People • Science • Regulation

PDA Letter

Volume XLVIII • Issue #3 www.pda.org/pdaletter March 2012

Take Control of Your Career

22

2012 PDA ANNUAL MEETING **Show Issue**

Follow the logo to find articles on the *2012 PDA Annual Meeting*

Advanced Notification – Sign up to receive an email when more information is available about this event! Visit www.pda.org/pdafda2012.

The Parenteral Drug Association presents the...

2012 PDA/FDA Joint Regulatory Conference

Compliance through Quality Systems: Implementing & Advancing a Sustainable Global Quality Culture

September 10-12, 2012

Baltimore Marriott Waterfront Hotel | Baltimore, Maryland

Together the Parenteral Drug Association (PDA) and the Food and Drug Administration (FDA) are changing the future of the medical products industry. For the 21st time, these two entities have created a conference that will address the pharmaceutical and medical device industries. The *2012 PDA/FDA Joint Regulatory Conference* will be held September 10-12, 2012 in Baltimore, Maryland.

Join us at this annual, collaborative event designed to share information on important and critical issues that include:

- Best practices that can be learned from peers and implemented by others in the pharmaceutical and devices industry on topics such as communicating the business case for quality, tracking and trending of compliance data, establishing a framework for quality vigilance, etc.
- Establishing and maintaining a state of control throughout the drug product lifecycle
- Challenges with assuring quality and reliability of outsourced functions and purchased materials
- Emerging areas and risk-based approaches that cover decision making theory, combination products, root cause analysis for recalls, manufacturing failure modes, signal detection, etc.
- Understanding how to integrate quality and compliance into the global business platform
- Leveraging results conveyed by peers to drive continuous improvement

Immediately following the conference, the PDA Training and Research Institute (PDA TRI) will be hosting seven stand-alone training courses.

"Cross-cutting topics such as combination products, global supply chain and emerging markets are just a few of the pulse areas for today's industry, where the collaboration of the PDA and FDA are vital in providing a forum for exchange. This conference truly provides something for everyone, regardless of your capacity in the industry."

Winston Brown, *Baxter Healthcare*

Visit **www.pda.org/pdafda2012** for more information.

Exhibition: September 10-11 | Courses: September 13-14

The Parenteral Drug Association presents...

2012 PDA Europe

Advanced Therapy Medicinal Products

Science Translating into Cures

See the Highlights

Cell-based products

- cancer immunotherapies
- stem cell therapies
- tissue engineering

Gene therapy products

- new developments in vector design
- recent clinical experiences with gene therapy products
- safety aspects of GT products

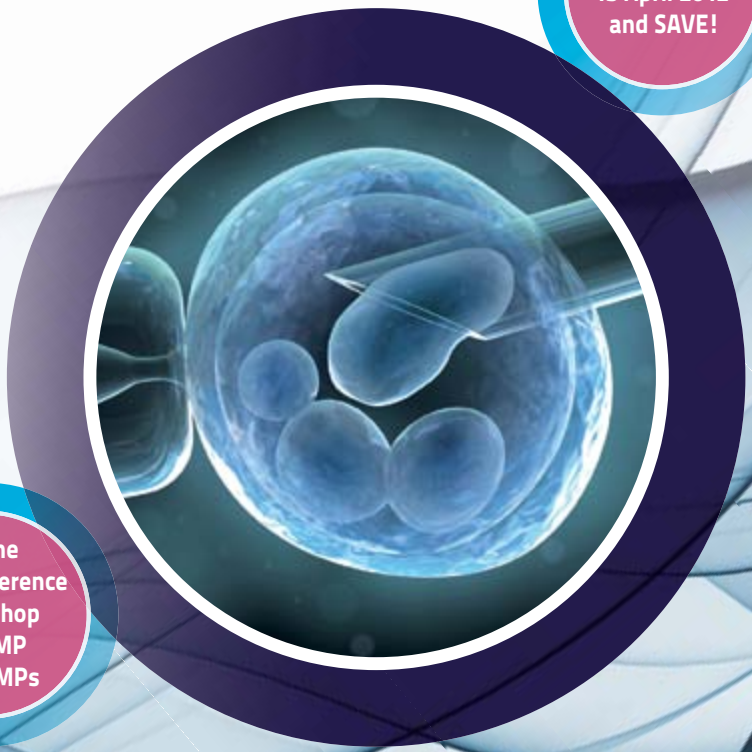
GMP related issues

- GMP for clinical trials and commercial production
- microbiological control during ATMP manufacture

Challenges and advances of ATMP development

- quality and CMC issues
- non-clinical and clinical challenges
- constraints in commercialisation

Register by 13 April 2012 and SAVE!



4 June Pre-Conference Workshop on GMP for ATMPs

5-6 June 2012

Hotel Cascais Miragem
Lisbon (Cascais)
Portugal

WORKSHOP 4 June | **CONFERENCE** 5-6 June | **EXHIBITION** 5-6 June

https://europe.pda.org/ATMP2012

PDA Letter

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Cover Art Illustrated by Katja Yount

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Features

PDA and U.S. FDA Co-Sponsoring Six Meetings in 2012

PDA and the U.S. FDA will work together in 2012 to generate industry-regulator dialogue on six topics of great import to both industry and the regulatory agency. These six PDA/FDA co-sponsored meetings provide PDA members plenty of opportunity to participate in the regulatory process.

First, *The Applying QbD Principles in Vaccine Development: PDA/FDA CMC Workshop* will be held May 14 in Bethesda, Md. The workshop will cover the challenges associated with attempting to apply QbD to vaccine development.

The *PDA/FDA Virus and TSE Safety Conference* will be held May 15-17 in Bethesda, Md. The conference will include presentations and panel discussions from regulatory and industry representatives from around the world who will share recent case studies, current and future trends, and hot topics in the industry.

The *PDA/FDA Glass Quality Conference* will be held on June 4-5 in Washington, D.C. This meeting will discuss best practice to preventing and/or detecting at risk glass packaging and review current expectations to ensure that recalls are avoided and container closure integrity is assured.

The *2012 PDA/FDA Joint Regulatory Meeting,* 21st year, will be held on September 10-12 in Baltimore, Md. Each year at this meeting, FDA speakers provide updates on the current state of efforts impacting the development of global regulatory strategies.

The *PDA/FDA Pharmaceutical Supply Chain Conference* will be held on November 13-14 in Bethesda, Md. 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.

Finally, the *PDA/FDA Vaccines Conference* will be held December 3-4 in Bethesda, Md. The conference will have a forum for discussion about many important vaccine developments and regulatory issues.

Go to www.pda.org/calendar for more on these co-sponsored events.

PDA-PIC/S Workshop Focuses on Inspection Issues

PDA is holding a workshop in collaboration with PIC/S that will focus on practical experiences in GMP inspections. Industry and regulatory participation is encouraged. The aim of the workshop is to get participants discussing issues where inspectors and a manufacturing site were in disagreement during inspections.

The workshop's closing plenary session will discuss how discrepancies raised during inspections between regulators and the manufacturing site can be managed to achieve harmonization of practices and expectation.

Sessions leading up to the closing plenary will address:

- Successful pharmaceutical quality management systems
- The correct procedure for manufacturing and batch release procedure
- Personnel issues—training
- Sterility assurance including filter integrity test
- Design and maintenance of facility/equipment (including dedicated facilities)
- How to perform a root cause analysis for an issue/recall/CAPA
- Chemical, physical, microbial contamination potentials

The results of the workshop will be summarized and published by PIC/S.

The conference will be held on May 9-10 in Geneva, Switzerland. Visit europe.pda.org/PICS2012 to learn more.

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Register Before **March 23rd** – The Largest Registration Savings Deadline!

"The *2011 PDA/FDA Glass Quality Conference* and subsequent TRI courses was the best conference I have attended in years. The topic was timely and relevant. The talks were clearly and openly presented by leaders in the world of pharmaceutical glass."
Dana Guazzo,
RxPax, LLC

The Parenteral Drug Association presents the...

PDA/FDA Glass Quality Conference

June 4-5, 2012

Renaissance Downtown Hotel | Washington, D.C.

The sold out *PDA/FDA Glass Quality Conference* in 2011 was an exclusive industry event, shining the light on several recalls and the increasing concerns about pharmaceutical glass packaging, both with regard to defects and/or incompatibilities with finished product over the shelf life. This year's meeting will elevate the dialogue, answering some of the more complex questions posed at last year's meeting.

Confirmed speakers for this year's meeting include:

- **William Bogle**, *Genesis Packaging*
- **Juan Cerdan-Diaz**, PhD, *Nipro Glass Americas*
- **Dave Cousins**, *Bosch*
- **Mark Fitzgerland**, *Nipro Glass Americas*
- **Carol Rea Flynn**, *Gerresheimer Glass, Inc.*
- **Dan Haines**, PhD, *SCHOTT Pharma Services*
- **Ron Iacocca**, PhD, *Eli Lilly and Company*
- **Jim J. Janimak**, PhD, *GlaxoSmithKline Biologicals*
- **Richard Johnson**, *PDA*
- **Robert Langer**, PhD, *MIT*
- **Maria Linzmayer**, *Merck and Company, Inc.*
- **Krista Liotta**, *Merck and Company, Inc.*
- **Dave Machak**, *American Glass Research*
- **Jim Nadlonek**, *Bauch & Stroebel Machine Company, Inc.*
- **Diane Paskiet**, *West Pharmaceutical Services*
- **George Quinn**, PhD, *Consultant*
- **Boris Schmid**, PhD, *OMPI*
- **John G. Shabushnig**, PhD, *Pfizer*
- **Gretchen Shearer**, PhD, *The McCrone Group*
- **Martin VanTrieste**, *Amgen*
- **Christoper Weikart**, PhD, *SiO2 Medical Products*
- **Bryan Williams**, *Lansmont Corporation*
- **Justin Wright**, PhD, *BD Medical – Pharmaceutical Systems*

Immediately following the conference, PDA's Training and Research Institute (PDA TRI) will be hosting two stand-alone training courses:

- Technical Report 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing (June 6)
- Selection and Utilization of Glass Containers in Pharmaceutical Packaging (June 7)

www.pda.org/glass2012

Exhibition: June 4-5 | Courses: June 6-7

Glass Task Force Needs You!

PDA is reforming the Glass Handling Task Force. Members from pharmaceutical companies, glass vial and syringe manufacturing companies and equipment manufacturers are welcome to join.

The Task Force will analyze each step of the parenteral packaging process, including: transit from the glass supplier, inspection, washing and depyrogenation, transfer, filling and stoppering, lyophilization, capping, post production activities, inspection, bulk handling, terminal sterilization and packaging operations for the purpose of identifying best practices.

If you are interested in volunteering, please send an email to the Task Force Chair **Bill Bogle** at bbogle@gen-techno.com.

First PCMO℠ TR Coming in March

PDA's first Paradigm Change in Manufacturing Operations (PCMO℠) Technical Report will be available in March!

The *PCMO Technical Report, No. R01 – Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations* provides detailed guidance for the application and implementation of quality risk management (QRM) principles throughout the product lifecycle. Intended to align with ICH Q9 and present information that can be helpful to the reader on how to implement QRM, the report emphasizes QRM application during commercial manufacturing and integrating QRM into the pharmaceutical quality system.

The goal of the PCMO initiative is to drive the establishment of "best practice" documents and/or training events in order to assist pharmaceutical manufacturers of Investigational Medicinal Products and commercial products in implementing the ICH guidelines on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10).

To learn more about the PCMO initative, visit page 8 of the 2009 July/August *PDA Letter*.

Volunteer

Jeff Hargroves, President, ProPharma Group

PDA Join Date: 1994

Why did you join PDA? I joined PDA for multiple reasons, but primarily it was to gain technical knowledge, stay abreast of industry trends and to keep connected with others in the industry.

Of your PDA volunteer experiences, which have you enjoyed the most? The challenge of starting a new PDA chapter has been rewarding. I heard many people expressing an interest in having a more local PDA presence in Missouri, Kansas and adjoining states. It has been a fun ride to get a chapter formed and off the ground to meet this need. It is not always easy and takes some elbow-grease, but the camaraderie with the Board and the knowledge shared at our initial meetings have made it worthwhile.

How has volunteering in PDA benefited you professionally? I still use, and encourage others to use, the technical reports and other wonderful guidance documents from PDA. Additionally, the relationships I have made and fostered through PDA over the past 15+ years are what make it fun to go to work each day.

Which PDA conference/training course is your favorite? The *PDA/FDA Joint Regulatory Conference* helps me stay current on the latest compliance trends and industry standards.

What would you say to somebody considering volunteering with PDA? Volunteering will enhance your career in many ways. If you like to share your knowledge, it is useful to remember that we generally learn the most when we try to teach others or when we roll up our sleeves to make things happen at a chapter level.

I have benefitted greatly from mentors and chapter leaders who in past years have openly shared their time and knowledge to help me and others succeed. There comes a point in your career when it is time to give back to others as a way to pay back those who helped you along in your career.

An Update from "Down Under"

Ano Xidias, Senior Consultant, PharmOut

Last year, the PDA Australian Chapter hosted three dinner events that provided both PDA members and nonmembers alike the opportunity to listen to industry representatives and regulators speak. Around 100 people showed up for each event.

On May 12, 2011, a meeting on the updated Process Validation Guidance was held. Since the guidance was last updated in 1987, there were important questions to consider, like: Did the new guidance practically redefine the entire concept of process validation? What does it mean to the pharmaceutical industry?

The Australian Chapter had the opportunity to hear three speakers give presentations on the guidance and its impact. **Andrzej Wozniak**, PhD, presented FDA's Process validation guidance with a presentation, entitled, "The Guidance, the Regulator and the Manufacturer." He also provided insight to current thinking, challenges and opportunities to the manufacturer. Next, **Brad Roberts** gave a talk on the value of simple statistics in retrospective process validation. He provided case studies to show the true value of trending. He also spoke about how to manage the data collected and how to set appropriate specifications. **Paul McDonald** presented a practical approach to process validation with a talk on a product lifecycle approach. He discussed process design, process qualification and continued process verification.

On July 26, 2011, the chapter held a meeting on media fills and environmental monitoring. Regulators from Austra-

(l-r) Greg Orders, TGA; Robert Caunce, Hospira; Bill Turner, TGA; and Ano Xidias, PharmOut at the PDA/TGA 2011 End of the Year Meeting

Visit PDA's Chapter Booth to Meet Chapter Leaders

2012 PDA ANNUAL MEETING

At the Annual Meeting we will give members a chance to network with chapter leaders at PDA's chapter booth. The booth will also give members a chance to learn more about volunteer opportunities and upcoming events.

Stop by the PDA chapter booth to learn more on Monday, April 16 or Tuesday, April 17!

lia's Therapeutic Goods Administration (TGA) and members from industry gave their approach and perspectives on this topic. **Kate Rustbridge** spoke about media fills, standards and guidelines applied, an update on ISO standards, problem areas and incubation of integral units. **John Garkinis** gave a presentation on a practical approach to media fills, which included the key elements required for an effective program. The last speaker, **Ano Xidias** spoke about the various challenges faced in developing and establishing a media fill and environmental monitoring program.

On December 6, 2011, the chapter held an end of the year meeting with the TGA. The chapter had the opportunity to hear directly from **Bill Turner** on future challenges for the Office of Manufacturing Quality and TGA's regional and international involvement. **Greg Orders** presented a review of the most recent TGA trends and compliance issues from audits. **Robert Caunce** also provided a case study on introducing a new molecule into one of Hospira's existing manufacturing facilities and the extent of risk assessment required for the project.

I wish to thank all of the committee for their efforts, PDA members, other participants and presenters for supporting the events for 2011 and look forward to what will be a challenging and exciting 2012 for us all.

We hope the meetings we have planned for this year will continue to provide valuable knowledge and opportunities to network and meet others. I encourage all of you to the help spread the word of the value on being a member and the contribution the PDA has to our industry, with many of its publications and networking opportunities.

PDA's Who's Who

Robert Caunce, Quality Manager, Technology Transfer, Hospira

John Garkinis, Quality Assurance Manager, CSL Biotherapies

Paul McDonald, Process Validation Manager, Hospira

Greg Orders, Auditor, Office of Manufacturing Quality, TGA

Brad Roberts, Senior Consultant and Partner, SeerPharma

Kate Rustbridge, Principal Microbiologist, Office of Laboratories and Scientific Services, TGA

Bill Turner, Head, Office of Manufacturing Quality, TGA

Andrzej Wozniak, PhD, Director, Executive Consultant, Quality GMP Consulting

Ano Xidias, Senior Consultant, PharmOut and Immediate Past President, PDA Australian Chapter

2012 PDA ANNUAL MEETING Relax at PDA's Annual Meeting Networking Events

Phoenix, Ariz. • April 15-17 • pdaannualmeeting.org/networking-events

There is plenty to do for members and their families outside the meeting rooms and exhibit hall at this year's Annual Meeting. Don't miss the fun!

Golf

Participate in the *6th Annual PDA Golf Tournament* at the Wildfire Golf Club on Sunday, April 15 from 7:30 a.m.–12:00 p.m. The Wildfire Golf Club features 36 holes designed by two golf legends, Arnold Palmer and Nick Faldo. Voted "Best Courses You Can Play" by *Golfweek Magazine* and "America's Top Golf Courses" by Zagat, come enjoy the scenic views and spacious fairways of the Palmer Signature Course. Team up with your colleagues, friends and family to experience the breathtaking background and take a swing at 18 holes surrounded by the McDowell Mountains. The cost is $160.00 per person. Price includes cart, green fees, practice and range balls, refreshments and lunch. Download the golf registration form at pdaannualmeeting.org/pdf/2012-Golf-Registration-Form.pdf

Walk/Run

Help out the Phoenix Children's Hospital during PDA's 6th Annual Walk/Run, Sponsored by Sartorius Stedim Biotech, the walk/run will be held on Sunday April 15 from 8:00 a.m.–10:00 a.m. You can start the week off with your heart rate up, your body energized and taking in the fresh air at the 3K walk and 5K run through the beautiful grounds of the JW Marriott Desert Ridge Resort.

100% of your donations will go to the Phoenix Children's Hospital and every dollar contributed will have a direct impact on their patients, families and community, from helping fund clinical programs and support services to supporting research and injury prevention programs. The cost is $20 per registered attendee or guest. Price includes a t-shirt, race bib, snacks and beverages (water, juice, coffee).

If you wish to donate to the Phoenix Children's Hospital, but can't make it to the walk/run, you can send a check payable to PDA. Please remember to put "Donation to Phoenix Children's Hospital" in the memo field.

Exhibit, Job Hunt and/or Sponsor at the Career Fair

Monday, April 16 and Tuesday, April 17 will bring an opportunity to exhibit at PDA's Annual Meeting Career Fair and interact with highly qualified, potential job candidates from regulatory, compliance, manufacturing, quality, research & development, laboratory science, process development and engineering. With a 10' x 10' booth and dedicated exhibit hall hours, you can showcase your company, employment opportunities and brand identity to hundreds of attendees seeking to advance their careers. Ample time will be provided for you to solicit resumes, screen candidates and conduct on site interviews. Conversely, if you are seeking a new job opportunity, make sure you bring your resume!

Sponsoring the PDA Career Fair is an excellent way to generate exposure and recognition for your company. Our sponsorship packages allow you to brand your company as an elite place to work as well as promote company events, products, and services.

If you wish to exhibit or sponsor, please contact David Hall at +1 (240) 688-4405 or hall@pda.org.

Watch Baseball

On Tuesday, April 17, there will be a baseball outing from 5:45 p.m.–10:30 p.m. This is the perfect time to take a 7th inning stretch from the Annual Meeting as the Arizona Diamondbacks take on the Pittsburgh Pirates at Chase Field. The cost is $50.00 per person. This includes one ticket (baseline reserve seating), transportation to and from the JW Marriott and a $10 food/beverage voucher.

