employing risk analysis and risk mitigation techniques to optimize any technology transfer program. With over 30 years of industrial experience, Kohn will provide information based on practical experiences and research data on the critical risk issues associated with the technology transfer process. Case studies and opportunities to discuss real industry experiences, both failures and successes will be emphasized in this course. In addition, regulatory issues will be discussed in terms of their global implications to companies transferring products from country to country.

On July 26, "Practical Applications of Risk Management," a new course will be taught by **Robert Kieffer,** President, RGK Consulting, who has been using risk management in daily pharmaceutical development, manufacturing and quality systems activities since the early 90's. Kieffer has spent years studying best practices and applying them to ensure against waste, inefficiency and excessive costs; he believes quality and compliance can be obtained at much lower costs than they are today. He also thinks that compliance is necessary but insufficient to meet today's need for quality and cost control, and that the continuous use of risk management when it's embedded in all processes, routine activities, and the culture of the organization, can significantly reduce patient risk, reduce company costs and enhance the quality of process output.

This course will present examples from selected processes such as product development, validation, annual product review, change control, failures and deviations, auditing and inspections, training, and documentation. Also, the obstacles preventing incorporation of risk management into the way people think and act will be discussed.

Be sure to take a look at other training courses scheduled this summer, which includes Lyophilization Week from June 20–24, as well as laboratory courses such as "Basic Microbiology for Aseptic Processes" taking place August 1–5.

If you don't have time to attend this summer's training schedule packed with insightful and informational classes, be sure to check out our website throughout the year for a broad selection of lecture and laboratory courses designed to enhance your professional growth and strengthen your career knowledge.

If you cannot attend a course at TRI's facility, consider in-house training.

For information about any of our courses or to schedule a training, check out www.pdatraining.org.

Parenteral Drug Association Training and Research Institute (PDA TRI)

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals

June 2011

Sterile Pharmaceutical Dosage Forms: Basic Principles
June 1-2, 2011 | Bethesda, Maryland | www.pdatraining.org/sterilepharma

Hosted in conjunction with the *2011 PDA/FDA Pharmaceutical Supply Chain Conference:*
Developing a Robust Supplier Management Process
June 8, 2011 | Bethesda, Maryland | www.pdatraining.org/suppliermanagement

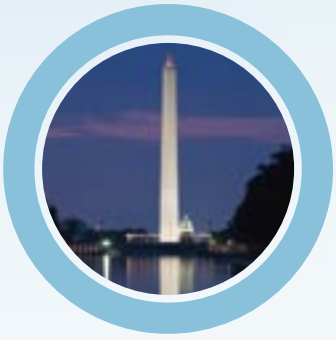
Lyophilization Week (Special pricing applies - call +1 (301) 656-5900, ext. 151 for details)
June 20-24, 2011 | Bethesda, Maryland | www.pdatraining.org/lyophilizationweek
- Fundamentals of Lyophilization (June 20-21)
- Economical Design of Lyophilization Experiments Workshop – *New Course* (June 22)
- Validation of Lyophilization – *New Course* (June 23-24)

Fermentation/Cell Culture Technologies Training Workshop
June 28-30, 2011 | Bethesda, Maryland | www.pdatraining.org/fermentation

July 2011

Biotechnology: Overview of Principles, Tools, Processes and Products
July 11-12, 2011 | Bethesda, Maryland | www.pdatraining.org/biotechnologyoverview

Risk Management Series (Special pricing applies - call +1 (301) 656-5900, ext. 151 for details)
July 25-26, 2011 | Bethesda, Maryland | www.pdatraining.org/riskmanagement
- A Risk Based Approach to Technology Transfer (July 25)
- Practical Applications of Risk Management – *New Course* (June 26)



August 2011

Basic Microbiology for Aseptic Processes
August 1-5, 2011 | Bethesda, Maryland | www.pdatraining.org/basicmicro

2011 Aseptic Processing Training Program - Session 4
August 22-26 (Week 2: September 12-16, 2011) | Bethesda, Maryland
www.pdatraining.org/aseptic

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.pdatraining.org**

Trevor Deeks Shares What It Means to be a QP

Trevor Deeks has had a lot of experience in pharmaceutical manufacturing, formulation development, QA management, process scale-up and validation project management of assignments ranging from small single systems to large aseptic filling, biotech and tableting facilities. He has had a momentous career as a hospital pharmacist, Qualified Person, TRI instructor and Manufacturing Operations and Engineering Senior Director.

