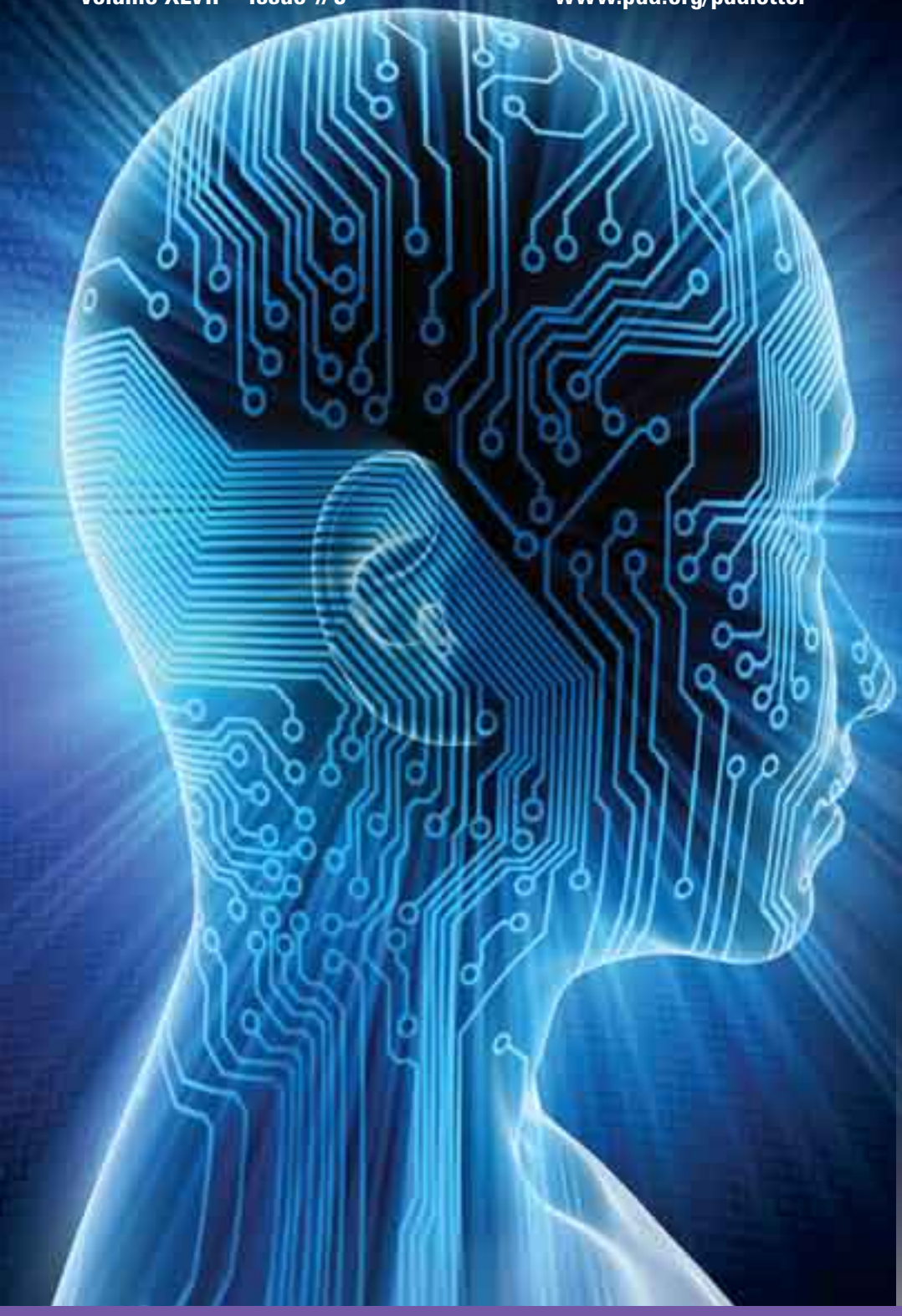
People • Science • Regulation

PDA Letter

Volume XLVII • Issue #3 www.pda.org/pdaletter March 2011



The Power of Knowledge

24

PDA Annual Meeting Show Issue

See Table of Contents for articles on the *2011 PDA Annual Meeting*

PDA/EMA 2011 Conference

Regulation, Cooperation, Innovation: An Effective Partnership among Authorities and Industry in Europe

Register by 7 March 2011 and SAVE!