Dine Out

Every night from 6:30 p.m.–9:30 p.m. participate in the PDA Dine Around. Spend the evening at Scottsdale Quarter and choose from a wide variety of cuisines, such as, steak, seafood, sushi, Italian, Mediterranean and Mexican. Gather your colleagues, family and friends early and sign up to reserve your spot at one of the selected locations with the PDA Concierge Service. It will belocated at the PDA Registration Desk on Monday, April 16, 2012 from 10:30 a.m.–4:30 p.m. and on Tuesday, April 17 from 10:00 a.m.–5:00 p.m. Transportation to the Scottsdale Quarter will be provided.

To find out more information or to sign up for a PDA Annual Meeting networking event, visit pdaannualmeeting.org/networking-events.

If you wish to donate to the Phoenix Children's Hospital, but can't make it to the walk/run, you can send a check payable to PDA. Please remember to put "Donation to Phoenix Children's Hospital" in the memo field

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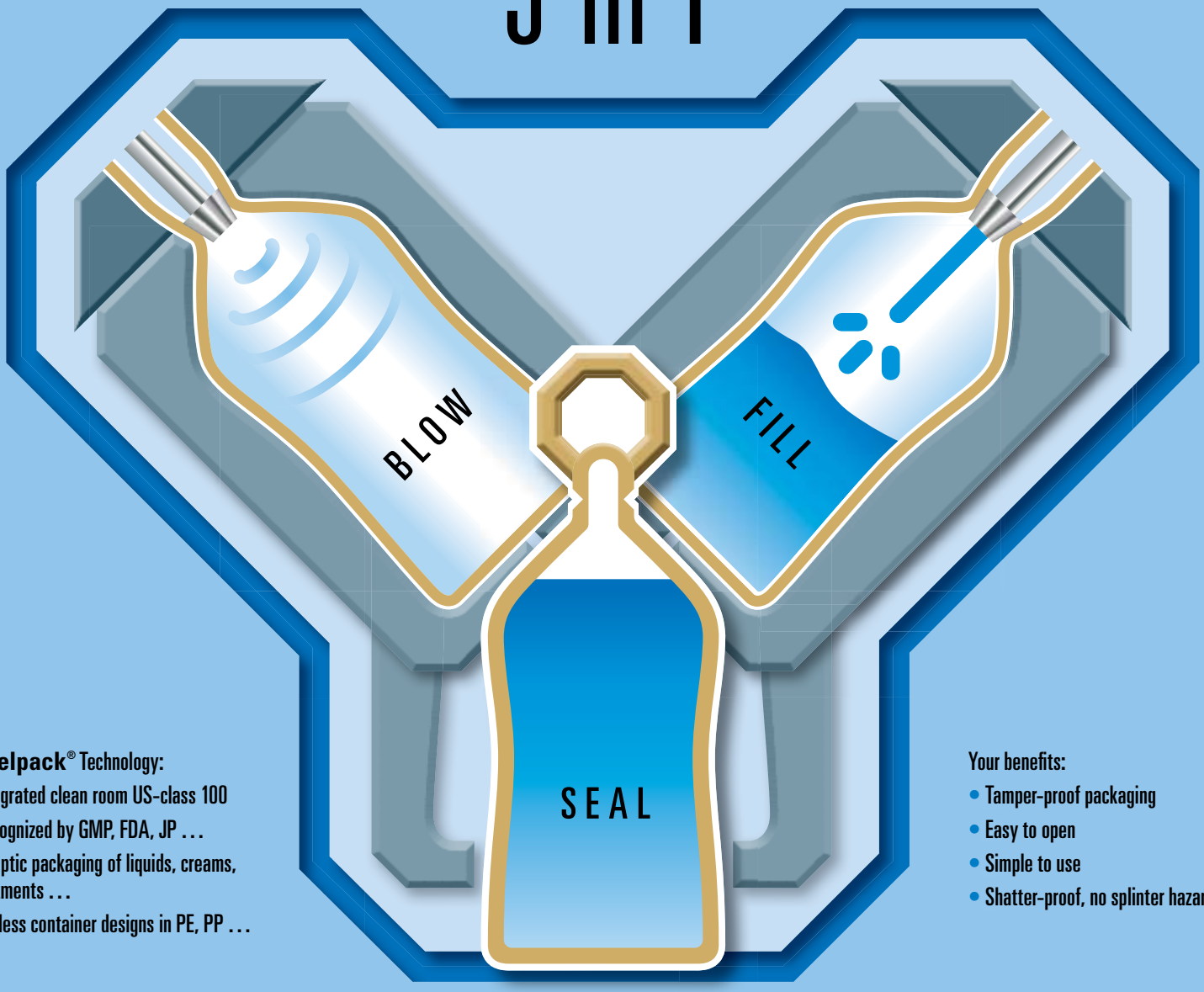

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Please Welcome the Following Industry Leaders to the PDA Community

Priya Aggarwal, Health Canada

Takashi Akiyama, TAC

Mohammad Ali, BenVenue Laboratories

Paul Andrea, Genentech

Anwar Anwaruzzaman, Bayer Healthcare

Pooja Arora, Bristol Myers Squibb

Kensuke Asada, Obayashi Corporation

Nethaneal Blacklock, Bayer Healthcare

Robert Bognar, Cubist Pharmaceuticals

Elyse Boyles, Eli Lilly

Dave Braggs, NextPharma

Donna Brandgard Ben Venue Laboratories

Lisa Chavez, Unique Pharmaceuticals

Mark Chipperfield, F.Hoffmann-La Roche

Aaby Chung, Mycenax Biotech

Simone Dahlmanns, Hameln Pharmaceuticals

Baher Daoud, Immunogen

Charles Dogimont Novartis

Jean Engela, Kinesis Pharma

Jeani Foxbower, Alkermes

Miho Fujimoto, Nagase Medicals

Shinichi Fukuzono, Hitachi High-Technologies

James Gebo, Microtest Laboratories

Adam Gettelfinger, Fresenius Kabi

Samir Ghodbane, Hospira

Jim Gibbs, Ben Venue Laboratories

Steve Golla, DPT Labs

Naotoshi Hara, Asahi Kasei Pharma

J. Michael Hatfield, Atticus BioConsulting

Kenichi Higuchi, Ajinomoto Pharmaceuticals

Wang Hong Yan, Pfizer

Craig Huffman, Ben Venue Laboratories

Elizabeth Hutzel, Sangart

Iljin Hwang, Sangart

Ai Ishidoshiro, Dainippon Sumitomo Pharma

Yasuyuki Kameshima, Nichiiko Pharmaceutical

Hiroomi Kamo, Denkikagaku Corporation

Tsutomu Katai, Ajinomoto Pharmaceuticals

Takayuki Kato, Eisai

Tomoaki Kato, Harada

Hidenori Kitade, Fuji Yakuhin

Eiko Kobayashi, Merck

Iveliz Kock, Bristol-Myers Squibb

Daniel Kockelkorn, F. Hoffmann-La Roche

Takaharu Kono, Mitsubishi Tanabe Pharma

Juan Kuang, Amgen

Dorothy Kucala, AstraZeneca

Naotaka Kuroda, Ajinomoto Pharmaceuticals

Renee Kyro, Abbott Laboratories

Rick LaScala, Ben Venue Laboratories

Christopher Lauderback, Sigma-Tau Pharmaceuticals

Travis Leeah, Unique Pharmaceuticals

Demei Leung, Onyx Pharmaceuicals

Nguyen Ly, Merck

Izumi Maegawa, Nipro Pharma

Cynthia Martino, Bionique Testing Laboratories

Naoko Matsushita, Meiji Seika Pharma

Tammis Matzinger, Gilead Sciences

Christy Mazzarisi, DPT Labs

Tom McDaniel, Bosch Packaging

Simone Meulenbelt, Xendo

Jennifer Morana, Lantheus Medical Imaging

Magdolna Morvai, Teva Pharmaceuticals

Mitsuru Nakagawa, Takeda

Alana Nelson, Genzyme

Juri Nishino, Takeda

Masayuki Nitta, Kyorin Pharmaceutecal

Camilla Nordlund, Orexo

Fuyumi Ochi, Takeda

Tasahiro Ogaya, Ajinomoto Pharmaceuticals

Kotono Ohta, Rohto Pharmaceutical

Alfonso Olmeda, Ben Venue Laboratories

Yoshitaka Ookawa, Yakult Honsha

Sadayuki Oomura, Benesis

Shizuko Oosima, SIOE Pharmaceutical

Catherine Palmer, Sheffield Pharmaceuticals

Mehul Patel, Banner Pharmacaps

Aniello Pennetti, Auxilium Pharmaceuticals

Emma Phillips, Contec

Alastair Powell, Teva

Joseph Raker, AMRI

Tsuneya Saito, Asahi Kasei Pharma

Satoshi Saitoh, Takenaka Corporation

Daniel Sanchez, Pfizer

Yamato Shiobara, Astellas Pharma

Balamani Sittampalli, VA Medical Center Research Association

Tehila Sonnenfeld, Immunovative Therapies

Nadejea Soukhareva, Sigma-Tau Pharmaceuticals

Padmamalini Srinivasan, Pfizer

Kalavati Suvarna, Food & Drug Administration

Hideki Syoji, Rion

Keiko Takakura, Toyama Chemical

Fujio Takeuchi, Haupt Pharma

Toshiharu Takeuchi, Haupt Pharma

Ayako Tamori, Otsuka Pharmaceutical

Akinori Tanaka, Merck

Keiichi Tokihiro, Astellas Pharma

Annalisa Torrente

Mitsuhide Toyoshima, Santen Pharmaceutical

Nicholas Turnbow, Ben Venue Laboratories

Makiko Ueda, Eisai

Shizue Urahata, Fuji Yakuhin

Denise Valentino, BioMarin Pharmaceutical

Teresa Varela, Laboratorios SYVA

Asi Veshler, Trialog

Shena Weeks, Kimberly-Clark Professional

Hideto Yoshida

Hideharu Yoshida, Fuji Yakuhin

Darin Zehrung, PATH

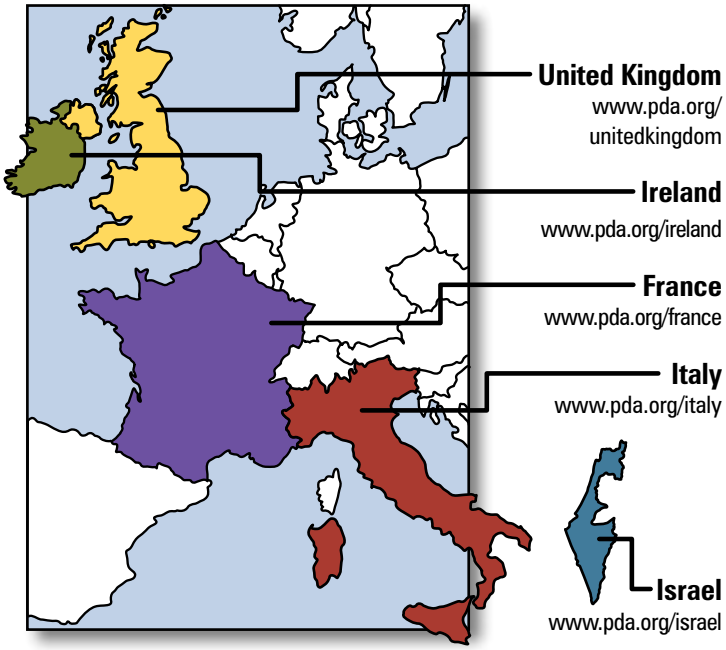
Rong-Rong Zhu, EMD Millipore

Hanna Zyruk, Iroko Pharmaceuticals

PDA Chapters

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

EUROPE



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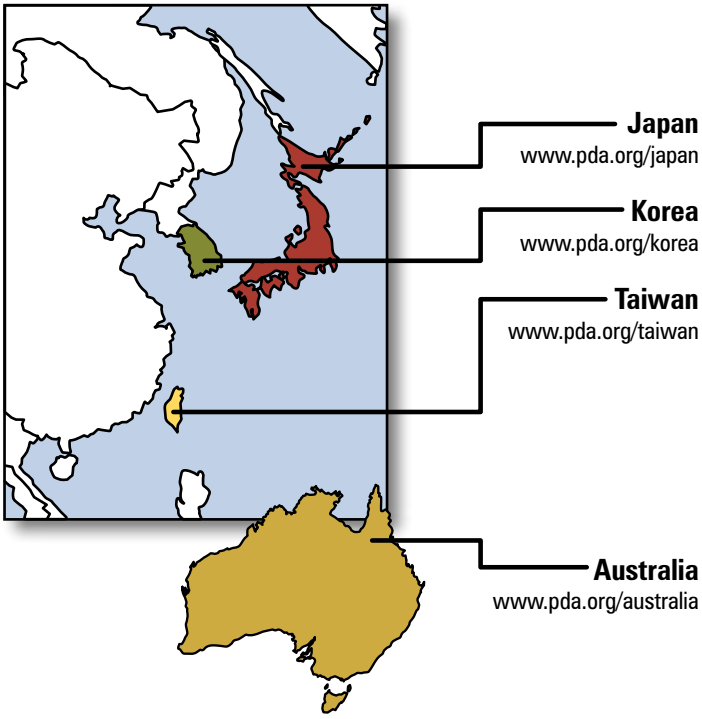
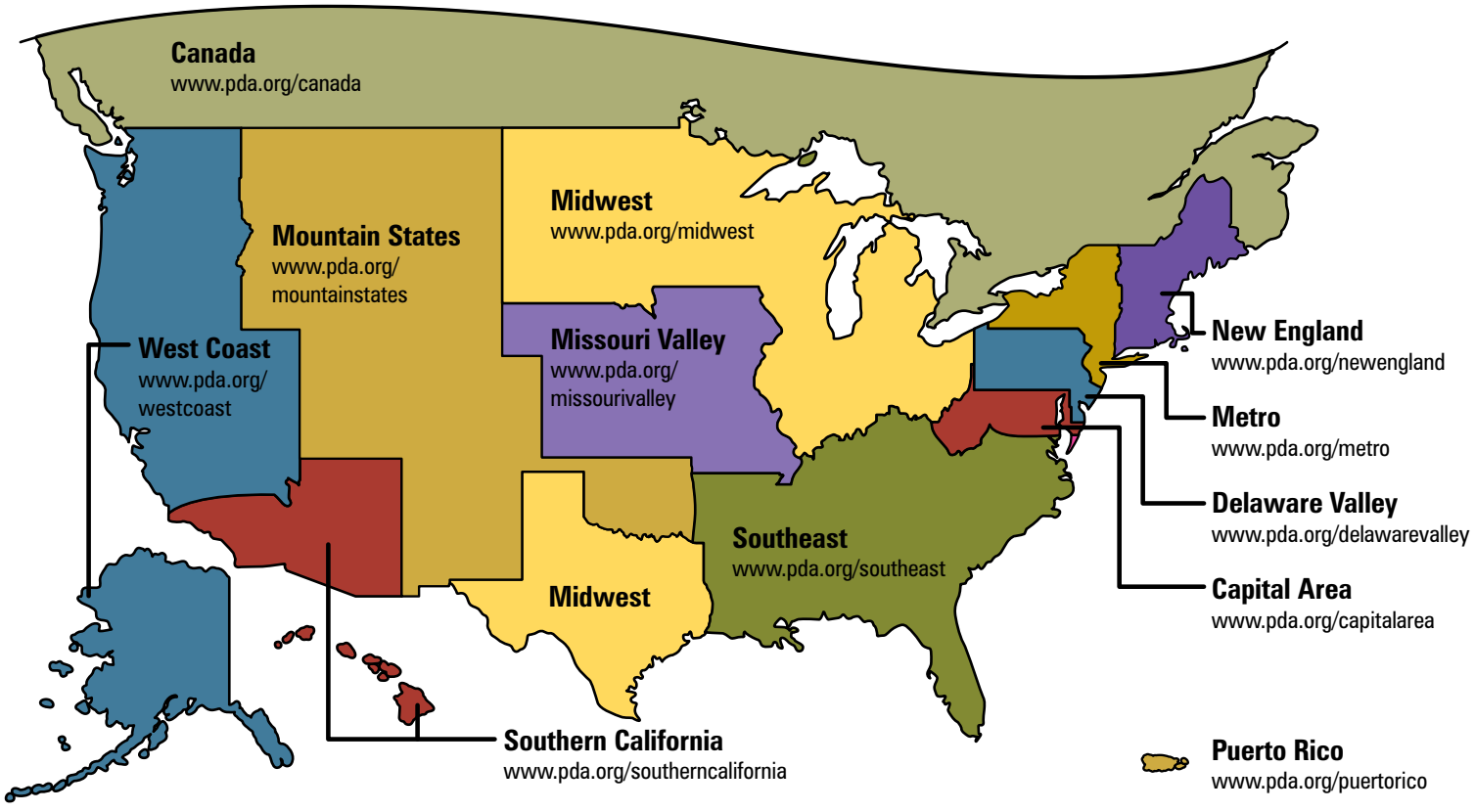


NORTH AMERICA



PDA Tools For Success

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

It's Time to Link Up with LinkedIn

Jean Kelley

Mention the phrase "social media" and most people automatically think of Facebook and Twitter. But if you have any dealings in the corporate world—whether you're a CEO, salesperson, human resource manager, administrative assistant or anything in between—you'll want to take a closer look at LinkedIn. You will find it a useful tool to make your business relationships more meaningful…and more profitable.

Before you dismiss the idea of using LinkedIn because you only know it as that "bland" social media site where people go when they're looking for a job, realize that currently there are 90 million LinkedIn users worldwide. One new user joins every second of every day. And unlike social media sites like Facebook, where many people use the site for entertainment, all LinkedIn users are business-minded. That means the connections you develop on LinkedIn are more likely to positively impact you or your company in some way. Therefore, if you want better or more professional business relationships, LinkedIn is the place to be. Even if you have a business profile on Facebook and Twitter, LinkedIn makes a perfect addition to your personal or business branding efforts.

An Essential Business Resource

The key to making LinkedIn work for you and your company is to use the site regularly. That means posting something, either an update or a question/answer, every seven days at a minimum. Why? Because the more you use any social media site, the higher your "Google Juice" will be. In other words, Google's algorithm will notice your regularity and you'll get a higher ranking with Google than you would otherwise. Additionally, the more you interact and post on LinkedIn, the more prominent you'll become within your network and your name recognition will grow.

Fortunately, staying active in LinkedIn and being a regular user is simple when you understand how LinkedIn can benefit you professionally. Use the following ideas and suggestions to make the most of your LinkedIn account:

Show off your skills

It's as easy to set up your profile in LinkedIn as it is in Facebook. Make sure your profile is well written and that it highlights what you currently do, what you have done, your strengths, your talents, your key attributes and your education. Remember that people will access your profile for many different reasons (recruitment, background information, professional contacts, etc.), so be thorough and always make your profile public. Since your LinkedIn profile is essentially a dynamic mini resume, keep it updated, tasteful and accurate at all times. Additionally, you have an opportunity to display recommendations for you. As a point of etiquette, when you ask someone to write a recommendation, you must reciprocate.

Say something meaningful

By posting status updates that contain valuable content, you show your network that you are a team player and that you care about other people's success. Remember that status updates are not the place to advertise your company's products or services nor is it a conversation group. A better idea is to share a best practice, announce a seminar/event you've been to, are going to or give a quick tip. If you can't think of anything to post, it's perfectly acceptable to post a meaningful or motivational quote. The key is to post something interesting and relevant to your network. Remember that what you post stays on the internet forever. So if you wouldn't want your comment on the front page of your local newspaper, don't post it on LinkedIn.