PDA Letter: How did you go from working as a hospital pharmacist to teaching a microbiology course?

Trevor: When I was in the hospital pharmacy in the UK, there were a lot of hospitals that had sterile production units, and I was associated with one of those units. My responsibilities, apart from end-product testing, included performing environmental monitoring, and what we then called, "commissioning and temperature mapping of autoclaves." It is now called validation. So that is where I got started, I was in quality control. I then moved into the pharmaceutical industry into formulation development.

PDA Letter: What does it mean to you to be a Qualified Person to these companies? Obviously it is something that bears a lot of responsibility.

Trevor: It's a phenomenal responsibility. To be honest I don't think that it is recognized by companies as highly as it should be. The buck stops with the Qualified Person (QP). Now the U.S. FDA would love to have somebody to pin that on in the United States. In the United States, the buck stops with the site manager or even the CEO of the company. The Qualified Person is the person who is named on the manufacturing license as the person who is responsible for the product that is released to the market. Most companies will have a number of QPs named on the license, because they don't want to rely on just one.

The buck stops with you. If anything goes wrong, it is your decision. When I studied pharmacy we were taught to take personal responsibility for what we did and the decisions we made. I think there is a lack of people who take personal responsibility today. Everything is a corporate decision. Sometimes the decision making process in industry does not lend itself to that. I think that is another part of being a QP, you have the responsibility, but you have to be given the authority as well. If a company tries to undermine that authority, the role of the QP is compromised.

PDA Letter: You must be quite dedicated to teaching. Besides your work with PDA in the classroom, you have authored and peer-reviewed books and many papers.

Trevor: I like to think that if I can't influence things in any other way, I can influence people with what I write. The pen is mightier than the sword.

PDA Letter: How do you measure your impact on the students you try to help?

Trevor: Sometimes I get follow up from my students, not so much for my philosophy. That is nice to have. People come back and ask for advice, because it means that you've had the right kind of impact. If someone comes to you for advice, it means they respect what you've got to say and that can't be a bad thing. I get a lot from being able to impart my knowledge and my opinions and having people recognize and appreciate it.

PDA Letter: How did you become involved with TRI?

Trevor: I used to be involved with the UK Parenteral Society, and I got more and more involved with PDA. [PDA's] **Jim Lyda** got me quite involved with PDA in Europe, and I spoke at a couple of conferences. **Amy Davis** got me interested in writing a book for PDA. I also contributed to two other books. She is the one who got me interested in writing a book on my own.

I think the TRI followed from there. I came across **Gail Sherman** [former TRI VP] when the Parenteral Society was thinking about doing an aseptic processing training course along the lines of a PDA TRI course, and we talked to Gail about that at that time. It wasn't long before Gail asked me to teach.

Trevor Deeks stresses the importance of a QP's responsibilities to his students at TRI

About the Instructor

Trevor Deeks is the Senior Director, Manufacturing Operations and Engineering at Emergent BioSolutions. He has had 30 years of experience in pharmaceutical manufacturing, development, quality assurance and validation, including senior management roles with major pharmaceutical manufacturing companies. He is a Qualified Person and a registered pharmacist. He has published over 30 papers in peer-reviewed journals and has been an active presenter at PDA, ISPE and Pharmaceutical Society conferences. He has sat on PDA, BSI, CEN, ISO and European Pharmacopoeia Commission expert working groups. He is a Past Chairman of the Parenteral Society and was Editor-in-Chief of the European Journal of Parenteral Sciences from 1996-2000.

Below are a sampling of course that he has taught for TRI:

"Risk Management in Pharmaceutical Process Development in Manufacturing"

"Risk Based Approach and Risk Management in the Pharmaceutical Manufacturing Processes"

"Bioprocess Validation"

Call for Papers and Poster Session

Submit your Abstract by 27 May (presentations) or 1 October (posters)

The 2011 Universe of Pre-filled Syringes and Injection Devices

Device Usability and Compliance

7-11 November 2011 | Basel, Switzerland

The **2011 Universe of Pre-filled Syringes and Injection Devices** Program Planning Committee invites you to submit a scientific abstract for presentation at the conference. This conference gives an update on all aspects of the development, production and use of pre-filled syringes and injection devices in a broad range of topics. PDA is seeking scientific abstracts for presentations and for posters. The theme of this year's conference is **Device Usability and Compliance**.