3-6 May 2011

London Heathrow, UK

The 2011 PDA-EMA Conference includes an expanded agenda with a full range of GMP, Quality and CMC issues relating to pharmaceutical development, production and quality management. Input from EMA's Quality Working Party, Biologics Working Party and GMP/GDP Inspectors Working Group have resulted in a conference which includes the following highlights:

- Over 25 speakers from EMA and National Health Authorities
- From over 15 speaker from industry & affiliated organizations
- Three morning plenary sessions
- Ten afternoon parallel tracks with open discussions
- Eight topic areas:
  - Process optimisation
  - Quality
  - Regulatory affairs
  - Advanced therapies
  - Supply chain
  - Trends in manufacturing
  - Biologics
  - Orphan drugs and SMEs
- Convenient venue at London Heathrow Airport

CONFERENCE, EXHIBITION TRAINING COURSES

https://europe.pda.org/PDAEMA2011

The Parenteral Drug Association Presents...

2011 PDA ANNUAL MEETING

Harnessing the Power of Knowledge to Drive World Class Science and Technology

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1946 65TH ANNIVERSARY 2011

April 11-15, 2011

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SAN ANTONIO, TEXAS

www.pda.org/annual2011

Join PDA for the 65th PDA Annual Meeting, themed *Harnessing the Power of Knowledge to Drive World Class Science and Technology*, which will support over 45 presentations in sessions which will include:

- Submissions – Perspectives from Both Sides
- Advances in Single-Use-Systems
- Advanced Approaches in Environmental Monitoring
- Applications for Integrating Risk Management
- Moist Heat Sterilization
- Freedom From Paper and Efficient IT Systems for cGMP's QC/QA Environments
- Post Implementation – Maintaining a Change Control Program
- Contamination Control
- Manufacturing Protein Therapeutics
- Plus many, many more excellent topics to be discussed!

PDA Annual Meeting Career Fair, April 11-12, 2011	**New Speaker Confirmation** Process Validation Post Conference Workshop, April 13-14, 2011	PDA TRI Courses, April 13-15, 2011
Attend the PDA Annual Meeting Career Fair and interact with employers from a variety of fields in the biopharmaceutical science and manufacturing industry. Ample time will be provided to find out about jobs, drop off resumes, and interview on site.	Grace McNally, Consumer Safety Officer, CDER, FDA to present at the PDA Process Validation Guidance Workshop following the 2011 PDA Annual Meeting! Grace McNally will be giving the opening workshop introduction and speaking on the following topics: • Background and Explanation of Guidance – Regulatory Perspective • Panel Discussion: Path Forward	Seven PDA Training and Research Institute (PDA TRI) courses like: **GMP 101, Steam Sterilizers: Getting It Right from the Beginning – *New Course*, DoE Basics for Validation by Design – *New Course***, plus many more.

www.pda.org/annual2011

MEETING April 11-13 | **EXHIBITION & CAREER FAIR** April 11-12
PDA PROCESS VALIDATION GUIDANCE POST CONFERENCE WORKSHOP April 13-14 | **COURSES** April 13-15

PDA Letter

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Cover Art by Henrik Jonsson

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PRESIDENT'S *message*

President Richard Johnson anticipates that 2011 will be one of PDA's busiest years

2011 Will Be A Busy Year for PDA

After a very successful 2010, PDA is gearing up for an equally active 2011. Energized by our newly-updated 2010-2015 PDA Strategic Plan, we are working to strengthen our focus on *Connecting People, Science, and Regulation.*

Always at the forefront is improving our service to our members. We are planning improvements to our publications and website that will offer more, easier to navigate information. We are working on global outreach, with ongoing efforts in China, Russia, India and Brazil, with continuing strong activity in Europe and the Pacific Rim, as well as in North America.

In 2011 we have a great mix of signature conferences and new topics. We hope to see you at the 65th PDA Annual Meeting in San Antonio, the 4th PDA/EMA Conference in London, the 20th PDA/FDA Joint Regulatory Conference in Washington D.C., and the 8th Prefilled Syringe Conference in Basel. We are also focusing on new issues at the Atypical Actives Workshop in March, two co-sponsored conferences, one on the Implementation of ICH Q10 and the other on Advanced Therapies Medicinal Products.

2011 will be a great year to engage with PDA TRI for all your training needs. Anchored by our popular Aseptic Processing Courses, we have over 40 courses arranged into eight curricular areas, including: Aseptic Processing, Biotech, Environmental Monitoring, Filtration, Microbiology, Quality/Regulatory Affairs, Specialized Training and Validation.