Uncover conversation starters

LinkedIn is a great place to get an inside glimpse of people. For example, you can look up potential clients or vendors on LinkedIn and see what kind of books they read, where they went to school, what their main interests are (based on the groups they belong to) and so much more. Now you'll have more to talk about when you meet the potential client, potential vendor or potential networking friend. Think of LinkedIn as a gateway to have a professional relationship with someone much quicker. In fact, some estimates show that by using LinkedIn to research the people you plan to interact with, you can have a six-month head start on the relationship.

Spot trends and hot topics

There's an amazing amount of real-time information available on LinkedIn. By being a member of various groups that interest you, you can see what people are thinking on a certain topic by the questions they're posting and the responses they're getting. So if you want to know what the current trends or best practices are in lean manufacturing, for example, you could join several lean manufacturing groups on LinkedIn and track each

group's activity. You can then use the information you discover in your own company.

Get an "in" with top companies

Whether you're looking for new clients, new vendors or even a new job, with LinkedIn you can search the companies you want to work with and see who in your network has connections there. You can then ask that person—your connection—for an introduction to a decision maker who can help you. Even if you find that no one in your network has connections with a particular company, perhaps someone in one of your group's works there. That's why it's important to belong to every group that interests you. Continually build your LinkedIn relationships and make those key connections before you actually need them. As Harvey Mackay says, "Dig your well before you're thirsty."

The Missing Link to Your Success

Even though 82 percent of people use some kind of social media regularly, social media itself—including LinkedIn—is much like the Wild West. It's not tame yet, and best practices are still being formed. With that said, if you've spent much of your time on other social media sites and feel they aren't working for building professional relationships, then it's time to give LinkedIn a try.

The key to making LinkedIn work is to work it regularly. Commit to spending at least thirty minutes per day on it, posting your ideas in updates, asking and answering questions, participating in groups and reaching out to potential connections. Yes, it's one more thing to schedule in your calendar, but by building relationships and gaining new information on people and topics, it's also something that can make your job easier and your company better positioned.

About the Author

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

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2012 PDA ANNUAL MEETING

New Members: Learn About Your Association

Phoneix, Ariz. • April 16, 7:00 a.m.-8:00 a.m. • howe@pda.org

Welcome new PDA members!

If you joined PDA on or after April 1, 2011 you are invited to kick-start your PDA membership by attending the New Member Breakfast hosted onsite at the *2012 PDA Annual Meeting* on Monday, April 16 from 7:00-8:00 a.m.

This is a wonderful opportunity to learn more about PDA and to meet other new members and PDA staff. Also, Chair **Anders Vinther**, PhD, VP Quality, Genentech, will be speaking at the breakfast.

Please note, you must be a full conference attendee to particiapte.

For more information and to RSVP by March 30, please contact PDA's **Hassana Howe,** Director, Membership and Chapters, at +1 (301) 656-5900 ext. 119 or howe@pda.org.

2012 PDA ANNUAL MEETING Annual Meeting *Preview*

Interest Group, Task Force and Advisory Board Meeting Schedule

The business of the Association will be conducted, as always, at the Annual Meeting.

Below is a schedule of the Science advisory board, committee, task force and interest group meetings taking place. **Note:** All interest group meetings are open to meeting registrants; all other ancillary meetings are by invitation only. (For Regulatory Affairs ancillary meetings, see the Regulatory Snapshot, p. 36)

Sunday, April 15

5:00 p.m.–6:00 p.m.

Interest Group Leaders Meeting

Monday, April 16

7:00 a.m.–8:30 a.m.

PCMO℠ Steering Committee

12:45 p.m.-1:45 p.m.

Science Advisory Board (Invitation Only)

12:45 p.m.–2:15 p.m.

Bioburden and Bio-film Task Force

3:45 p.m.–4:30 p.m.

Gene & Cell Based Therapy Task Force

4:30 p.m.–6:00 p.m.

Microbiology/Environmental Monitoring Interest Group

Process Validation Interest Group

Prefilled Syringe Interest Group

Visual Inspection of Parenterals Interest Group

Lyophilization and Vaccines Interest Group

Supply Chain Management Interest Group

Tuesday, April 17

12:15 p.m.–1:45 p.m.

Biotechnology Advisory Board Meeting (Invitation Only)

4:00 p.m.–5:30 p.m.

Facilities and Engineering/Pharmaceutical Water Systems Interest Group

Packaging Science Interest Group

Filtration Interest Group

Sterile Processing/Blow-Fill-Seal Interest Group

Biotechnology Interest Group

Wednesday, April 18

12:30 p.m.-3:00 p.m.

Mycopasma Task Force

Interest Group *Corner*

Facilities and Engineering Interest Group Changes Focus to Include "Green" and Single-Use Technology

The Facilities and Engineering Interest Group has gone "green."

The six-year-old group, led by **Christopher Smalley**, Associate Director, BioSterile Validation, Merck, has turned its focus on how facilities can reduce, reuse and recycle energy through the implementation of single-use systems. The group changed its direction from HVAC systems and calibration preventive maintenance after its members wanted more meetings held on ecofriendly technology.

Smalley took some time to speak with the *PDA Letter* about his group's interest in "green" technology.

PDA Letter: Why is the interest group focusing on single use systems?

Smalley: For the Facilities and Engineering Interest Group, it is important to stay relevant and engaged with members. For the interest group to be the most successful, it is necessary to discuss the topics that resonate with the membership and ensure that the interest group meetings provide ample opportunity for members sharing common interests time to network.

PDA Letter: What are some upcoming major projects that the interest group is working on right now?

Smalley: In addition to discussing single-use systems and "green" technology, we are working on how to make existing manufacturing facilities more "flexible" without the massive construction projects that are typically associated with re-engineering a site to

continued at top of page 20

Tech *Trends*

Single-Use Products Create Playgrounds, Pallets

Emily Hough, PDA

Single-use technology provides many inherent advantages. Key among those benefits is the ability to put a validated disposable bag into a process, fill it with product and then discard it. However, many companies struggle at the end of the lifecycle trying to decide what to do with the leftover waste.

Johanna C. Jobin, Sustainability Manager, and **Mani Krishnan**, Director, Mobius Single-use Processing Systems, both with EMD Millipore Corporation, talked with the *PDA Letter* about how their company is committed to product stewardship by taking responsibility for products to the end of its life. By conducting a lifecycle assessment of disposable products, the firm has discovered that waste coming from the disposal of a product rarely has the biggest environmental impact. According to Jobin, though this phase accounts for less than 5% of most environmental impacts measured in the lifecycle assessments, people react strongly when they see all the used disposable products pile up.

Jobin and Krishnan have been developing product take-back programs that are used to divert sanitized single-use products from ending up in landfills or incinerators, the traditional disposal methods available today. This reclaims the materials for the highest-value use possible.

One such program reclaims materials for the highest-value use possible. It utilizes large quantities of disposed single-use products used in biopharmaceutical manufacturing processes, such as filtration cartridges and disposable bags.

Non-hazardous or already sanitized products are disassembled and separated. From there, recyclable components, mostly plastic, are reused for other items, including recycled-content pallets and playground equipment. Non-recyclable parts can be used as an alternative fuel, replacing coal and other fossil fuels in cement kilns and other energy intensive processes.

According to Jobin and Krishnan, EMD Millipore will coutinue to pursue ways to make single-use technology more palatable by integrating sustainability across the product lifecycle.

PDA will be holding a Single Use Systems Workshop after the Annual Meeting in April. This workshop will help guide participants through the challenges of single-use technology by helping them to ask the right questions when considering implementation. Visit www.pda.org/singleuse2012 to learn more.

Interest Group Corner continued from page 18

change a manufacturing focus.

We hope to work with the Single Use System Task Force, which will be conducting a workshop at the Annual Meeting to facilitate implementation of single-use systems.

"Being green" is not just one topic, but involves energy reduction, aggressive recycling programs and reduction of waste. It also means that the pharmaceutical industry needs to ensure that waste streams from production facilities—for example, discharge from stacks or solid waste being carted to landfills—are not polluting the environment.

At previous meetings we have tackled the issues of adding solar arrays to roof tops and installing soil and plantings to roof-tops to add insulation and extend roof life.

PDA Letter: What do you hope that your interest group accomplishes by the end of this year?

Smalley: We hope to identify topics crucial to the membership that we can relay to the relevant scientific advisory boards and appropriate meeting program committees. We are also trying to develop concepts for PDA deliverables and podium presentations to reach out to meet the needs and expectations of the membership.

About the Expert

Chris Smalley is the Associate Director of BioSterile Validation at Merck. He is responsible for innovative processes of biotechnology implementation and validation and single-use-systems worldwide in the vaccine and pharmaceutical businesses of the organization. Previously, he had been the Director of Quality Operations for Wyeth Pharmaceuticals for 12 years with responsibility for setting validation standards and conducting validation activities globally in the pharmaceutical, biotechnology, consumer health and nutritional businesses. Chris is currently a member of the PDA Board of Directors as well as a member of the Science Advisory Board.

For more information on any interest group or task force or to volunteer, email **Iris Rice** at rice@pda.org.

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Take Control of Your Career

Phoenix, Ariz. • April 17, 7:30 a.m.-8:30 a.m. • www.pda.org/annual2012

Emily Hough, PDA

2012 PDA ANNUAL MEETING

Have you worked in the same position for a while and are being passed up for promotions? Are you searching for a job, but don't know what employers are looking for? What should you do if you want to move to a different department?

You might find yourself in a situation where you need answers to these and similar questions. PDA is working hard to help you get those answers. The upcoming Annual Meeting includes a breakfast session called "Career Development Strategies," and the three career experts participating in the session shared some insights on these questions with us.

Roy Blitzer, Executive Coach and Management Consultant, RJB Consulting, said if you are not being promoted after working at the same company for 25 years, it will be hard to advance. People in your firm are going to see you as "too ingrown" in your current position. Usually, he said, there is a message as to why you are not being promoted.

It does not hurt to talk to a trusted confidante in your organization about what traits those who are being promoted have. Next, examine how those qualities compare to you and amend your behavior accordingly.

If you still are not being promoted, take those lessons and look for new job opportunities elsewhere, advised Blitzer.

But how do get your foot in the door of the next firm?

To be considered for a senior-level position, **Dave Fortier,** Managing Director, ZRG Partners, says you should convey critical thinking skills, sound judgment and decision-making skills. You should

Article at a Glance

- It does not hurt to talk to a trusted confidante in your organization about what traits those who are being promoted have
- Employers want senior-level employees who are customer-centric and have the ability to recruit, develop and retain the best team

Employers want senior-level employees who are customer-centric and have the ability to recruit, develop and retain the best team

have a clear vision and communicate well. Employers want senior-level employees who are customer-centric and have the ability to recruit, develop and retain the best team.

Fortier advises those earlier in their careers to present initiative/drive, ability to collaborate, intelligence, willingness and the ability to learn, adapt and focus on the customer.

Perhaps you want to make a lateral move in your organization and work for a different department or section—let's say from regulatory affairs for traditional drugs to the section that handles combination products.

Cheri Spolin, Global Human Resources Business Partner, Roche/Genentech, discussed one way this can be handled. First, Spolin said, find a manager or a peer who works or worked in the combination drugs area and set up an informational meeting with them. If you do not have contacts in the other department, approach a relevant HR representative. The HR representative will be able to contact a manager in the combination drugs area who can then meet with you to discuss combination products, tell you what skills are needed, etc. After the meeting, if you are still interested, the HR representative can set you up with a mentor from the department. To find a position in the combination products department, you can consult with your company's staffing person/recruiter responsible for placement in that department.

Need more tactics or have other questions? Additional strategies and tips for advancing your career will be given at the breakfast session, such as:

- Insights on developing many of the important leadership and networking skills needed to advance from the technical arena into senior management as well as highlighting fatal career derailers to avoid
- Observations and advice on current trends in biopharmaceutical recruiting, as well as the attributes and experiences most sought after in today's executive job market
- The perspective of a corporate senior HR manager discussing successful strategies and techniques for internal career transitions and successful navigation of corporate cultures

Don't miss this opportunity to understand today's demanding job market from some of the industry experts in career and leadership development. Make sure you bring your questions to the session on April 17 at 7:30 a.m.–8:30 a.m.

About the Experts

Roy J. Blitzer is an Executive Coach and Management Consultant at RJB Consulting. He has had 30+ years experience as a human resources and business management professional. He is also certified in various executive leadership development assessments and account management.

Dave Fortier is the Managing Director of ZRG Partners. He recently joined ZRG Partners and brings nearly ten years of executive search experience and an extensive record of senior level placements within the Life Sciences and Healthcare industry.

Cheri Spolin is a Global Human Resources Business Partner at Roche/Genentech. She has held senior HR positions in a number of high tech organizations.

Career Fair and "Quality and Regulatory Job Market Outlook 2012" Breakfast Session at Annual Meeting

Make sure you bring your resume to the Annual Meeting career fair on Monday, April 16 and Tuesday, April 17. This two day event will leave you plenty of time to find out about potential new job opportunities.

There will also be a "Quality and Regulatory Job Market Outlook 2012" breakfast session on Wednesday, April 18 at 7:30 a.m.–8:25 a.m. It will focus on trends in the job market. In this session, a panel of executives from biotech companies, consulting firms and the public sector will discuss trends they see in the job market for manufacturing, quality and regulatory arenas and the hiring profiles they will be looking for in 2012. Don't miss this unique opportunity to hear from the hiring executives themselves "where the jobs are!"

Topics in this session include:

- Career strategies for quality, manufacturing and regulatory professionals
- Hiring trends in the pharma and biotechnology sector
- Hiring trends in the consulting industry and public sector
- Skill sets and hiring profiles in demand
- Skill sets needed for compliance companies

2012 PDA ANNUAL MEETING

Getting Personal

Phoneix, Ariz. • April 16 • www.pda.org/annual2012

Walter Morris, PDA

The *2012 PDA Annual Meeting* will offer participants a look at the latest advances in manufacturing and technology under the theme, *Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology*. There will be many hands-on opportunities for participants to learn about and to see new technologies in seesions and in the exhibit hall, currently with more than 100 exhibitors.

The meeting begins with discussion of truly innovative technologies and drug products—those falling into the cohort known as "personalized medicine." Advances in gene and cellular therapy have allowed new treatment approaches and hope for patients with a wide range of serious and life threatening disorders.

David Shanahan will kick things off with a discussion of future benefits to patients. As President of the Mary Crowley Cancer Research Centers, Shanahan bears witness to some of the most innovative advances in cancer therapies. He will share the story of the Institute and the belief that a paradigm shift is occurring in cancer care by which personalized medicine will ultimately transform the way patients are treated. With an ultimate goal to cure cancer, the ongoing objective at Mary Crowley is to administer novel agents in innovative ways to transform cancer into a manageable disease. Today Mary Crowley Institute is involved in over 200 U.S. FDA-approved trials.

Gradalis Takes a Bite out of Cancer

Shanahan told the *PDA Letter* that he is "most excited" about a autogolous cancer vaccine named FANG, under development by Gradalis. Based on "extraordinary results" in Phase I, the drug is is currently in multiple Phase II trials.

"We believe that FANG represents a new class of cancer therapeutics that all stakeholders will be clamoring for, including patients, clinicians and payors," said Shanahan.

"FANG is derived from the patient's own tumor, creating a personalized therapy aimed at teaching the patient's immune system to seek out and kill cancer cells. First and foremost, it appears from early clinical trials that FANG works—in fact several immunotherapies in clinical trials are showing promising results."

Patients will benefit from personalized drugs like FANG for many reasons. First, Shanahan said, "Because the vaccine is derived from the patient's own tumor cells, there are little to no side effects from receiving FANG. This is something that all stakeholders can appreciate." He added, "The patient comes in once a month for a single injection in their arm like a flu shot and they are done until the next month."

The company has developed an assay called the ELISPOT which, used in conjunction with the FANG vaccine, allows clinicians to monitor the results of the vaccine. "The ELISPOT shows if the patient is mounting an immune response to their own (nontreated) tumor cells," Shanahan said. "We have found anecdotally that patients who have a response using FANG have a durable response of greater than a year. Again, this is another benefit to payers as well—the ability to see noninvasively and quantitatively how a patient is responding to what will likely be an expensive therapy."

The vaccine is in several Phase II trials so the firm can determine how many cancers it can fight. Right now, Gradalis is looking at ovarian, advanced melanoma and advanced colorectal with liver mastases.

"Gradalis is tackling some tough indications with FANG that represent unmet medical needs," noted Shanahan. "Each of these patient populations qualifies as an 'orphan' indication in the eyes of the U.S. FDA and Gradalis has received orphan drug status for FANG in two groups already." This status could accelerate commercialization.

Article at a Glance

- Manufacturers developing personalized medicines face interesting and new challenges as the rules for traditional biopharmaceutical production do not always apply
- There are still regulatory concerns regarding personalized medicines

Manufacturers developing personalized medicines face interesting and new challenges as the rules for traditional biopharmaceutical production do not always apply

"In addition to regulatory activities related to commercialization," Shanahan said, "Gradalis is streamlining its manufacturing process and scaling its manufacturing resources in order to meet future demand upon commercialization. Gradalis will be utilizing modular clean rooms made by G-Con Manufacturing (College Station) in order to adapt its vaccine manufacturing process from doing hundreds of vaccines per year to tens of thousands."

Stem Cells Fight Cancer

The opening session continues with an insightful look at the challenges involved with bringing stem cell therapies to market in a presentation by **Ted Love,** MD, Executive Vice President, R&D and Technical Operations, Onyx Pharmaceuticals, entitled "The Future of Personalized Medicine –Challenges Ahead." Love serves on the 29-member California Independent Citizen's Oversight Commission, which oversees $3 bil. allocated to stem cell research authorized by California Proposition 71. He also serves as an executive officer of the California Institute for Regenerative Medicine.

Love will share the promising safety and efficacy results of stem cell therapies to date, but also the challenges ahead in making these therapies widely available. He spoke to the *PDA Letter* about some of the points he will make during his talk.

"In its simplest format, the challenge with stem cell therapy is going to be able to essentially manipulate the cells so that you can identify a highly purified source of progenitor cells which behave exactly as you want them to as you implant them," said Love. To get there, he explained, "there is a lot of science."

One challenge is inherent to the nature of a human embryonic stem cell, which represents the building blocks of everything in the human body. "It is very potent," Love said. "It could become anything. That is good news and bad news."

Harnessing the cells to do exactly what is needed is the current challenge. As an example, Love discussed using stem cells for spinal cord injuries. "All you really want is restoration of the nervous system," he noted. "You do not want those cells to get inside and become connective tissue, bone or blood. You want them to become exactly what you want them to become. Staying with the analogy of spinal cord injury, you want the cell to also form a conduit along the exact path that you need nervous stimulation. You do not want it to go places that you do not want it to go. You do not want it going off and innervating some muscle that you don't want to innervate."

The second challenge comes with implanting the cell and making sure it integrates into the patient as planned.

"Underneath all of that are a lot of issues around getting the right cells, manipulating the right cells," said Love. "A lot of that is CMC, because there is no doubt that there is going to be a lot of science regarding what kind of growth factors you expose those cells, how long you expose them to it and how you purify alpha cells."

Love believes these "extraordinarily complicated" issues will be solved over time. "It is very exciting in terms of its potential, but it is also daunting in terms of the complexity of issues that are going to have to be solved."

Finally, Love mentioned that regulatory concerns will need to be managed. "Given that the U.S. FDA works generally to manage risk, anytime anything is new, that often brings delays and more cost. So I do worry that the regulatory pathway for bringing these therapies is uncharted and that is going to take some time." The regulatory challenge will exist around the world, not just in the United States.