Suggested Topics include but are not limited to:

Factors influencing Selection of Injection Devices

- End user needs: doctors, hospitals and patients
- Human Factors, Patient Compliance, Safety Aspects
- Market trends, patient compliance studies
- Autoinjectors, pen systems, safety devices and add-ons
- Patient selfmanagement
- Electronic enabled delivery systems
- Health economics

Advances in Pre-filled Syringe/Injection Device Technologies

- Novel delivery systems and concepts
- Materials, components, methods
- Safety Devices
- Supplier issues: Quality agreements, logistics, partnerships, cooperations
- Combination products

Development and Manufacturing

- Development, incl. PAT, QbD, Upscaling, Tech Transfer
- Manufacturing technologies: Equipment, machines, IPC tools
- Zero defect challenges
- Aseptic processing, sterilization methods, single use systems
- Packaging, labeling, track and trace issues
- Contract manufacturing best practice
- New trends

Regulatory Trends and Inspection Issues

- New guidances
- Track and Trace
- Container quality/functionality aspects
- ICH guidances: impact on submissions and inspections

Case studies are particularly desired. Commercial abstracts featuring promotion of products and services will not be considered. After 20 June 2011, you will be advised in writing of the status of your abstract. PDA will provide one complimentary registration per podium presentation. Additional presenters are required to pay appropriate conference registration fees. All presenters are responsible for their own travel and lodging, with the exception of health authority speakers.

Please send your abstract and the required information to Ailyn Kandora (PDA Europe) at kandora@pda.org. If you have any questions, please do not hesitate to contact us.

Deadlines

Abstracts for Presentations: **27 May 2011**
Abstracts for Posters: **1 October 2011**

Editor's Message

Fun with Infographics

This is the fifth issue of 2011, and by now, we hope readers have noticed our new designs, particularly on the cover. In this issue, we developed our first "infographic" (see page 22). It is fun working with our publication designer, **Katja Yount,** to add a little visual creativity to each issue. We hope readers enjoy them. If so, there will be more in the future.

While we had some fun with the concept of the supply chain in creating the infographic, naturally, the topic is no joking matter. The four articles in this issue dedicated to the topic provide a number of recommendations that we hope readers find useful. We are happy to highlight the work of other organizations in the effort to ensure high quality, safe pharmaceutical ingredients and products are exchanged in commerce. Rx-360 and IPEC are contributing sound solutions and participate in PDA's efforts to help, so we felt justified in highlighting their work. Of course, PDA's efforts include articles, conferences and task forces writing technical reports, so members have much to look forward to from PDA. This June's *PDA/FDA Pharmaceutical Supply Chain Conference & TRI Course* promises to provide more material for the Letter.

We are always looking for good articles

We also pay tribute to recently deceased **Kirby Farrington.** I had the opportunity to talk with Kirby last year when we interviewed him for his "Eye on TRI" article. He was a good sport and offered us plenty of material to work with. We know he will be missed in our community.

This issue includes another update on the PDA Journal. As PDA's Director of Publishing, I've been involved firsthand in expanding the capabilities of the online Journal since its inception in 2009. The expansion of the online archives by 18 years is a major step toward bringing the entire archive online. Only 33 more years to go before it is complete! We will keep you informed in the Letter.

We recently began placing the final touches on a summary of *PDA Letter* activities in 2010 for the Annual Report that touts the strong member participation in the magazine last year. Indeed, we published a record number of submissions. This year, however, we are set to either meet or break that record, and we are very excited about it! With the expanded Editorial Committee, I expect submissions to continue at a strong rate. In the coming months, readers can look forward to a number of member submissions covering topics like regulatory intelligence, quality near hits, and an analysis of recently sent U.S. FDA warning letters.

We are always looking for good articles, so if you want to contribute, contact me at morris@pda.org. Also, we would love to hear what you think about articles already published. Send your comments to the same email.

PDA Letter

The PDA Letter is published 10 times per year, exclusively for PDA members.

Subscriptions are not available.