Manufacturers developing personalized medicines face interesting and new challenges as the rules for traditional biopharmaceutical production do not always apply. Following the plenary session, conference participants can choose to hear talks on these manufacturing issues in Breakout Session B. ➤

Personalized Medicine/Cellular Therapeutics: Challenges in QA/QC

Greg Whitehead, Dendreon

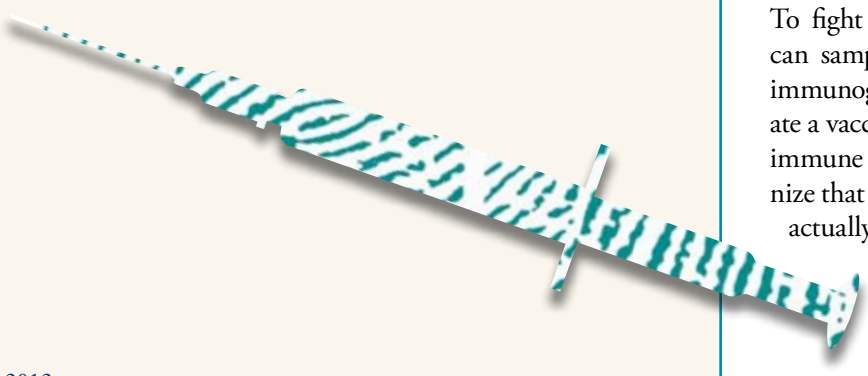
In an industry where people's health and well being depend on our products, being in quality isn't easy. Every day we must make decisions that are fact and risk-based keeping in mind both patients and regulations. Ensuring that safe and effective products are manufactured in a compliant GMP operation certainly keeps us busy.

Quality assurance and quality control in the arena of personalized medicines/cellular therapeutics is generally consistent with the pharmaceutical and biotechnology industry, but differ in key ways. The patients' own cells, with their inherent variability, are the starting material. They must be collected, shipped to a processing facility, treated in a manufacturing process, shipped to an infusion site and returned to the patient, all in an extraordinarily short product lifecycle, which is measured in hours or days. Clearly, the existing quality paradigms must be reassessed.

Personalized autologous production creates many challenges, including:

- Strict chain-of-identity controls are required in any supply chain for autologous products. These controls must incorporate assurances that the cells "loaned" to the manufacturer are returned to the patient who "loaned" them. The requirements of 21 CFR Part 1271, Good Tissue Practices must be taken into consideration in addition to the GMP regulations.
- Performing product investigations that are thorough, yet timely enough for a product with a shelf life measured in hours or days. Investigations must be completed in time to allow evaluation for lot disposition. Multiply that by thousands of individual lots and it's easy to see how the conventional concepts of investigation closure must be adjusted.
- Adequate root cause analysis during investigations, again with short product shelf life and high volume. Additionally, the high variability in patient starting material must be considered for its contribution to out-of-specification investigations.
- Thousands of production lots magnify the difficulties in managing and implementing changes.
- Determining precision, ruggedness and robustness in analytical methodology in light of tremendous variability in the starting material adds to the complexity of method validation. No two patients' cells are the same and awareness of that variability is important in the determination of final product quality.

Manufacturers of personalized medicine/cellular therapeutics base their operations on the same regulations as traditional pharmaceutical manufacturers: CFR, USP, ICH, etc. Extrapolating the requirements and guidance found in these resources for cellular-based therapies personalized for individual use is challenging. The pharmaceutical/biotechnology industry has overcome comparable challenges to create today's modern medicine; this is but a new chapter in our story.



"Challenges in Manufacturing" will be presented by **John E. Butler,** PhD, Global Project Leader, Bayer Innovation. He spoke to the *PDA Letter* about his presentation and Bayer's involvement in the field of personalized therapies.

"It is important to understand what people mean by personalized medicine," said Butler. "Most of the so-called personalized treatments do not require personalized manufacturing. Most of the time people are talking about genetically informed medicines—stratifying your patients and tailoring the therapy to minimize side effects or increase efficacy based purely on genetic or genotype/phenotype of a patient."

Butler explained that there are some medicines that do require individual manufacturing, particularly vaccines, and that is the type he is involved with at Bayer. "Of course on the other side," he added, "looking for biomarkers for stratification of patients, Bayer is just as active as anyone else. These are two different things."

[Editor's Note: See "Personalized Medicines: The Next Big Thing in Healthcare" in the October *PDA Letter* for more on personalized medicines.**]**

Tobacco's Anti-Cancer Use!

What makes personalized vaccines so challenging is that they require one antigen per patient.

"We are involved in personalized manufacturing. The vaccine we are making addresses the surface immunoglobulin of degenerative B cells, which are the origin of lymphoma. Normally lymphomas are monoclonal disease where all of the tumor cells are derived from one that went out of control, and they all have the same surface immunoglobulin."

To fight them, Butler continued, Bayer can sample the tumor to determine an immunoglobulin sequence. "We generate a vaccine that will hopefully wake the immune system of the patient to recognize that J-molecule as foreign, which is it actually is not, because it comes from a B cell from your body. We are

continued at bottom of page 34

There is more to safety than meets the eye.

BioMonitoring by EMD Millipore.

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www.emdmillipore.com/biomonitoring

Interview with James Akers On Revised USP <1116>

When the *PDA Letter* learned that USP Chapter <1116> was updated and about to publish, we went right to the top—the top of the USP Committee of Experts of Microbiology and Sterility Assurance—to find out what is new.

PDA: Dr. Akers, thanks so much for taking time to talk with PDA. I know you have spoken often about <1116>, which used to be titled, "Microbiological Evaluation of Clean Rooms and Other Controlled Environments." The revised chapter is now titled, "Microbiological Control and Monitoring of Aseptic Environments." You have discussed the revision many times over the last few years, including at the annual PDA pharmaceutical microbiology conference. There are a few aspects of the changes that I find particularly interesting and worth exploring. One is that the Expert Committee made an effort to extricate from <1116> all information relating to aseptic process validation. Another is the replacement of alert and action limits with recommended incidence rates.

Before we talk about those, would you like to comment on how you feel about the revised chapter and whether or not there will be more revisions to what has already been written?

Akers: Let me preface my remarks by saying the opinions I'm giving are my own. I'm not speaking for the USP or the Expert Committee.

Certainly I'm satisfied with the contents of <1116> at this time. That said, the revision process is really unending. There is no fixed timetable for the next revision, but as contamination control technologies and analytical methodologies continue to evolve so must guidance and standards.

PDA: Why was it important to focus the chapter strictly on environmental monitoring, thus the removal of information relating to aseptic process validation? Is the implication here that environmental monitoring is not part of validation?

Akers: This question reminds me of a comment a professor made in the first lecture of a course on microbial taxonomy. She said that, "Microbial taxonomists fall into two basic categories: lumpers and splitters." In this case, I suppose we were splitters. Seriously, we felt it best to focus <1116> on environmental monitoring. In fact, we got considerable input in the form of stakeholder comments that the chapter's information on process control and validation would be better placed in another chapter. As reported at the PDA Global Microbiology Conference, we have a series of chapters in preparation which cover sterilization and sterility assurance. Again we are "splitters" as we'll have one chapter devoted to each relevant sterilization or sterility assurance related technology.

The fact that validation as a subject is no longer within the contents of the chapter doesn't mean that prospective verification of the contamination control properties of a facility or process is discouraged.

PDA: This focus is reflected in the new title for the chapter, is that true? Could you discuss why the title was changed?

Akers: I think the title change reflects only the fact that the chapter is focused on monitoring of aseptic processing environments exclusively. I don't think there is any more to it than that. The conditions for evaluation of aseptic processes are unique and should be treated as such. For example, an ISO 7 room used in aseptic processing will typically have different gowning requirements for entry and different contamination control requirements than one used for a form of contamination control that doesn't require full aseptic gowning. Focusing this iteration of <1116> only on aseptic processing enabled us to consider only the aseptic "core" in our recommendations. The contamination rates in <1116> are intended only for facilities in which complete aseptic gowning is done and in which the ventilation systems are designed for aseptic processing.

PDA: What was the problem with the alert/action limits as described in the chapter originally? What was happening in industry that the Expert Committee thought needed to be addressed?

Akers: The reasons for eliminating alert and action levels were purely scientific.

Scientifically we have very limited information regarding the sensitivity or the limit of detection of monitoring programs

Note, please, that I used the word "level" rather than "limit," because environmental monitoring is not, and never can be, a direct test on product. Turning back to the basic issue, alert and action levels evolved without sufficient consideration given to the metrology of environmental monitoring. Somewhere along the way we seem to have lost sight of the fact that an individual monitoring event is a limited snapshot in time of a contamination control program. Monitoring really is not a secondary sterility test. Nor does it provide a means of defining or establishing sterility assurance or, equally importantly, a lack thereof. Monitoring can, when viewed over a sufficient period of time, give insight regarding whether or not a consistent state of control is maintained.

Scientifically we have very limited information regarding the sensitivity or the limit of detection of monitoring programs. We can rest assured, however, that for many clear scientific reasons the limit of detection is not zero and that the sensitivity is circumscribed by the nature of the test itself.

The actual unit of measure in monitoring is the colony forming unit (CFU), which is not the same thing as a viable cell count. Theoretically, a single viable organism may result in a colony but this is not a given. In fact, it probably isn't common. Another consideration is the inherent variability in sampling technologies, which can, depending upon the technical choices made by the designer, vary considerably in terms of recovery efficiency.

Additionally, there is the matter of the inherent variability in growth and recovery microbiology. It is a mistake to assume that because a test is enumerative in the sense that the outcome is numerical implies sensitivity, accuracy or precision. Saying the alert level is zero and the action level is one CFU is not logical, because in analytical microbiology zero does not mean no viable cells present. It simply means nothing grew. One CFU may not mean a single cell present. This was impressed upon me very early in my career as a microbiologist, I recall doing plate counts in a laboratory rotation and in the serial dilution scheme labeling a sample with no growth, "sterile." I was quickly asked, "How can it be assumed that the sample is sterile?". The next time I wrote "no growth." That said, I hear people say all that time that all the monitoring results confirmed "sterility," or that a media fill test produced a "sterile" result.

Actually, a zero sample or a one CFU sample may be equivalent or they may not be. We simply do not have methods with sufficient discrimination to make such a distinction. Realistically, we don't know if a 1 CFU result is different from say a 5 CFU result from the perspective of what it's telling us about contamination control. It makes more sense to take a longer view in assessing the contamination control capability in aseptic processing. It really isn't appropriate analytically to have control levels that imply we can discriminate between samples that are different by a small number of CFU. I'm seeing a lot of reports written because of a recovery of 1 CFU. Frankly, I think most microbiologists find that expectation puzzling. I know I do.

PDA: Could you briefly describe "incidence rate" and why this is better than alert/action limits?

Akers: Thinking in terms of incidence rate logically forces us to take the more appropriate long view I previously mentioned. It also obviates the issue of overreacting to a single sample outcome and instead requires one to answer the question: "How are we doing in terms of maintaining our aseptic operations in a consistent state of control?" Perhaps most importantly though, thinking in terms of incidence rate would no longer require us to try to discriminate between analytical results that should be treated the same. Treating a result of 4 CFU as dramatically different from one of 2 CFU is simply not scientifically justifiable in my opinion. The idea is to keep the overall incidence of contamination consistently low rather than trying to force distinctions between or among results that from an analytically point of view are not significantly different.

PDA: You made a point in a slide presentation a few years ago to point out that RMM technologies are compatible with the incidence rate approach. Why is that important to note?

Akers: Nongrowth based microbiological methods are going to give us a signal that is different from the colony forming unit. I can't think of any reason why we should in environmental monitoring be concerned about trying to correlate a cell count based signal to a colony forming unit. Given the variety of methods which could potentially be used, there will likely be multiple types of signals.

If we deem that a facility is suitable for aseptic processing, by design it won't be any less suitable if different sampling and detection technology results in a different signal. We may have to have another look at what the target incidence rate should be at some point. Hopefully, there won't be a lot of time wasted trying to correlate data back to CFU, which wouldn't be time well spent, in my opinion. I've seen quite a bit of data regarding modern nongrowth based sampling methods in unmanned environments,

Article at a Glance

- The Expert Committee made an effort to extricate from <1116> all information relating to aseptic process validation
- Action/Alert limits have been replaced by "incidence rate"

and while I want to see more such data, I have no doubt that an incidence rate approach will work.

In manned environments, methods with greater sensitivity will almost certainly result in higher incidence rates. It will be critical not to overreact to that. If a facility manufactures safe product, that product will still be safe if a more sensitive method reflects a higher incidence rate than that observed by traditional growth-based methods.

PDA: The revised chapter makes a distinction between open and closed RABS. There was an interview in the P*DA Letter* in 2008 about "bad RABS" with **Rick Friedman** from FDA, in which he said that not all RABS are equal, particularly those that are opened. USP must share this opinion.

Akers: In terms of separating a human operator from the critical zone of aseptic processing closed RABS is more like an isolator than open RABS, but we should avoid the term "bad" here. There is a fundamental problem with the idea of "bad RABS," in my opinion. We still accept aseptic processing done in manned cleanrooms do we not? Isn't open door RABS likely an improvement over a cleanroom that has no separative technology at all? I'd say that it may well be so. Considering that, I'd be very uncomfortable using the word "bad" to describe any form of enhancement over a manned cleanroom. If we call a system with some RABS "bad," what do we call a cleanroom with no restricted access systems at all? In implementation open and closed RABS may not be equivalent, but conventional manned aseptic cleanrooms aren't all the same in contamination control capability either. Open RABS could be a very useful way to improve a manned cleanroom, and that isn't "bad."

I am afraid that we spend too much time discussing labels in aseptic processing. I also worry that we spend too much time talking about things we have no way to measure

What we need to eliminate is the idea that we can measure the attribute of sterility by monitoring. Whenever I hear the opinion expressed that better analytical methods will enable us to measure sterility, I cringe because that discounts sampling statistics. To prove that an environment is sterile would require both an infinite sample size and perfect sensitivity. Arguing about how to measure a negative absolute or requiring significant additional expenditure on programs unlikely to yield safety improvements certainly does not benefit the healthcare consumer, particularly in parts of our world, where resources are scarce and the sensitivity to cost is high.

We accepted long ago that it is not possible to test quality into a product, and we also need to accept that we can't monitor quality into the product either. Monitoring of an environment is not the same thing as direct process control monitoring on a fermentor or chemical reactor; although, sometimes there is a tendency to act as though it is.

I am afraid that we spend too much time discussing labels in aseptic processing. I also worry that we spend too much time talking about things we have no way to measure, for example, "sterility assurance." That's rather like the old philosophical joke about how many angels can dance on the head of a pin. We know before we ask the question that no one has the real answer.

Instead we'd be better served just focusing on making safe medicines for everyone and doing so with maximal cost effectiveness and operational efficiency. I'd characterize an aseptic processing facility making safe and effective product as "good," and one which is unable to do that as "bad." What I'd like to see, and I think we can all share this desire, is for all of our aseptic facilities—both industrial and pharmacy compounding—across the world to fall into the "good" category.

We have enough collective experience to be able to define what general characteristics a safe aseptic process ought to have.

About the Expert

James Akers, PhD, is the president of Akers Kennedy & Associates, Inc., located in Kansas City, MO. Dr. Akers has over 30 years of experience in the pharmaceutical industry and has worked at various director level positions within the industry and for the last decade as a consultant. He is a chairman of the USP Committee of Experts Microbiology and Sterility Assurance, as well co-chairman of the PDA Isolator Technology Task Force, Aseptic Processing Task force, and member of task forces on sterilization, environmental monitoring, VPHP decontamination, and media fill testing.

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A Look at New Sterilization Methods

Phoneix, Ariz • April 16, 2:15 p.m.-3:45 p.m. • www.pda.org/annual2012

Emily Hough, PDA

New sterilization methods are always in demand as many products cannot withstand traditional dry and wet heat sterilization. Recent developments in terminal sterilization technologies have allowed biological, combination and sensitive small molecule products to undergo sterilization treatments.

Terminal sterilization has long been held as the preferred method of sterility assurance for drug products since the drug products are sterilized within their final container closure systems. However, its application has been limited to those products that can withstand the harsh conditions of the sterilization process. With a growing market of biologic products, combination products as well as an existing market of sensitive small molecule products, the industry has pursued advances in terminal sterilization to address these product types.

Advances in terminal sterilization like those that will be discussed at the PDA Annual Meeting will likely save industry time and money

PDA's Annual Meeting includes an informative session on advanced sterilization techniques ("Microbial Control in the Manufacturing Environment: Advanced Sterilization Techniques" will take place on Monday, April 16 at 2:15 p.m.-3:45 p.m.).

The *PDA Letter* asked the expert speakers of the session about these recent developments and what it means for the industry.

When it comes to products that can't be steam sterilized, **Miguel Nogueras**, Global Manager of QA Microbiology, Quality & Compliance, Abbott, said "Historically sterilization assurance levels (SAL) have been set at 10^{-6} based on the probability of an organism surviving a sterilization treatment, specifically in parenteral drug products, to minimize patient risk.

However, small molecules and biologics tend to be susceptible to sterilization assurance levels of 10^{-6} or higher; they can change their fit and/or form leading to a change in potency and application. This is unlike medical devices and nonsusceptible products, which typically can withstand more abrasive sterilization regimens."

Nogueras said that some products have been deemed safe with a lower sterilization assurance level of 10^{-3} after validating aseptic processes and lower sterilization doses.

He forecasts that "as the industry evolves into [developing] new drug products, technology and drug delivery systems, combination devices will now represent a challenge as they will more likely be composed of an item historically sterilized at a SAL of 10^{-6} and a minimum of a second component sterilized at 10^{-3}."

David Opie, Vice President, R&D, Noxilizer, agreed that combination products will present a difficulty to sterilize since there not a one-size-fits-all sterilization technique: "Some combination products are highly temperature sensitive, others are sensitive to moisture, and still others cannot tolerate radiation."

He said that in order to find a sterilization method that is best suited for a specific product, the available sterilization methods and method that best meets the requirements of the product need to be considered. "In one case, gamma may be a suitable method of sterilizing a biological material that can tolerate radiation (and the concomitant altered molecular structure). However, another product may require a room temperature, non-ionizing process, like the nitrogen dioxide sterilization method."

Over the last year, Noxilizer has optimized the process of sterilization using nitrogen dioxide as a gas sterilant. Shown is a picture of Noxilizer's first potential commercial RTS 360 unit

The nitrogen dioxide sterilization works best for parenteral combination drugs, according to Opie. It also provides the manufacturer with cost-saving benefits. "The nitrogen dioxide process can be completed in less than one hour (depending on cycle parameters). Once the cycle is completed, the sterilized products can be handled immediately, without lengthy aeration, as is needed with ethylene oxide sterilization. Using a nitrogen dioxide sterilization system, whether in a batch or in-line process, saves time and reduces inventory costs, which saves money."

Low dose gamma terminal sterilization can also save a firm looking to sterilize biologics "a great savings in cost production," according to **Niki Fidopiastis**, Director of Consulting, SteriPro, Consulting, Sterigenics International. Fidopiastis said it also"…allows the ➤

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manufacturer to decrease the manufacturing area classification from aseptic processing to an 'ultra clean' area. This means that all the cost and effort in building an aseptic area may be bypassed."

Advances in terminal sterilization like those that will be discussed at the PDA Annual Meeting will likely save industry time and money. This is a perfect way to capitalize on technology that also helps assure patient safety.

Want to learn more? Come to this session and learn about application hurdles that provide enhanced sterility assurance for those products that have historically been unable to withstand existing sterilization methods.

About the Experts

Miguel Nogueras is the Global Manager of QA Microbiology, Quality & Compliance at Abbott. He specializes in quality, regulatory and compliance with an emphasis in aseptic fill operation, final moist heat, EtO and gamma sterilization.

David Opie, PhD, is the Vice President, Research and Development, at Noxilizer. He has extensive medical device development experience with both start-ups and industry leaders, including Johnson & Johnson and Cook Medical. He has employed a thorough knowledge of Good Laboratory Practices, Good Manufacturing Practices, and design control and product development procedures.

Niki Fidopiastis is the Director of Consulting, SteriPro, Consulting, Sterigenics International. She joined Sterigenics International in 1998, as SteriProTM Validation Specialist, after nine years with North American Science Associates. She is responsible for developing and implementing ISO and FDA compliant sterilization validations for E-beam, GAMMA and EO sterilization of disposable medical products and pharmaceuticals.

Getting Personal continued from page 26

trying to put a red flag on these sick cells."

The primary manufacturing problem "is twofold and are interconnected," according to Butler. "The main challenge in my view is making these things affordable—widely available. The big challenge is production cost. You can imagine what it means to make a recombinant protein, purify it, and characterize it—one for each patient. It is not trivial to make it at a price where it is profitable for the company and affordable to the patient."

The second, interconnected challenge for this vaccine compared to others with the same vaccine design is the yield. Butler said these low yields prevent the gathering of sufficient amounts of antigen allow for multiple boosters during vaccination. "In other words, we believe some of these failed studies were due to insufficient or infrequent vaccination."

Bayer is tackling these problems with "a very robust, very reliable and reasonably simple expression system based on tobacco plants." How this system is working will be the topic of his talk at the 2012 PDA Annual Meeting.

Joining Butler in Session B is **Greg Whitehead,** Director, Corporate Quality Assurance, Dendreon. See sidebar, page 26, for more on his talk.

The meeting includes a second breakout session on personalized medicines that will feature an addition presentation from industry and one from the U.S. FDA. As can be seen, the *2012 PDA Annual Meeting* promises to get personal.

About the Experts

David Shanahan is the President of Mary Crowley Cancer Research Centers, a cancer therapy charity specializing in gene and viral therapies. In 2005 he founded Gradalis, a biotech startup company manufacturing personalized cancer therapies for use in clinical trials. Gradalis uses genomic and proteomic analysis to understand the molecular makeup of a patient's cancer. By harnessing shRNA technologies, Gradalis is validating unique cancer targets and began clinical trials on these therapies in 2007.

Ted W. Love, MD, is the Executive Vice President of Research & Development and Technical Operations at Onyx Pharmaceuticals. He was Chairman and Chief Executive Officer of Nuvelo, a biopharmaceutical company, from March 2001 to January 2009. He was the appointed President and Chief Operating Officer of Nuvelo in January 2001 and served as a director of that company since February 2001. He became Chairman of the board of directors in September 2005. He joined Nuvelo from Theravance, Inc., a biopharmaceutical company, where he served as Senior Vice President of Development from February 1998 to January 2001. Prior to that, he spent six years at Genentech, Inc., a biotechnology company, holding a number of senior management positions in medical affairs and product development.

John Butler has been the Vice president, Global Project Leader Plant Made Pharmaceuticals, Bayer, for the past five years. Before that, he was the Head of Product & Business Strategies, Strategic Planning and Head of Coordination Research & Development at Bayer.

Greg Whitehead has been with Dendreon Corporation since 2004, starting as the Manager of the Quality Control Laboratories and moving to Quality Assurance in 2009. He is currently the head of corporate quality assurance, with oversight of quality systems and responsibility for standardization of quality assurance across multiple manufacturing plants. Additionally, he is responsible for third party manufacturing oversight in support of Dendreon's supply chain.

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2012 PDA ANNUAL MEETING Annual Meeting *Preview*

Interest Group and Advisory Board Meeting Schedule

The business of the Association will be conducted, as always, at the Annual Meeting.

Below is a schedule of the Regulatory advisory board, committee and interest group meetings taking place. **Note:** All interest group meetings are open to meeting registrants; all other ancillary meetings are by invitation only. (For Science ancillary meetings, see the Science Snapshot, p. 18)

Sunday, April 15

11:00 a.m.-4:00 p.m.

Regulatory Affairs/Quality Advisory Board (Invitation Only)

2:00 p.m.-3:00 p.m.

Interest Group Leaders Meeting

Monday, April 16

4:30-6:00 p.m.

Quality Systems Interest Group

Tuesday, April 17

4:00 p.m.-5:30 p.m.

Inspection Trends Interest Group

Quality Risk Management Interest Group

Task Force *Corner*

Task Force to Publish Technical Report by End of 2012

The three-year-old Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials Task Force is working on a technical report about the extemporaneous preparation of early phase clinical supplies.

The group, co-led by **Vince Mathews,** President, Mathews Quality Consulting**,** and **Kathleen Greene**, Executive Director, Global Head Training and Knowledge Management, Quality Assurance, Novartis, hopes to publish the report by the end of 2012.

The *PDA Letter* interviewed Mathews about the task force's effort.

PDA Letter: What is the main focus of the technical report the task force is working on?

Mathews: Our task force is creating a technical report on the extemporaneous preparation* of early phase clinical supplies. The main driver for this technical report is that the governing regulations and quality requirements for utilizing EP techniques to prepare clinical supplies are not clear, even to those who perform these operations. The task force wishes to clarify the regulatory requirements, where possible, and to state clear quality requirements that should be in place when performing these types of operations to help ensure patient safety and data integrity of the studies.

Even though the applicable regulations are different between countries and the exact applicable regulations are not always clear, the type of operations performed in the various locations/countries to prepare these simple formulations of clinical trial materials are similar.

* Extemporaneous preparation is the manipulation of drugs and excipients for a particular patient using traditional compounding techniques

These formulations include preparations such as powder-in-a-bottle, powder-in-a-capsule, solutions, suspensions, etc. Since the types of operations that are being performed are similar, the quality controls required to ensure the preparation of quality early phase clinical trial material are also similar. Our team has reviewed multiple regulations around the globe which pertain to these type of operations and have assessed current practices. In utilizing the broad knowledge of the members on the team, we have developed what the team believes are the appropriate quality requirements for these types of operations. This is the important part of the report—giving quality guidance to ensure the preparation of safe early phase clinical trial materials.

PDA Letter: How is the project of clarifying regulatory requirements progressing?

Mathews: This task is challenging because the governing regulations are not the same in various countries (e.g., European Union, United States, Canada, and Australia) where these operations are performed. In addition, in some countries, the exact regulations which govern these operations are not clear. The team is working with regulators in these countries to ensure that there is alignment on the identification of these applicable regulations.

continued at bottom of page 41

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U.S. FDA Paves the Way for Biosimilars in US

Emily Hough, PDA

2012 PDA ANNUAL MEETING

Learn more about the new U.S. FDA Biosimilar guidances at the PDA Annual Meeting

Don't miss your opportunity to learn more and ask FDA questions about the biosimilar guidances. **Emily Shacter,** PhD, Chief, Laboratory of Biochemistry, CDER, U.S. FDA, will speak about these guidances in more depth at PDA's Annual Meeting during the closing plenary session on Wednesday, April 18 at 10:30 a.m.-12:00 p.m.

The U.S. FDA's Center for Drug Evaluation and Research has released three draft guidance documents on biosimilar products:

- *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*
- *Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product*
- *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*

The draft guidances provide the Agency's current thinking on key scientific and regulatory factors involved in submitting applications for biosimilar products under the Biologics Price Competition and Innovation (BPCI) Act of 2010.

In advance of the release of the draft guidances, FDA held a webinar called "Biosimilars 101" (Feb. 3). During it, **Rachel Sherman**, MD, Associate Director for Medical Policy, CDER, provided an overview of the law and FDA's progress in implementation. Four days later, the Agency held a media briefing in conjunction with the release of the draft guidances.

Scientific Considerations in Demonstrating Biosimilarity to a Reference Product is the key guidance among the trio; it is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application.

The document covers:

- Complexities of protein products
- U.S. licensed reference products and other comparators
- Approaches to developing and accessing evidence to demonstrate biosimilarity
- Postmarketing safety monitoring considerations
- Consultation with FDA

The second draft guidance, *Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,* is highly technical. It provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application. This document provides definitions and outlines general principles, factors for consideration and other relevant FDA guidances.

The "Factors for consideration" section addresses nine areas that manufacturers should assess in determining if their products should be considered highly similar. These are:

- Expression System
- Manufacturing Process
- Assessment of Physicochemical Properties
- Functional Activities
- Receptor Binding and Immunochemical Properties
- Impurities
- Reference Product and Reference Standards
- Finished Drug Product
- Stability

The third draft guide, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009* is a "living document" that the FDA will add to as necessary, according to Sherman during the media briefing. It provides answers to common questions from people interested in developing biosimilar products.

The BPCI Act has created an abbreviated licensure pathway for biological products shown to be biosimilar or to be interchangeable with an FDA-licensed reference product (section 351 of the Public Health Service Act).

The general requirements of the 351 application specify that the product must be a biosimilar to a reference product, utilize the same mechanism of action for the purpose condition of use and have the same route of administration, dosage form, and strength as the reference product. Under the BPCI Act, a protein, except any chemically synthesized polypeptide, will be regulated as a biological product.

Historically, some proteins have been approved as drugs under section 505 of the FD&C Act and other proteins have been licensed as biologics under section 351 of the Public Health Serivce Act. According to the *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009* draft guidance "a proposed biological product will be considered in the same 'product class' as a protein product previously approved under section 505 of the FD&C Act, if both products are homologous to the same gene-coded sequence (e.g., the INS gene for insulin and insulin glargine) with allowance for additional novel flanking sequences."

The FDA has said that it will take ten

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U.S. FDA Considers Modifications to Biosterility Test

Emily Hough, PDA

The U.S. FDA's Center for Center for Biologics Evaluation and Research has proposed to amend an existing regulation on sterility test requirements for biological products to clarify and update the sterility test requirements.

On June 21, 2011, the FDA announced in the *Federal Register* that it would modify 21 CFR 610.12 by:

- Eliminating the specified sterility test methods, culture media formulae (or formulations), and culture media test requirements
- Eliminating the specified membrane filtration procedure requirement for certain products
- Eliminating the specified sterility test requirements for most bulk material
- Modifying the repeat sterility test requirements, so that repeat tests would occur only once for each lot. These tests would be limited to situations when the quality control unit conclusively determines, after conducting an investigation upon detection of viable microbial contamination during the initial test of the lot, that the contamination is the result of laboratory error or faulty materials used in conducting the sterility test
- Replacing the storage and maintenance requirements for cultures of test organisms used to determine the "growth-promoting qualities" of culture media with: **1)** Validation requirements specifying that any sterility test used is able to consistently detect the presence of viable contaminating microorganisms and **2)** verification of "growth-promoting properties" or microorganism-detection capabilities of test and test components
- Replacing the sample size or amount requirement with a requirement that the sample be appropriate to the material being tested
- Replacing the interpretation of test results paragraph under § 610.12(c) with a requirement that manufacturers establish, implement, and follow written procedures for sterility testing that describe, at a minimum, the test method used, the method of sampling, and the written specifications for acceptance or rejection of each lot
- Simplifying the Exceptions paragraph under § 610.12(c)

According to the Agency, the update is intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products.

Industry comments to the modifications were positive. Many firms agreed that the rule needed to be updated and had similar concerns.

For example, GlaxoSmithKline said in comments submitted on Sept. 6 that it "fully supports this proposed rule and agrees that it will provide manufacturers of biological products greater flexibility, will promote improvement and innovation in the development of sterility test methods, and will allow manufacturers to use the most appropriate and state-of-the-art test methods for assuring the safety of biological products."

WuXi AppTec, a pharmaceutical, biotechnology, and medical device research and development (R&D) outsourcing company, said in its Sept. 19 comments that it supported all proposed amendments, "specifically, the use of alternative methods and tests systems other than the traditional culture based methods and the proposed validation and verification requirements. The use of 'growth promoting properties' rather than 'growth promoting qualities' ; we feel use of the term 'properties' imparts requirements to understand the components that promote microbiological growth in test systems. Throughout when requirements are deleted or revised, listed alternatives assist industry in understanding acceptable options."

In comments dated Sept. 6, ISPE said that it "fully supports this proposed rule and agrees that it will provide manufacturers of biological products greater flexibility, will promote improvement and innovation in the development of sterility test methods, and will allow manufacturers to use the most appropriate and state-of-the-art test methods for assuring the safety of biological products. We have no other comments on the proposed changes and would encourage their implementation."

The Plasma Protein Therapeutics Association said on Sept. 19, "In general, FDA's proposed amendments to 21 CFR parts 600, 610, and 680 are favorable. FDA's proactive approach offers greater flexibility and leaves responsibility to companies to determine appropriate testing scenarios; this flexibility will allow application of alternative sterility test methods (e.g. culture-based or non-culture-based rapid methods). Many of the proposed changes appear to eliminate older (i.e., outdated and obsolete), detailed prescriptions regarding the sterility test methodology (e.g., number of samples, sample volume, composition of nutrient media, detailed description of growth promotion tests, etc.) that are inconsistent with the current United States Pharmacopeia (USP) and European Pharmacopeia (Ph. Eur.) chapters on sterility testing."

PDA commented on the regulation through the periodic review of existing regulations on June 27. One of its comments about the specific sterility method outlined in 21 CFR 610.12 was addressed in the proposed amended rule. "Based on the fact that many current biologics are not considered to have a "sterile bulk stage," performing a sterility test on the bulk material is of no value in this case and because of the complex-

ity of obtaining a sterile bulk sample after sterilizing filtration may actually contribute to potential contamination of the product, PDA proposes this regulation be modified to require bulk sterility testing for those bulk materials that cannot be filtered through one or more sterilizing filters prior to filling." **[Editor's Note:** PDA's comments can be found on pg. 52 of the November/December 2011 *PDA Letter*.**]**

A few pharmaceutical companies asked the Agency for further clarification about the standard reference test.

For example, Sanofi Aventis, on September 16, wanted to know if the pharmacopoeial sterility test would be considered as a standard reference test, particularly in the case of questions over batch sterility. The Biotechnology Industry Organization, which provides advocacy, business development and communications services, on September 19 also asked for clarification regarding validation of novel methods and any methods that could potentially deviate from the USP compendia.

Sanofi and Bio asked that the new version of the rule reference the harmonized ICH sterility test method as the compendial method. Sanofi said, "In the global marketplace, a novel method different from the USP <71> would no longer be harmonized with EP, JP, other compendia and might pose risks to approval of marketing authorizations if new tests are not recognized or accepted by foreign Health Authorities."

PDA proposed that the specific sterility method outlined in 21CFR 610.12 be removed and that reference to appropriate compendia sterility tests or other scientifically supportable test methods as outlined in the license application. Celenge, a multinational biopharmaceutical company on September 12, agreed saying, though FDA may approve of the use of alternate sterility methods, "these would not be globally applicable in the absence of compendial harmonization." Jubilant HollisterStier on September 16 also said that the "baseline or standard for sterility testing should be listed in the regulations as USP chapter <71> and European Pharmacopiea 2.6.2."

The FDA is still in the process of reviewing comments that it received.

Task Force Corner continued from page 36

PDA Letter: What are the backgrounds of the people on the task force?

Mathews: We are fortunate to have a very diverse team of experts that provide viewpoints from various pharmaceutical companies, pharmacies, clinical research units, USP, U.S. FDA and academia. This has enabled us to thoroughly analyze this topic and arrive at appropriate quality requirements for these type of operations in a variety of settings and consider a variety of governing regulations. The people on our team are also very interested in this topic, see the value that it adds and have been very diligent in assisting with the preparation of the document. All members clearly have patient safety in mind, while desiring to provide needed guidance which will also increase the efficiency of the drug development process.

PDA Letter: Do you think the technical report will be done by the end of this year?

Mathews: The working draft of the technical report has been through a couple of review cycles, including a review by Regulatory Affairs/Quality Advisory Board. We are now in the process of verifying our interpretation of governing regulatory requirements with the relevant regulatory agencies. Subsequently, the technical report will be ready for review by a wider PDA audience, including the PDA Clinical Trial Material Interest Group. We hope to be able to finalize the technical report by the end of 2012.

PDA Letter: Would you like to add anything else?

Mathews: PDA task forces serve as an important role in helping to clarify positions on important topics which ensure patient safety and improve operations. This is invaluable to not only pharmaceutical company personnel who have responsibilities in these areas, but serve as valuable guidance for regulatory agencies. The support of PDA in helping to facilitate the formation and operation of these teams is much appreciated and is an essential part of the role that the PDA serves.

For more information on any interest group or task force or to volunteer, email **Iris Rice** at rice@pda.org.

Members of the Task Force

Co-Leader **Kathleen Greene,** Novartis

Amy Antipas, Pfizer

Bob Dana, PDA

Cathy Moll, Covance

Gerald Finken, CSM

Lesley Dandoy, AstraZeneca

Loyd Allen, PhD, International Journal of Pharmaceutical Compounding

Mark Leney, PhD, University of Massachusetts

Paul Cummings, PJC Pharma Consulting

Richard Hoffman, Eli Lilly and Company

William Marinaro, Merck

About the Expert

Vince Mathews is currently the President of Mathews Quality Consulting. In this position, Vince offers consulting and auditing on the GMPs, for both development and commercial operations. Prior to this, Vince served in various quality positions within Eli Lilly and Company for 34 years. Vince is an ASQ certified Pharmaceutical GMP Professional.

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

Draft Guidance Released on Heparin for Drug and Medical Device Use

The U.S. FDA has released a draft guidance, entitled, *Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality*. The draft guidance is intended to alert manufacturers of active pharmaceutical ingredients, pharmaceutical and medical device manufacturers of finished products, and others to the potential risk of crude heparin contamination.

The document provides recommendations to better control the use of crude heparin that might contain oversulfated chondroitin sulfate (OSCS) or non-porcine material (especially ruminant material) contamination and suggests strategies to test for contamination.

The draft guidance should be used in addition to the USP monograph testing required for other forms of heparin to detect the presence of OSCS.

Comments are due by April 13.

U.S. FDA Releases Three Draft Guidances on Biosimilars

The U.S. FDA has announced the availability of three draft guidance documents on biosimilar products.

The *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* draft guidance is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application.

The Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product draft guidance provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application.

The *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009* draft guidance provides answers to common questions from people interested in developing biosimilar products.

The documents provide the Agency's current thinking on key scientific and regulatory factors involved in submitting biosimilar applications under the abbreviated approval pathway that was approved in March 2010.

Comments are due on April 16. **[Editor's Note:** See related story on page 38.**]**

U.S. FDA Releases Product-specific Bioequivalence Recommendations

The U.S. FDA has provided draft and revised draft product-specific bioequivalence (BE) recommendations on the design of BE studies to support abbreviated new drug applications.

The BE recommendations identified were developed using the process described in the *Bioequivalence Recommendations for Specific Products* draft guidance.

Comments are due March 26.

Europe

EC Requests Consultation on Extending GMP to Active Substances

The European Commission (EC) is requesting comments on its concept paper on extending the GMP for medicinal products to cover active substances. The concept paper is part of the implementation of Directive 2011/62/EU which requires the Commission to adopt, by means of a delegated act, the principles and guidelines of good manufacturing practice for active substances. Adoption of the GMP rules from this process is planned for 2013.

Comments are requested by April 20.

EMA Issues Draft Guidance on how to Evaluate Potential Risks via a Risk-based Approach in ATMPS

The European Medicines Agency has issued a draft guideline on how to evaluate potential risks via a risk-based approach in advanced therapy medicinal products (ATMPS).

The aim of the risk-based approach is to help the applicant of a Marketing Authorisation Application (MAA) determine the extent of quality, non-clinical and clinical data that should be included in the MAA.