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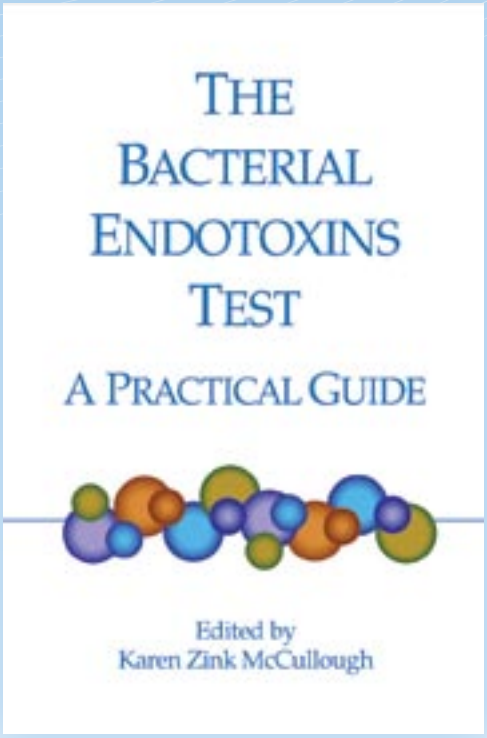
New Release at the PDA Bookstore



The Bacterial Endotoxins Test: A Practical Guide

Edited by Karen Zink McCullough

This unique publication is comprised of a collection of interdependent chapters that are part lab manual, essay, historical context, consultant and plain sage advice that provide a practical and compliant approach to the execution and use of BET.

It will provide you with sensible technological and compliance advice that comes from the contributors' collective experience of over 200 years with BET. You will learn how standard compliance and control measures apply to this seemingly hybrid technology. It offers advice on setting appropriate process action and alert limits, controlling variability, efficient and value-added test methodology, setting limits for non-compendial materials and applying medical device testing strategies to screening of testing accessories and much more.

Lab managers and analysts will find this book indispensable as they view their current processes with a goal of continuous improvement.

www.pda.org/bacterialendotoxins

The PDA Bookstore's April Top 5 Best Sellers

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Edited by Siegfried Schmitt
Item No. 17296
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Edited by Karen Zink McCullough
Item No. 17297
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3 **Environmental Monitoring: A Comprehensive Handbook, Volume I, II, III, IV and Protocol CD**
Edited by Jeanne Moldenhauer
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4 **PDA Technical Report No. 49, Points to Consider for Biotechnology Cleaning Validation**
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PDA Member $150
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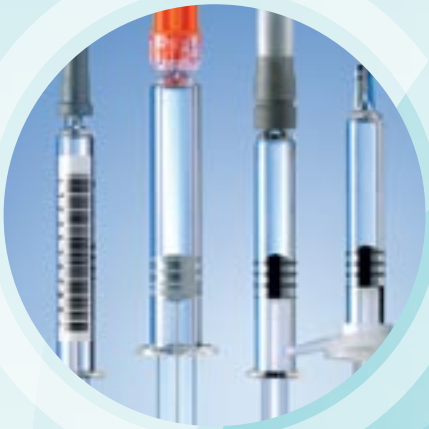

The exhibition will feature leading suppliers available to discuss solutions with attendees!

Recent quality issues related to glass packaging defects and incompatibilities with finished products over the shelf life has resulted in pharmaceutical manufacturers and glass suppliers to recognize that improvements are needed in glass packaging and glass handling practices throughout the product lifecycle.

At the *2011 PDA/FDA Glass Quality Conference & TRI Courses* industry and global regulatory authorities will provide you with an overview of issues that resulted in product recalls, results of an industry survey on glass packaging supplier quality, and global regulatory perspectives and expectations of both the glass supplier and product manufacturer.

Participate in numerous presentations in sessions on Pharmaceutical Glass that include:

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- Supply of Glass
- Glass Supply Control - Best Practices
- Pharmaceutical Packaging in Glass
- Finished Drug Product Inspection
- Distribution/Packaging/ Transportation
- Monitoring Customer Feedback and Other Factors to Consider in Glass Defect Prevention
- What Are We Going to do to Make it Better?

PDA's Training and Research Institute will be hosting two training courses following *2011 PDA/FDA Glass Quality Conference & TRI Courses*. For more information please visit www.pdatraining.org/glasscourses.

www.pda.org/glassquality2011

CONFERENCE May 23-24 | **EXHIBITION** May 23-24 | **COURSES** May 25-26