It is anticipated that on completion of the profiling of the identified risks/risk factor combinations, a specific profile for each risk can be concluded.

The deadline for comments is June 30.

Key Regulatory Dates

Comments Due:

March 26 — U.S. FDA product-specific bioequivalence recommendations draft guidance

April 13 —U.S. FDA Heparin for Drug and Medical Device Use draft guidance

April 16--Biosimilar draft guidances

April 20 — EC consultation about extending GMP to active substances

June 30 — EMA draft guidance on how to evaluate potential risks via a ATMPS risk-based approach

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PDA Single Use Systems Workshop –

Following the 2012 PDA Annual Meeting

Knowledge Enables Implementation – A Consensus Approach

April 18-19, 2012

JW Marriott Desert Ridge Resort | Phoenix, Arizona

The advantages of Single Use Systems are clear: reduced up-front capital investment in fixed systems, the flexibility in processes to adapt to changing market requirements or process modifications, savings in cleaning and associated cleaning validation and decreased facility renovation and start-up, among other advantages.

Join PDA for the *PDA Single Use Systems Workshop* to explore these advantages and the practical application (qualifications, implementation and regulatory issues) associated with Single Use Systems.

Top regulatory and industry advisors speaking at this year's workshop include:

- **Ingrid Markovic**, PhD, Expert Review Scientist, *CDER, FDA* (via teleconference)
- **Tor Graberg**, Chair of PIC/s and Head of Inspection, *Medical Products Agency (MPA)*
- **Robert Repetto**, Director, External Affairs, *Pfizer, Inc.*
- **Morten Munk**, Vice President, Business Development, *CMC Biologics A/S*
- **Niels Guldager**, Senior Consultant, *NNE Pharmaplan*
- **Duncan Low**, PhD, Scientific Executive Director, *Amgen, Inc*
- **Jeffrey Carter**, PhD, Director, Filtration Research and Development, *GE Healthcare*
- **Paul Priebe**, Director of Marketing, *Sartorius Corporation*
- **Russell Wong**, PhD, Manufacturing Sciences, *Bayer HealthCare LLC*
- **Stephen Brown**, PhD, Chief Technology Officer, *Vivalis*
- **Robert Shaw**, Technical Director, *Ark Therapeutics*
- **Christopher J. Smalley**, PhD, Associate Director, Bio/Sterile Manufacturing, *Merck*
- **Jerold Martin**, Senior Vice President, Global Scientific Affairs, *Pall Corporation*
- **Andy Walker**, PhD, Senior Director, Manufacturing, *CMC Biologics*

Please join us for *can't miss* information crucial to professionals using or considering using Single Use Systems.

Visit www.pda.org/singleuse2012 for more information.

Exhibition: April 18-19

Photo courtesy of Sartorius Stedim Biotech

2012 PDA ANNUAL MEETING

Last Chance: Register for the Annual Meeting

Phoenix, Ariz. • April 16-20 • www.pda.org/annual2012

2012 Program Planning Committee

Still trying to convince your supervisor to let you attend PDA's Annual Meeting? Share this article with them and hopefully, you will be booking your ticket to Phoenix, Ariz. in no time!

On the first day of the meeting, an opening plenary session with **David Shanahan**, President, Mary Crowley Research Center and President, CEO and Founder, Gradalis, and **Ted Love, MD,** Executive Vice President, R&D and Technical Operations, Onyx Pharmaceuticals, will expound on the advances in gene and cellular therapy.

The meeting will then be divided into three tracks:

- Innovation and Productivity in Large Scale Manufacturing
- Personalized Medicine/Cellular Therapeutics
- Control Strategies for Biopharmaceuticals

Countless ancillary meetings for the advisory boards, task forces and interest groups will also be held throughout the meeting.

On the last day of the meeting, Wednesday, April 18, we will hold a breakfast session that is new this year! This session will detail the quality and regulatory job market outlook in 2012. We felt this session was necessary as the demand for quality, manufacturing and regulatory professionals is on the rise. Increased globalization is also changing geographic trends for many parts of the biotechnology and pharmaceutical industries, while emerging technologies such as cellular based therapies are creating demand and new "hot" spots. In addition, the growth of regulatory agencies and overall enforcement climate is creating new opportunities in the consulting and third party support industries.

At this session, a panel of executives from biotech companies, consulting firms and the public sector will discuss trends they see in job market for manufacturing, quality and regulatory arenas and the hiring profiles they will be looking for in 2012.

Don't miss this unique opportunity to hear from the hiring executives themselves! These names include industry and regulatory experts, such as:

- **Harold S. Baseman,** Chief Operations Officer, ValSource
- **Ursula Busse,** PhD**,** Head of Project Office, Global Biopharmaceutical Operations, Novartis Pharma
- **Steven Lynn,** Acting Director, Office of Manufacturing and Product Quality, CDER/OC, U.S. FDA
- **Morten Munk,** Vice President**,** Business Development, CMC Biologics
- **Lisa Skeens,** PhD, Vice President, Global Regulatory Affairs and Pharmaceuticals, Baxter Healthcare
- **Anders Vinther**, PhD, Vice President, Quality Biologics, Genentech

If that wasn't reason enough to attend, additional regulators have been confirmed for the closing plenary session!

Since the healthcare product industry is facing changes and challenges as a result of innovative products, new technologies, expanded supplier networks and the growing needs of public health, "Tried and true" traditional methods may not offer the optimal approach to process design, manufacturing, process control, quality assurance and regulatory compliance as they once did. New approaches are needed.

However, this raises many questions, such as:

How will the industry and regulators change current approaches in order to meet these new challenges? How can industry and regulators work together to make these changes and develop these new approaches? How can industry and regulators anticipate the challenges they may face and the changes needed to meet those challenges in the future?

The following regulatory experts will answer those specific questions and more at the panel discussion:

- **Steven Lynn,** Acting Director, Office of Manufacturing and Product Quality, CDER/OC, U.S. FDA
- **Emily Shacter,** PhD**,** Chief, Laboratory of Biochemistry, CDER, U.S. FDA
- **Andy Hopkins**, Sterile Products Inspector, Medicines and Healthcare Products Regulatory Agency
- **Tor Gråberg,** Chair of PIC/s and Head of Inspection, Medical Products Agency

Following the meeting, the Training and Research Institute will also hold eight courses on PDA's technical reports and paradigm change in manufacturing operations documents, which reflect the best practices currently available in the industry from April 19-20. To learn more, turn to page 58.

Hopefully, we will see you at the meeting! Visit www.pda.org/annual2012 to register or for more information.

Hungry for More Knowledge?

The Single Use Systems (SUS) Workshop will start at the conclusion of the 2012 Annual Meeting. This new technology offers several challenges which must be overcome for successful implementation. This workshop, held April 18-19, will help guide participants through these challenges by helping them to ask the right questions when considering SUS implementation. For more information and to register, please visit www.pda.org/singleuse2012

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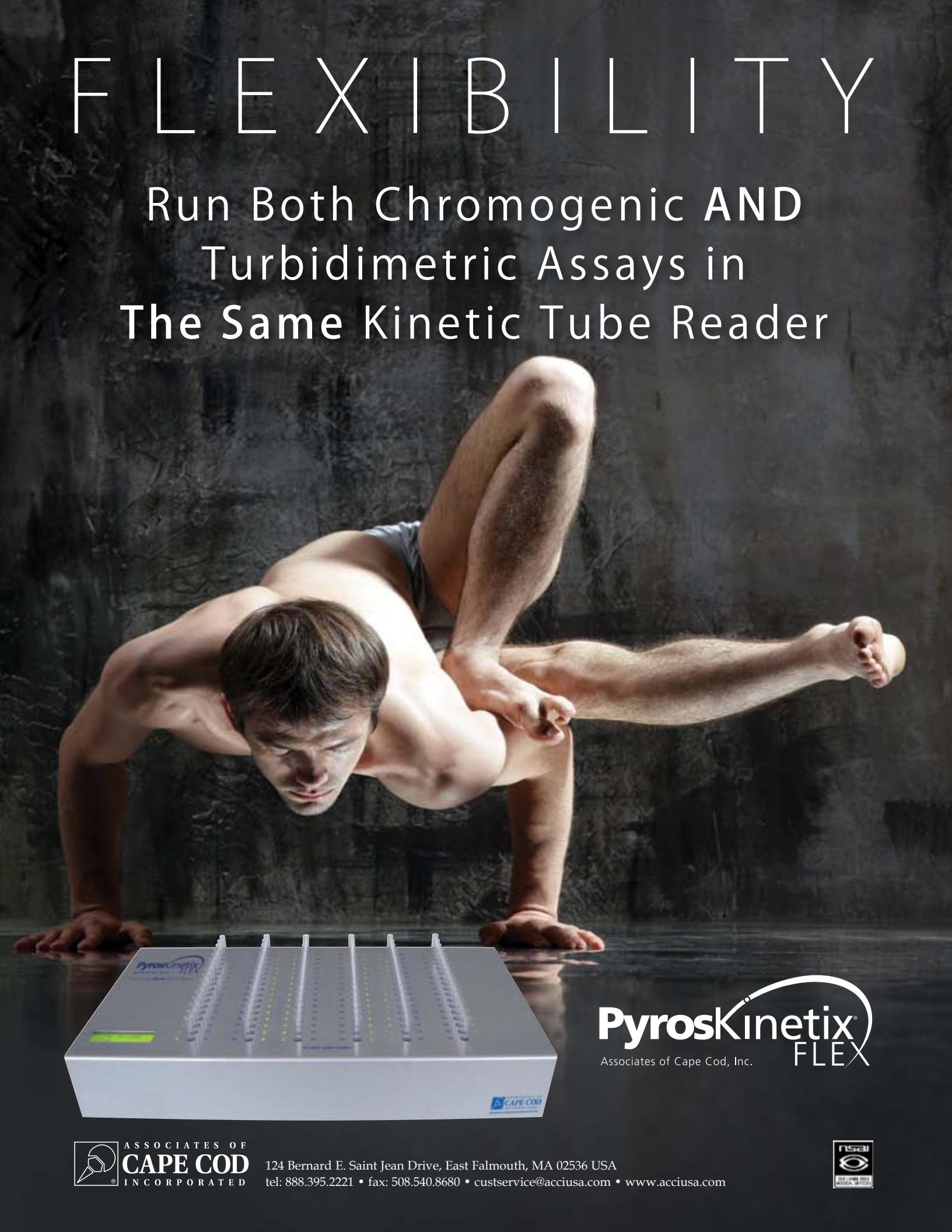

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Cell Substrate Susceptibility Covered at Conference

Bethesda, Md. • May 15-17 • www.pda.org/virustse2012

Kurt Brorson, PhD, U.S. FDA and Hannelore Willkommen, PhD, RBS Consulting

The *FDA/PDA Virus & TSE Safety Conference: Proactive Approaches to Mitigate Virus & TSE Risk,* held on May 15–17 in Bethesda, Md., will provide a forum for discussion between the industry and regulatory bodies. The effectiveness of current virus removal technologies and the current knowledge about cell substrate susceptibility to TSE agents are the major topics of this conference.

The first day will center on the discussion of the significant body of data which have been accumulated over the past 20 years demonstrating virus removal by specific unit operations used for production of mAbs (low pH, AEX, virus filters). The modular approach or the use of in-house data has been proposed for some unit operations; for others, investigations are still needed to fully understand the mechanism of viral clearance and associated critical process parameters. Furthermore, the different elements of the QbD approach related to viral safety will be discussed and demonstrated that an adequate control strategy can be developed on the basis of DOE experiments.

On the second day, the epidemiology of Hepatitis E virus (HEV) will be taken into consideration: the presence of HEV may affect the safety of human plasma products and it may be a risk for raw materials like trypsin derived from porcine tissues. Risk mitigation strategies for raw materials to prevent contamination of bioreactors as well as selection of appropriate model viruses and quality attributes of virus preparations used for virus clearance studies will be covered.

The focus will turn to TSE on the third day. Cell substrates used for vaccines or for biotechnology products could be inadvertently exposed to TSE agents from cell culture reagents. It has also been proposed that spontaneous development of TSE infectivity could occur in PrP-expressing cell lines. The in-vitro mechanisms of TSE infectivity, current state of knowledge about cell substrate susceptibility to TSE agents, and experimental and regulatory approaches to this issue will be discussed. The development of in-vitro infectivity assays, challenges, and what criteria may scientifically assure that in vitro infectivity assays could be adequate replacement for in vivo assays will be reported as well.

We look forward seeing you May 15-17 in Bethesda, Md. for this unique and interactive learning opportunity!

Best Practices Reviewed at Glass Quality Conference

Washington, D.C.• June 4-7 • www.pda.org/glass2012

Program Planning Committee

In the recent past there have been several recalls and increasing concerns about pharmaceutical glass packaging, both with regard to defects and/or incompatibilities with finished product over the shelf life.

Standards, glass supplier reliability and pharmaceutical manufacturer handling and distribution best practices are all necessary elements to maintain container integrity and product sterility assurance throughout the product lifecycle of sterile injectable pharmaceutical and biopharmaceutical products. In the recent past, there have been several recalls and increasing concerns about pharmaceutical glass packaging, both with regard to defects and/or incompatibilities with finished product over the shelf life.

Pharmaceutical manufacturers, regulators, and glass suppliers all share a common goal of assuring the highest quality products (including packaging) for patients. The *PDA FDA Glass Quality Conference* on June 4-5 will discuss these issues, best practices to preventing and/or detecting at-risk glass packaging, and review current expectations to ensure that recalls are avoided and container closure integrity is assured.

Conference session topics include discussions on:

- Development Considerations/Glass
- Pharmaceutical Packaging in Glass
- Glass Handling Equipment Manufacturers Perspective
- Quality Control Issues
- Distribution/Packaging/Transportation
- Monitoring Customer Feedback & Other Factors to Consider in Glass Defect Prevention
- What Are We Going To Do To Make It Better?

Pharmaceutical and biopharmaceutical professionals in the following areas are encouraged to attend:

- Quality assurance
- Packaging
- Supplier control
- Glass suppliers
- Product development

Two one-day TRI courses will be offered from June 6-7. The course on June 6 will be on PDA's *Technical Report No. 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing*. The course on June 7 will cover the selection and utilization of glass containers in pharmaceutical packaging.

To view more information or to register for this upcoming event, visit www.pda.org/glass2012.

PDA and FDA Host Joint Regulatory Conference for 21st Year

Baltimore, Md. • September 10-14 • www.pda.org/pdafda2012

Committee member David Cummings, U.S. FDA

Together PDA and the U.S. FDA are changing the future of the medical products industry. The PDA/FDA Conference Planning Committee invites you to attend the jointly sponsored *2012 PDA/FDA Joint Regulatory Conference* in Baltimore, Md.

On September 10–12, the conference and sponsor exhibition will be held at the Baltimore Marriott Waterfront Hotel and will be followed by seven courses held on September 13–14 at the same location.

For those who are unfamiliar with our PDA/FDA conference, sharing the missions of FDA and PDA can help you understand the genesis of this conference and the partnership that has been formed.

FDA is charged with protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

Specifically, FDA is responsible for advancing the public health by:

- Helping to speed innovations that make decisions and foods safer and more effective
- Providing the public with accurate, science-based information they need to use medicines and foods to improve their health
- Regulating the manufacture, marketing, and distribution of tobacco products to protect the public and reduce tobacco use by minors
- Addressing the Nation's counterterrorism capability and ensuring the security of the supply of foods and medical products

PDA supports the advancement of pharmaceutical technology by promoting scientifically sound and practical technical information and education for the industry and regulatory agencies.

The overlap in the mission statements for PDA and FDA establishes the basis for the annual, collaborative opportunity for these organizations coming together with a common goal of sharing information on important and critical issues that include:

- Best practices that can be learned from peers and implemented by others in the pharmaceutical and devices industry on topics such as communicating the business case for quality, tracking and trending of compliance data, establishing a framework for quality vigilance, etc.
- Establishing and maintaining a state of control throughout the drug product lifecycle
- Challenges with assuring quality and reliability of outsourced functions and purchased materials
- Emerging areas and risk-based approaches that cover decision making theory, combination products, root cause analysis for recalls, manufacturing failure modes, signal detection, etc.
- Understanding how to integrate quality and compliance into the global business platform
- Leveraging results conveyed by peers to drive continuous improvement

It is apparent why these two organizations are coming together for the 21st year to address the pharmaceutical and medical device industries.

Although the medical products industry, is more than a decade into the new millennium and nearly a decade into the Food and Drug Administration's Good Manufacturing Practices for the 21st Century (Product Quality) initiative, we must continue to strive to improve the quality, compliance, and security of our products around the globe. By attending the conference and sharing in the conversations on this new paradigm, you will have the opportunity to interact with FDA, PDA, industry representatives, and other experts as we continue our exploration of topics, including:

- Risk management and quality risk management systems
- Quality systems
- Quality by design
- Science-based decision making
- Design space
- Innovation and collaboration with the goal of advancing the industry and impacting public health on a global scale

Please join us September 10-14 for the 21st PDA/FDA Joint Regulatory Conference. We promise to offer you another outstanding experience (whether it is your first or twenty-first conference) and access to the leaders and experts in the industry.

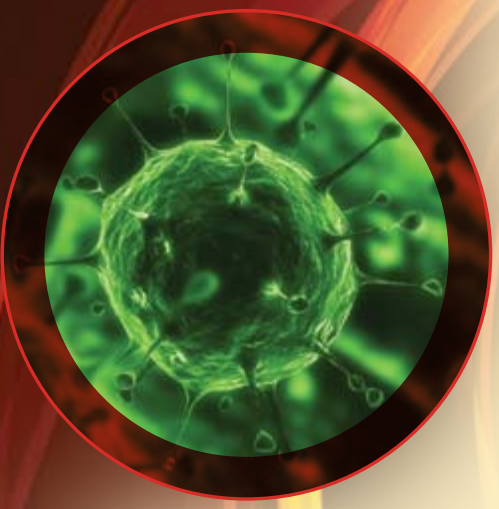
To learn more, view www.pda.org/pdafda2012.

PDA is planning to run seven courses at the PDA/FDA meeting. For more information, view www.pda.org/pdafda2012

Register by **April 13th** – the last registration savings deadline for this event!

PDA/FDA Virus and TSE Safety Conference

Proactive Approaches to Mitigate Virus & TSE Risk



May 15-17, 2012

Hyatt Regency Bethesda | Bethesda, Maryland

There is worldwide regulatory and industry recognition that challenges, gaps **and opportunities exist** for improvement of viral clearance technology.

As freedom from viral contaminants continues to be a paramount concern for recombinant biopharmaceuticals and plasma-derived medicinal products, PDA is gathering top regulatory, industry, health and academic professionals to discuss and demystify the underlying science of virus and TSE safety.

HOT TOPIC at this Year's Meeting: TSE Safety of Cell Substrates

Cell substrates used for vaccines or for biotechnology products could be inadvertently exposed to TSE agents from cell culture reagents, animal-derived enzymes, or raw materials used for manufacturing. Discuss in vitro mechanisms of TSE infectivity, current state of knowledge about cell substrate susceptibility to TSE agents, and experimental and regulatory approaches to this issue.

Presentations from experts on this topic include:

- Potential for Cell Substrate Exposure to TSE Agents and FDA Regulatory Approach to TSE Safety of Cell Substrates, **David Asher**, Supervisory Medical Offer, *CBER, FDA*
- Relationship Between Infectivity and Abnormal Prion Protein, **Pedro Piccardo**, Biologist, *CBER, FDA*
- Risk Assessment Approaches for Cell Substrates, **Nathan Roth**, PhD, Director, Virology and TSE Pathogen Safety, *Grifols, Inc.*
- Prp-res Uptake by Cells – Correlates of Uptake, Strain and Cell-type Independence, **Suzette A. Priola**, PhD, Investigator, Laboratory of Persistent and Viral Diseases, *NIAID, NIH*
- Q&A/ Panel Discussion Panel
  - **David Asher**, Supervisory Medical Offer, *CBER, FDA*
  - **Johannes Bluemel**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*
  - **Gerald Feldman**, Research Biologist, *CDER, FDA*
  - **Pedro Piccardo**, Biologist, *CBER, FDA*
  - **Suzette A. Priola**, PhD, Investigator, Laboratory of Persistent and Viral Diseases, *NIAID, NIH*
  - **Nathan Roth**, PhD, Director, Virology and TSE Pathogen Safety, *Grifols, Inc.*

Visit **www.pda.org/virustse2012** to download the conference brochure and register!

Pre-Conference Workshop: May 14 | Exhibition: May 15-16 | Courses: May 18

CMC Workshop Addresses QbD Approaches for Vaccines

Bethesda, Md. • May 14 • www.pda.org/CMC2012

Michael P. Schwartz, PhD, GSK-Biologicals

This year's *Applying QbD Principles in Vaccine Development: PDA/FDA CMC Workshop*, is scheduled for May 14 and will feature sessions related to the implementation of a Quality by Design (QbD) approach for the development of vaccines.

A consortium of vaccine manufacturers has created a case study describing development of the fictitious vaccine—A-Vax.

The biopharmaceutical development and manufacturing strategy for A-Vax was guided by the product's quality target product profile. QbD principles were applied from the onset of product definition and development, and intended to ensure:

- The product is designed to meet patient safety and efficacy requirements
- Critical sources of variability are identified and controlled through appropriate control strategies
- Process is designed to consistently meet product critical quality attributes (CQAs)
- Process is continually monitored and evaluated to ensure that product quality is maintained throughout the product lifecycle
- Updates to the control strategy are made when necessary

The goal of the workshop is to initiate a discussion of the case study and to provide a review of the QbD approaches employed for the development of A-Vax.

One of the workshop's sessions will be dedicated to exploring an approach to developing CQAs and a control strategy for the vaccine.

Potential CQAs were selected on the basis of prior knowledge and current understanding of structure-function relationships, and a risk-assessment tool was developed and applied to each quality attribute. CMC-related activities focused on refining structure-function relationships and their impact on safety and efficacy. This information was used to iteratively update the CQA risk assessments throughout the product lifecycle. The CQAs in combination with the unique properties of A-Vax and identified key process performance attributes were then used in development of the vaccine's control strategy.

This included the coupling of vaccine release with quality requirements to help assure acceptable vaccine properties throughout the products shelf-life. In addition, key assays, such as potency assays, were developed to the same standards as the product, employing quality by design principles to assure reliable measures of vaccine quality.

Due to the strategic nature of vaccine quality measurements, the workshop will also emphasize the roles and distinctions between specifications and control limits as well as proper analysis of vaccine quality measurements.

Critical quality attributes and their specifications were the foundation for the identification of critical process parameters and itstheir ranges.

Vaccine unit operations throughout the process were evaluated, both scientifically and experimentally, to optimize the process and identify the regions throughout the process space, which yielded acceptable product performance. Thus, experiments were performed at a small scale to link process parameters to process performance, while the robustness of the control strategy was monitored at a large scale through continuous verification.

The control strategy can be described as a living plan, which is modified and improved throughout the lifetime of a vaccine. The control strategy for A-Vax was based on a lifecycle management point of view and encompassed a comprehensive approach. Early development experience such as identification of potential critical quality attributes together with prior knowledge was built upon throughout development. Nonclinical and clinical experiences, in addition to key process performance attributes, were also used to identify analytical and process control parameters as well as their appropriate specifications and operating ranges.

The workshop marks a significant opportunity to expand critical discussions on the implementation of QbD concepts in vaccine development within the vaccine community

A session at the workshop will discuss how the final control strategy was the synthesis of early through late process, analytical, preclinical and clinical experiences.

Furthermore, discussion will encompass the importance of sound scientific and risk-based approaches in the development of the control strategy and their importance in providing greater confidence in product quality and process control.

We anticipate an exciting opportunity to discuss the case study document, which will be made publicly available in early 2012.

The workshop marks a significant opportunity to expand critical discussions on the implementation of QbD concepts in vaccine development within the vaccine community. We hope you will be able to join us at the worksho which will be held in Bethesda, Md. on May 14. For more information, view www.pda.org/cmc2012.

Register for this workshop and the *PDA/FDA Virus & TSE Safety Conference* and Save $150!

The Parenteral Drug Association presents the...

Applying QbD Principles in Vaccine Development: PDA/FDA CMC Workshop

Implementing Quality by Design Principles in Vaccine Development: A-Vax Case Study

May 14, 2012

Hyatt Regency Bethesda | Bethesda, Maryland

Brochure Just Released!

Five vaccine manufacturers (GlaxoSmithKline, MedImmune, Merck, Pfizer and Sanofi Pasteur) formed a collaboration to tackle the shared goal of preparing a case study illustrating how Quality by Design (QbD) can be applied to vaccine development.

The *Applying QbD Principles in Vaccine Development: PDA/FDA CMC Workshop* will stimulate discussions within industry as well as between industry and regulatory agencies to better understand the challenges associated with attempting to apply QbD to vaccine development; including Critical Quality Attributes (CQA) and a control strategy for the vaccine.

Plenary sessions include:

- A-Vax: A QbD Case Study and Study Guide
- Case Study for Post Approval for Drug Substance
- Case Study in a Post Approval Change for Drug Product
- Brining It All Together and Next Steps

Attend this year's workshop as it marks a significant opportunity to expand critical discussions on the implementation of QbD concepts in vaccine development.

Visit **www.pda.org/cmc2012** for more information.

Exhibition: May 14

Decode Sterile Product Manufacturing Issues

Chicago, Ill. • June 18-21 • www.pda.org/steriletechnology2012

Committee member Hal Baseman, ValSource

The sterile healthcare products industry has always faced challenges. However, today we seem to have added complexities. Companies are relying more on outsourcing and supplier sources for knowledge and support. Global regulatory authorities expect organizations to use complete process understanding and good scientific product quality risk criteria to make and justify manufacturing decisions. New product configurations and manufacturing technologies must be considered to design effective processes. It is more important than ever to be aware of the trends in our industry, to keep up with new information and to understand the implications and requirements these challenges present.

This summer*, PDA will hold an important conference, which can help you obtain the knowledge needed to address the complexities of today's manufacturing. The *Innovation & Best Practices on Sterile Technology Conference* will be held on June 18-June 19 at the Conrad Chicago in Chicago, Ill.

The conference will focus on:

- The state of sterile product manufacturing for the healthcare industry
- Updates on regulatory expectations
- Innovative technologies
- Process design and decision making methods
- Sources of valuable knowledge

The conference organizers have invited sterile processing industry experts and regulators to present papers, provide case studies, meet with attendees and answer questions on:

- The practical application of quality risk management principles to design effective aseptic processing and product sterilization programs
- Methods to identify, control and remediate bioburden, biofilm and other sources of microbiological contamination
- The selection and use of evolving, novel and alternate sterilization methods
- New sterile product manufacturing facilities, utilizing innovative technologies and approaches
- Regulatory requirements, expectations and trends

* While technically this conference occurs in late spring, we have been assured by the committee leaders that the weather will be positively spectacular, absolutely beautiful and summer-like. And if that wasn't enough, the location can't be beat—all the more reason to attend.

In addition, the conference will showcase a series of new and revised PDA technical reports on sterilization and aseptic processing. This offers the attendee a unique opportunity to meet with task force members to discuss the content and basis of the principles presented in the reports in an effort to further promote understanding of the technologies.

Four training courses based on technical reports will also be held after the conference.

Two newly developed courses are: "Validation of Dry Heat Processes," based on *PDA Technical Report No. 3, Validation of Dry Heat Processes Used for Sterilization and Depyrogenation* and "Parametric Release," based on PDA *Technical Report No. 30, Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat*.

The other two courses have been offered before. The courses are on moist heat sterilization, which is based on PDA *Technical Report No. 1, Revised 2007: Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control* and on steam sterilizers, which is based on PDA *Technical Report No. 48: Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance.*

Now that the conference format has been designed, the speakers are invited and the content is being developed, we need the most important element for an enlightened exchange of ideas—*you*, the industry professional. Attending and participating in this important conference, networking with colleagues, listening to common experiences and understanding expectations, will help provide the knowledge needed to meet the challenges of manufacturing sterile healthcare products in today's challenging regulatory and industry environment. Look for more information at www.pda.org/steriletechnology2012.

We hope to see you in Chicago, Ill. this spring.

PDA Technical Reports (TRs) to be discussed at this meeting!

Register Before **April 6th, 2012** and Save up to $400!

The Parenteral Drug Association presents the...

2012 PDA Innovation & Best Practices on Sterile Technology Conference

Sterility Assurance for Aseptic Processes and Terminal Sterilization

June 18-19, 2012 | Conrad Chicago | Chicago, Illinois

Agenda Now Posted!

The sterile healthcare products industry has always faced challenges however; today we seem to have added complexities. Companies are relying more on outsourcing and supplier sources for knowledge and support. Global regulatory authorities expect organizations to use complete process understanding and good scientific, product quality risk criteria to make and justify manufacturing decisions.

The *2012 PDA Innovation & Best Practices on Sterile Technology Conference* will help prepare you to better understand and meet the challenges of manufacturing sterile healthcare products in the modern global technological and regulatory environment.

Take a look at some of the sessions from this year's exciting agenda:

- **Contamination Control and Remediation:**
  - Biofilm Prevention and Eradication: Treatment Efficacy Evaluation via an in vitro Model, **Mark Pasmore**, PhD, Senior Principal Engineer, *Baxter Healthcare*
  - The Challenges of Remediating Low-Level Bioburden in a Purification Column at an Intermediate Process Step, **Richard Pettijohn**, PhD, Staff Scientist, Pharmaceuticals Manufacturing Technology, *Bayer Healthecare*
  - PDA Biobudren and Biofilm Task Force Update, **Harold Baseman**, Chief Operations Officer, *Valsource LLC*
- **Application of TR1 Sterilization Science Concepts:**
  - Applications of Biological Indicators – FBio verses FPhy, **Michael Sadowski**, Director, Sterile Manufacture Support, *Baxter Healthcare Corporation*
  - Alternatives to An Over-kill Approach to Sterilization, **Jeanne Moldenhauer**, Vice President, *Excellent Pharma Consulting*

Immediately following the conference, the PDA Training and Research Institute (PDA TRI) will be hosting four stand-alone courses.

Visit **www.pda.org/steriletechnology2012** for more information and to register.

Courses: June 20-21

7th Annual Conference Premier Global Event for Microbiologists

Bethesda, Md. • October 22-26 • www.pda.org/microbiology2012

Co-chairs Ed Tidswell, Baxter Healthcare and Marla Stevens-Riley, U.S. FDA

In terms of pharmaceutical microbiology, the PDA's Annual Microbiology conference is arguably the premier global event.

There is no better venue to attend if you are a pharmaceutical microbiologist:

- Working in the lab, on the production floor or trapped at a desk
- Advanced in your career
- Entering the field
- Or, simply have an interest in the craft of microbiology associated with the manufacture, control, and testing of drugs, devices and biologics

PDA's 7th Annual Global Conference on Pharmaceutical Microbiology conference is renown as offering a unique forum for pharmaceutical microbiology experts from both industry and regulatory agencies to introduce best practices and innovations that can improve product and process quality.

This three-day event offers opportunities for you to receive the most up-to-date information on issues surrounding pharmaceutical microbiology and associated technologies through presentations, panel discussions, poster sessions, training courses and product vendor displays, coupled with the opportunity to network with leading scientists and engineers.

This year's conference will gather industry and global regulatory experts specifically to address microbial control issues. Key note, plenary and individual sessions will tackle a variety of topics concerning microbial control including endotoxins, pyrogens, biofilms, global regulatory challenges, and application of new/alternative/rapid technology. This year's conference will also address emerging issues of developing scientific competency and microbiological training in the future workforce in pharmaceutical manufacturing

Immediately following the conference, five courses will be held from April 25-26.

Join us and attend, contribute and become a part of *PDA's 7th Annual Global Conference on Pharmaceutical Microbiology* and TRI courses from October 22-26. Visit www.pda.org/microbiology2012 for more information or to register.

Global Supply Chain Integrity Reviewed at Conference

Bethesda, Md. • November 13-14 • www.pda.org/supplychain2012

Committee Co-chairs Steven Wolfgang, PhD, FDA and Lucy Cabral, Genentech

The program planning committee would like to invite you to attend the *2012 PDA/FDA Pharmaceutical Supply Chain Conference* on November 13-14 in Bethesda, Md.

Improving the integrity of the entire supply chain for pharmaceutical ingredients and finished products ultimately helps ensure the quality and safety of medicines for patients.

Globalization of pharmaceutical manufacturing and distribution is bringing manufacturers and suppliers to public forums to discuss how to manage emerging concerns, including illegal acts such as counterfeiting, diversion and intentional adulteration. Globalization is also prompting legislators and regulators to seek enhancement to existing standards and practices for improved supplier quality management, manufacturing and distribution. Regulators are also developing cooperative approaches to share information and the burden of oversight.

Management of today's globalized supply chains by manufacturers requires a greater volume of knowledge about suppliers, careful consideration of a multitude of factors and a variety of science- and risk-based approaches. There is a great deal of information to manage and a need for timely sharing of newly acquired knowledge about emerging risks in the global pharmaceutical supply chain. Cooperative efforts and innovation within industry and regulatory agencies aiming to enhance oversight and the integrity of pharmaceutical supply chains are starting to come to fruition.

Building on earlier PDA-cosponsored conferences and workshops, this conference will provide a forum for presentations by thought leaders and group discussions to foster implementation of innovative ideas for enhancing supply chain integrity to protect patients from potentially unsafe or ineffective medicines. This program will provide participants the opportunity to:

- Hear from senior personnel from the U.S. FDA and other regulatory agencies
- Share improvements in programs for supplier management and new technology
- Identify any barriers and associated actions to enable implementation of feasible solutions
- Learn about proven monitoring and testing methods as preventive measures
- Benchmark your systems with leading pharmaceutical companies

We encourage you to attend this conference to help in the development of initiatives to ensure the integrity of the global pharmaceutical supply chain.

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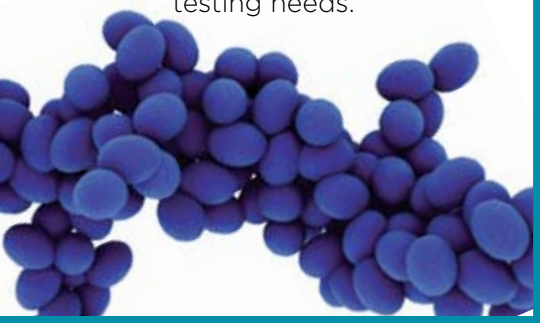

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Carol Lampe, JM Hansen & Associates

Long-time PDA member, contributor and TRI instructor for the "Recommended Practices for Manual Aseptic Processes" course, **Carol Lampe** has built her career in the area of aseptic processing.

She was a member of the PQRI Committee that evaluated the U.S. FDA draft guidance, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice.* She also was on the PDA training team, who along with the FDA, provided training and interpretation of the guidance.

Carol also served on the PDA task force for the original and revised PDA *Technical Report, No. 22, Process Simulation for Aseptically Filled Products.* Recently, Carol was the co-chair for the soon to be issued technical report, titled, *Recommended Practices for Manual Aseptic Processes*.

I think one of the greatest benefits is that this training is that the information imparted is the product of the experience of multiple industry experts

Course that you teach for PDA: "Recommended Practices for Manual Aseptic Processes"

How long have you been an instructor for PDA: It has been a number of years since I taught for PDA. I was one of the authors and original instructors for "The Investigation of Sterility Test Positives." I have more recently done training courses related to aseptic processing for other organizations.

What are the challenges/problems that this course identifies and offers solutions to? This course will outline methods and approaches for control and evaluation of aseptic processing operations for drug products/medicinal products which use all or partial manual procedures. Manual aseptic processing (MAP) operations differ from automated operations in several ways. These differences pose unique operational and evaluation challenges not generally encountered with automated operations. These challenges must be considered thoroughly when designing the evaluation procedure or protocol for the MAP operation.

What makes this course different than others which may be out there? I don't think there are any courses that specifically deal with MAP and the challenges associated with process design and evaluation. The guidance provided in this course builds on published guidances (e.g., PDA TR-22) that are generally more focused on automated large-scale operations.

Why should people attend this course over others? I think one of the greatest benefits is that this training is that the information imparted is the product of the experience of multiple industry experts, so it provides a good depiction of current practices.

What would you say to people considering taking a PDA course? When taking any PDA course, you are getting the latest information on a subject that you (or your company thinks) is important to your future. You are also meeting a group of individuals from other companies, the participants in the course, who have similar interests and with whom you can set up a network of future information sharing.

I think networking is one of the greatest benefits of PDA.

2012 PDA ANNUAL MEETING

"Recommended Practices for Manual Aseptic Processes" will take place on April 19 in Phoenix, Ariz. For more information or to register, visit pdaannualmeeting.org/courses

U.S. FDA Paves the Way for Biosimilars in US continued from page 38

months to review a firm's application to see if a product meets the biosimilar requirement. Once a product is deemed to be "biosimilar," it then is eligible to be considered "interchangeable," which means the product is expected to produce the same clinical result as the reference product in any given patient. However, this is a separate statute under the law.

FDA is seeking public comment on the draft guidance documents by April 16. PDA's RAQAB is currently forming a task force to comment on these documents.

The Universe of Pre-filled Syringes and Injection Devices

October 15-17, 2012 | Red Rock Resort and Spa | Las Vegas, Nevada

CALL FOR ABSTRACTS / CASE STUDIES

The 2012 Pre-filled Syringe Program Planning Committee invites you to submit a scientific abstract for presentation at PDA's 2012 Universe of Pre-filled Syringes and Injection Devices. The theme of this year's conference is: ***Integrating the Unmet Market Needs: Bringing it All Together for Tomorrow's Success.***

Suggested topics include, but are not limited to:

- **Advances in Primary Container/ Prefilled Syringe Technology:**
  - Analytical Characterization Methods
  - Quality Improvements
  - Protein/Syringe Interactions
  - New Materials/Injector Technologies
  - Multiple Chamber Injector
  - Safety Devices
  - Autoinjectors and Add-ons
- **Factors Influencing the Selection and Development of Delivery Devices:**
  - Human Factors
  - End User Needs and Perspectives
  - Interaction between Device and Syringe
  - Regulatory Filing Process
  - Impact of Drug Characteristics
- **Case Studies: Market and Regulatory**
  - Global Market Trends
    - Asia Market
    - Europe Market
    - Latin America Market
    - North America Market
  - Regulatory and Clinical Strategies
  - Combination Products
- **Case Studies: Manufacturing**
  - Vial to Pre-filled Syringe Conversion
  - Integration of PAT and Q8
  - Manufacturing Technologies Based on Disposable Processing Units
  - Material Selection
  - Stability Study Strategies
  - Aseptic Processing and Final Packaging Best Practices
  - Tech Transfer Best Practices
  - Contract Manufacturing Best Practices
  - Clinical Trails with Prefilled Syringes
  - Release Testing
    - Incoming Components
  - Microbial Control
  - Quality Agreements

Abstracts must be received by March 30, 2012 for consideration.

Pleas visit **www.pda.org/prefilled2012** to submit your abstract.

Case studies are particularly desired. Commercial abstracts featuring promotion of products and services will not be considered. After June 1, 2012, you will be advised in writing of the status of your abstract. PDA will provide one complimentary registration per podium presentation. Additional presenters and all poster 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.

QUESTIONS?

Contact PDA:
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Programs and Meetings
Tel: +1 (301) 656-5900 ext. 149
Fax: +1 (301) 986-0296
Email: lewis@pda.org

ALL ABSTRACTS WILL BE REVIEWED

All submitted abstracts will be reviewed by the Program Planning Committee for inclusion as a podium presentation or for poster presentation.

ATTENTION EXHIBITORS

PDA is seeking vendors who provide excellent products/services in support of this conference. Space is limited and is on a first-come, first-service basis. To reserve your space, please contact David Hall at hall@pda.org or +1 (301) 656-5900 ext.160.

www.pda.org/prefilled2012

2012 PDA ANNUAL MEETING

Six New TRI Courses Offered at Annual Meeting

Phoenix, Ariz. • April 19-20 • www.pdaannualmeeting.org/courses

Stephanie Ko, PDA

The PDA Training and Research Institute provides unique training courses that coincide with major PDA conferences so that attendees may have multiple educational opportunities in one trip. Attendees of the *2012 PDA Annual Meeting* will have the benefit of choosing from *eight* training courses immediately following the conference on April 19–20.

Frequent attendees may think they've seen it all, but they haven't! We will be offering six new courses at the Annual Meeting.

The new courses are based on PDA's very own technical reports and paradigm change in manufacturing operations documents, which reflect the best practices currently available in the industry.

Courses Offered on April 19

The "Reprocessing of Biopharmaceuticals" course will provide guidance for the development and execution for reprocessing plans for biotechnology-derived products. Attention will be given to regulatory and technological considerations when reprocessing. Participants will be able to apply the lessons learned from case studies of actual reprocessing activities to reprocessing options in their jobs.

The "Recommended Practices for Manual Aseptic Processes" course will discuss the challenges of manual aseptic processing and how to address the challenges associated with the design, operation and evaluation of manual aseptic procedures. Students will be able to apply the lessons learned to the design and conduct of manual aseptic processing operations at their own facility.

The "Investigating Microbiological Data Deviations" course will provide insights into both the regulatory and scientific considerations when investigating microbiological data deviations. By the end of the course, students will be knowledgeable in designing, conducting and documenting investigations of microbiological test data that deviate from anticipated results and trends. Participants will also be able to use flowcharts, checklists and process flow diagrams as they apply to the investigation process.

Courses Offered April 20

The "Process Simulation Testing for Aseptically Filled Products" course will update participants on the current scientific and regulatory advances in the design, conduct and interpretation of process simulations for a media fill. Topics include the concepts, principles and application of process simulation, use of risk management, environmental monitoring and documentation. Knowledge gained can be applied immediately to media fill operations in their own jobs.

Courses offered on April 19-20

The "Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotechnology Manufacturing Operations" course will build on the content and principles of ICH Q9. Participants will receive detailed guidance on the application and implementation of quality risk management throughout the product lifecycle of pharmaceutical and biopharmaceutical products.

The "Process Validation and Verification: A Lifecycle Approach" course will address the most current U.S. FDA recommendations to a process validation program based on the publication of FDA's Process Validation Guidance. Expectations for what is required to demonstrate that a manufacturing has been and remains in a state of validation will be covered, including the implementation of process validation and continued process verification from a practical perspective. Students will be able to utilize risk assessment and management tools for the process validation lifecycle.

Back by popular demand, on April 19-20, the "Biotechnology: Overview of Principles, Tools, Processes and Products" and "Sterile Pharmaceutical Dosage Forms" courses will be offered as well.

The "Biotechnology: Overview of Principles, Tools, Processes and Products" course is designed for everyone in biotech organizations, the experienced and non-experienced, to provide a fundamental understanding of the theory, principles, techniques and potential of this advancing field. Participants will understand the current applications of biotechnology and its products, the fundamental tools and how they are used in biotechnology, as well as key steps in the typical biopharmaceutical manufacturing process.

The "Sterile Pharmaceutical Dosage Forms" course will give an introduction to Sterile Dosage Forms and include topics, such as:

- Principles of Sterilization
- Cleanroom Facilities
- Dosage Form Development and Stability Requirements
- Processing the Dosage Form
- Regulatory Trends
- Pyrogens and Bacterial Endotoxin Testing

Don't lose the opportunity during PDA's Annual Meeting to expand your educational experience, meet the experts in the field and gain knowledge and tools that you can apply immediately to your job. Go to www.pdaannualmeeting.org/courses to learn more about each courses mentioned here. You can also go to www.pda.org/courses for a list of other training courses offered throughout the year.

The 2012 Aseptic Processing Training Program is **SOLD OUT!** Visit **www.pda.org/aseptic** to sign up to receive an email notice when registration opens for the next session.

Parenteral Drug Association Training and Research Institute (PDA TRI)

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals

May 2012

Environmental Mycology Identification Workshop
May 2-4, 2012 | Bethesda, Maryland
www.pda.org/mycology2012

PDA/FDA Virus and TSE Safety Conference Course Series
May 18, 2012 | Hyatt Regency Bethesda | Bethesda, Maryland
www.pda.org/virustse2012

- Viral Contamination and Remediation – New Course
- Basic Virology as it Applies to the Biopharmaceutical Industry – New Course

June 2012

PDA/FDA Glass Quality Conference Course Series
June 6-7, 2012 | Renaissance Downtown Hotel | Washington, DC
www.pda.org/glasscourses

- Technical Report 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing | June 6
- Selection and Utilization of Glass Containers in Pharmaceutical Packaging | June 7

Preparation of Virus Spikes Used for Virus Clearance Studies – New Course
June 19-20, 2012 | Bethesda, Maryland
www.pda.org/viruspikes

Virus Filtration – New Course
June 21-22, 2012 | Bethesda, Maryland
www.pda.org/virusfiltration

2012 PDA Innovation and Best Practices on Sterile Technology Conference Course Series
June 20-21, 2012 | Conrad Chicago | Chicago, Illinois
www.pda.org/sterilecourses

- Moist Heat Sterilization | June 20
- Steam Sterilizers: Getting it Right from the Beginning | June 20
- Validation of Dry Heat Processes – New Course | June 21
- Parametric Release – New Course | June 21

Basic Microbiology for the Pharmaceutical and Biopharmaceutical Industries – New Course
June 27-29, 2012 | Bethesda, Maryland
www.pda.org/basicmicro

July 2012

Quality Systems for Aseptic Processing
July 30 - August 3, 2012 |
Bethesda, Maryland
www.pda.org/qsaseptic

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

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.

Editor's Message

Cogs in the Machine

As we were preparing the March *PDA Letter*, I had to take off a day for jury duty. As I sat in the waiting room, I was struck by the shared responsibility we all have in our day-to-day lives. Just as the justice system relies on people coming in for jury duty, so a trial "by your peers" can be held; the *PDA Letter* depends on the *PDA Letter* Editorial Committee (PLEC) to ensure that articles follow current regulatory standards, and won't get us into hot water with anyone!

Without the PLEC, there wouldn't be a sounding board for our feature articles. The committee recently reviewed **James Akers** interview (page 28). One committee member looked at a passage in the article and felt that even though James' article was clearly expressing his opinion, we should not publish his sentiment. While we debated amongst ourselves here at PDA, the PLEC also debated. We finally decided to leave the sentence in—after all it is an opinion. These sixteen people time-and-time again review articles we send their way and have brought up questions that make us think and query authors with additional suggestions and questions. Without them, the Letter wouldn't be as strong as it is. So, a heartfelt "thank you" goes out to them.

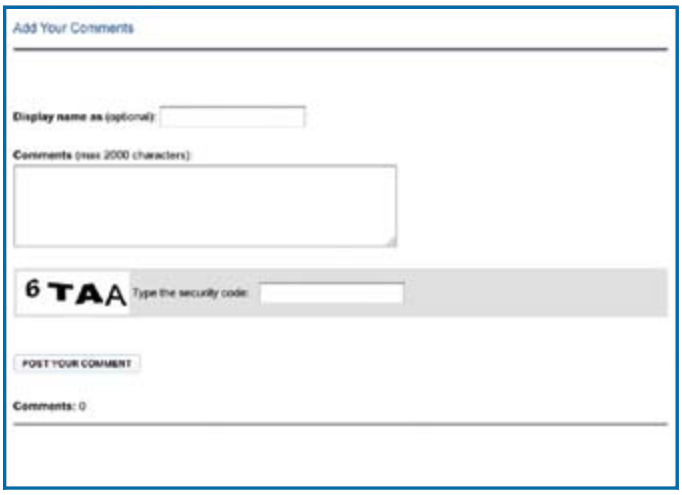
And, we can't do it without you. Every month we post a select number of articles from the current Letter to PDA's website at www.pda.org/pdaletter. Below each article is a comments box. However, we've noticed in recent months that we haven't had many comments. Let's change this streak. Comment on an article today!

You might have noticed a common theme in this issue: the *2012 Annual Meeting*. If you haven't already, I urge you to register for this meeting. If you need more incentive, read the issue! You'll find a feature articles on career development, advances in sterile technology as well as personalized medicines. We also have included the schedules of interest groups, task forces and advisory boards.

We had so much content for this issue that we had to move back one of the scheduled features on targeted drug delivery systems to next month!

We have also written in this issue about the biosimilar draft guidances that were released by the U.S. FDA in February. PDA is currently forming a task force to comment on these draft guidances.

Hope to hear from you soon! **— Emily Hough**



Post your comments to stories listed at pda.org/pdaletter

PDA Letter

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

Subscriptions are not available.

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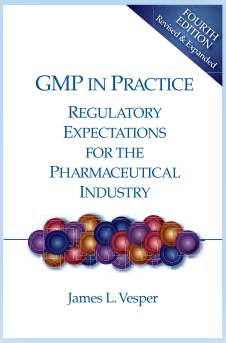
Save 15% on these publications at the 2012 PDA Annual Meeting!

Recommended Reading for the 2012 PDA ANNUAL MEETING

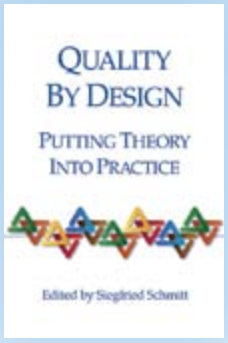
April 16-18, 2012

JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

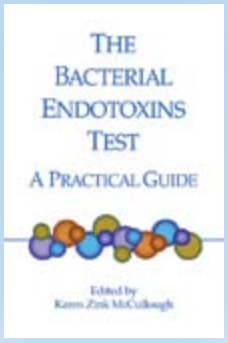
www.pdaannualmeeting.org



GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded
By James L. Vesper

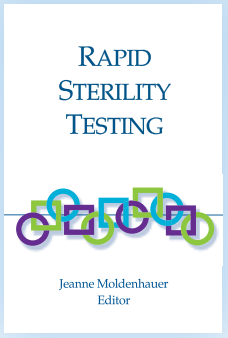


Quality by Design: Putting Theory Into Practice
Edited by
Dr. Siegfried Schmitt



The Bacterial Endotoxin Test: A Practical Guide
Edited by
Karen Zink McCullough

Pharmaceutical Quality
Edited by
Richard Prince, PhD



Rapid Sterility Testing
Edited by
Jeanne Moldenhauer

For more information on these publications please visit – **www.pda.org/annualreading**

The PDA Bookstore's February Top 5 Best Sellers

1 **Environmental Monitoring: A Comprehensive Handbook, Volume I, II, III, IV, V and Protocol CD**
Edited by
Jeanne Moldenhauer
Item No. 17301
PDA Member
$1,365
Nonmember
$1,699

2 **GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded**
By James L. Vesper
Item No. 17269
PDA Member
$225
Nonmember
$279

3 **Practical Aseptic Processing: Fill and Finish, Volume I and II**
Edited by
Jack Lysfjord
Item No. 17283
PDA Member
$425
Nonmember
$530

4 **Quality by Design: Putting Theory Into Practice**
Edited by
Dr. Siegfried Schmitt
Item No. 17296
PDA Member
$210
Nonmember
$259

5 **The Bacterial Endotoxin Test: A Practical Guide**
Edited by
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Item No. 17297
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2012 PDA
Visual Inspection Forum
25-26 September 2012 | Berlin | Germany

Call for Papers and Posters

On behalf of PDA Europe and the Co-Chairs John Shabushnig and Markus Lankers we would like to invite you to submit a paper or poster abstract for presentation at the **2012 PDA Visual Inspection Forum** to be held in Berlin/ Germany on **25-26 September 2012.**

Paper abstracts and posters must be essentially non-commercial in nature, describing new developments or work that significantly contributes to the knowledge relating to visual inspection processes as applied to injectables. **Case Studies by end users are particularly desired.**

Topic areas of interest include but are not limited to the following:

- **Qualification of manual inspections and validation of automated inspection systems**
- **Case studies in root cause investigation or process improvements by elimination of particle sources**
- **Case studies in the implementation of a two-step inspection process**
- **Preparation and use of standards and defect test sets**
- **Classification of defects and preparation of defect libraries**
- **Automated container integrity/leak testing**
- **Recent compendial and regulatory activity**
- **Recent component quality and supplier qualification**
- **Special considerations for the inspection of biopharmaceuticals**
- **Challenges of inspecting products in pre-filled syringes (e.g. silicon oil droplets)**
- **Detection and characterization of protein aggregation**
- **New inspection technologies**

All submitted abstracts will be reviewed by the Program Planning Committee for acceptance.
Upon review by the Program Planning Committee, PDA Europe will advise each submitter of the status of the paper for presentation in writing by **15 May 2012.** PDA Europe will provide one complimentary registration per podium presentation. Additional presenters and poster presenters are required to pay appropriate conference registration fees.

Submissions received must include the following information:

- Title
- Presenter
- Presenter's biography (approx. 100 words)
- Additional authors
- Full mailing address
- Phone number
- Fax number
- E-mail address of the presenter
- Key objectives of your topic
- 2-3 paragraph abstract, summarizing your topic

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

Attention Exhibitors
PDA is seeking vendors who provide excellent products or services in support of the conference. Space is limited and is allocated on a first-come, first-serve basis. To reserve your space, please contact Creixell Espilla-Gilart at espilla@pda.org or via telephone +49 (0) 33056 23 77 14.

Deadlines **Abstracts of papers for presentation: 13 April 2012**
Poster abstracts: 20 August 2012

CONFERENCE 25-26 Sep | **EXHIBITION** 25-26 Sep | **TRAINING COURSE** 27-28 Sep

On the forefront - Mab developments in Europe

Emerging Trends for Therapeutic Monoclonal Antibodies and Related Products

Considerations for Quality Attributes throughout the Development Continuum and Registration

Session 1: Development for biological IMPs

- What is the appropriate level of quality detail needed for biological IMP dossiers?
- Are acceptance criteria and details for in-process control required for early stages?
- How can an IMP dossier be built based on QbD principles?
- Degree of characterization of IMPs in early drug development?
- To what extent can shelf life dating be based on supportive data?

Session 2: Molecular Approaches to Optimization

- Can certain routine testing be eliminated based on molecule optimization strategies?
- Is it possible to optimize a monoclonal antibody drug substance to the point of having no critical quality attributes related to its molecular properties?
- How should molecule design features be communicated in the market application?
- What are the expectations for in vitro bioassays when more than one cell-killing target is involved?

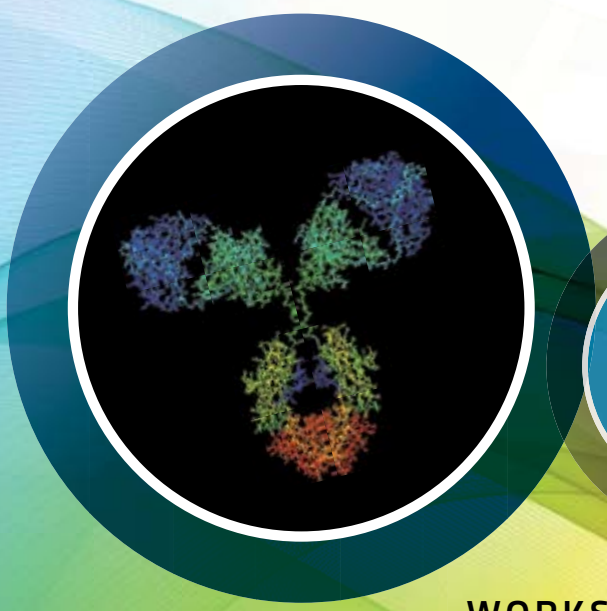
Session 3: Late-stage Process Development

- How is process parameter criticality assessed and confirmed?
- How much can we rely on prior knowledge to support process characterization?
- What are the most frequent questions health authorities ask regarding the control strategy. What are the major missing elements in the dossier?
- What information on the control strategy needs to be provided during an inspection? How far back into process development does the inspector look?

Session 4: Development, Regulatory and Future

- What are Molecular particulars and how are they characterized?
- How do we characterize the starting material used to manufacture the Antibody Drug Conjugate (ADC)?
- What are the test methods used to investigate and quality control ADC and multifunctional antibodies?
- How do we characterize the linker-quality, its mechanism in-vivo and the relevant data requirements?
- What are the unique dossier structure and data requirements for ADC and multifunctional antibodies?

Workshop Co-Chairs:
Steffen Gross, *Paul-Ehrlich-Institut, Germany*
Michael DeFelippis, *Eli Lilly*



Not to be missed: Nathan Ihle, PhD, Seattle Genetics!

12-13 June 2012

Hotel NH Danube City
Vienna | Austria

Register by 20 April 2012 and SAVE!

WORKSHOP 12-13 June | **EXHIBITION** 12-13 June

https://europe.pda.org/Monoclonal2012

The 2012 PDA Annual Meeting Starts Next Month! Register today at www.pda.org/annual2012!

The Parenteral Drug Association presents the...

2012 PDA ANNUAL MEETING

Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology

April 16-18, 2012

JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

Just Confirmed: Steven Lynn, Office Director *(acting), Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA* to speak in the closing plenary session.

Featuring:

A New Contamination Issue Never Before Experienced: A Novel Bacterial Contamination in Biopharmaceutical Manufacturing, by PDA Chair, **Anders Vinther**, PhD, Vice President, Quality Biologics, *Genentech*. One of Genentech's biopharmaceutical manufacturing facilities recently experienced bacterial contamination events with a novel organism never previously observed within the manufacturing network. Come learn about a novel bacterial contaminant in CHO cell culture processes that has implications for the biotech industry at large.

Highlights of this year's program include:

- Presentations from top pharmaceutical and biopharmaceutical industry, regulatory and academic professionals
- Concurrent tracks:
  - Innovation and Productivity in Large Scale Manufacturing
  - Personalized Medicine/Cellular Therapeutics
  - Controls Strategies for Biopharmaceuticals
- **NEW in 2012:** Career Development Strategies and the Quality and Regulatory Job Market Outlook in 2012 breakfast sessions
- For those new to the industry: the Foundations Breakfast Sessions
- The PDA Single Use Systems post-conference workshop on April 18-19
- Eight stand-alone courses hosted immediately following the meeting by PDA's Training and Research Institute (PDA TRI)
- Numerous networking opportunities including:
  - 6th Annual PDA Golf Tournament at the Wildfire Gold Club
  - PDA's 6th Annual Walk/Run *(benefiting the Phoenix Children's Hospital)*
  - New Member Breakfast
  - PDA Annual Meeting Baseball Outing
  - PDA Dine Around

Don't miss the *2012 PDA Annual Meeting*, it will keep you abreast of the latest innovations in biopharmaceutical manufacturing and emerging cellular technologies.

www.pda.org/annual2012

EXHIBITION: April 16-17 | **CAREER FAIR:** April 16-17
POST-CONFERENCE WORKSHOP: April 18-19 | **COURSES:** April 19-20