PDA Technical Reports continue to be a major area of activity of our volunteer members, and in 2011 we are nearing the publication of:

- *PDA Technical Report No. 3 (revision): Validation of Dry Heat Processes Used for Depyrogenation and Sterilization*
- *PDA Technical Report No. 13 (revision): Fundamentals of an Environmental Monitoring Program*
- *PDA Technical Report No. 22 (revision): Recommended Practices for Manual Aseptic Processes*
- *PDA Technical Report No. 30 (revision): Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat*
- *PDA Technical Report No. 33 (revision): Evaluation, Validation and Implementation of New Microbiological Testing Methods*
- *PDA Technical Report No. 43 (revision): Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing (with e-lexicon)*

Yes, it will be a busy year, but thank you for your support and all of the volunteer efforts that make all of these activities happen.

Please let us know if there are other areas you would like us to address, if you would like to volunteer in a task force, interest group or a committee, or if you would just like to stop by. This is *your* association. We would love to hear from you.

PDA Chair Offers Virtual Orientation Session

PDA Chair **Maik Jornitz** will host the first Virtual New Member Orientation on March 25 at 11:00 a.m.–12:00 p.m. EST. He will give a brief introduction to member benefits, products, services and volunteer opportunities.

To RSVP for this complimentary web seminar, please email **Hassana Howe** at howe@pda.org by March 23.

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Volunteer

Nik Seidenader, Managing Director, Sales and Marketing, Seidenader Maschinenbau

PDA Join Date: 1995

Interesting fact about yourself: The Alps are in my backyard. I am a passionate skier and mountain biker. The rest of my free time is dedicated to my wife and four children.

Why did you join PDA? My father, **Robert Seidenader,** was an active member. He was an exhibitor at PDA annual meetings since the mid 80's. I understood very early the advantage of being a member of a professional network to share new ideas and technical solutions.

Of your PDA volunteer experiences, which have you enjoyed the most? I was co-Chair of the Parenterals 2010 Conference held in Berlin in October. It was great to be involved with the other committee and all the speakers in what will be a key event for PDA in coming years. Two other situations stand out: My first presentation at a PDA Congress in Basel in the 1990s (the audience was huge, and I was really nervous), and my first PDA exhibition in Philadelphia in 1990 (and those unforgettable evenings in the West lounge!).

How has volunteering in PDA benefited you professionally? We manufacture inspection machines for parenterals. Our support, promotion and exhibition at the Parenterals Conference, the Visual Inspection Forums and the Prefilled Syringe activities give us immediate feedback from users. Since I took over Seidenader, we have participated in current topics like flexible containers, leak testing and other workshops. PDA programs attract exactly the audience we need to talk to.

Which PDA conference/training course is your favorite? The Visual Inspection Forum: It gives hands on information, and it allows for very focused, passionate discussions.

What would you say to somebody considering PDA membership? Join now, you will not regret it. Use it for your personal and professional growth and enjoy networking with interesting people from all corners of the globe.

Upcoming PDA Web Seminars – Interactive Online Learning

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

March 2011

March 15, 1:00 p.m. - 2:30 p.m. ET
Cleaning and Cleaning Validation — Principles, Development, Performance, and Maintenance
Paul L. Pluta, PhD, Associate Professor, *University of Illinois-Chicago*

March 17, 1:00 p.m. - 2:30 p.m. ET
Cleaning and Cleaning Validation — Problems and Misunderstandings
Paul L. Pluta, PhD, Associate Professor, *University of Illinois-Chicago*

March 31, 2011, 1:00 p.m. - 2:30 p.m. ET
Risk Assessment and Risk Management in the Pharmaceutical Industry
James L. Vesper, President, *LearningPlus Inc.*

April 2011

April 5, 2011, 1:00 p.m. - 2:30 p.m. ET
GMP Compliance and the Bacterial Endotoxins Test — Workshop One: Prerequisites to Testing
Karen Z. McCullough, RMS, Principal Consultant, *MMI Associates*

April 7, 2011, 1:00 p.m. - 2:30 p.m. ET
QbD: An Overview of QbD Applications with some Real Practical Examples
Siegfried Schmitt, *PAREXEL Consulting*

April 19, 2011, 1:00 p.m. - 2:30 p.m. ET
GMP Compliance and the Bacterial Endotoxins Test — Workshop Two: Routine Testing
Karen Z. McCullough, RMS, Principal Consultant, *MMI Associates*

April 21, 2011, 1:00 p.m. - 2:30 p.m. ET
GMP Compliance and the Bacterial Endotoxins Test — Workshop Three: GMP Applications of BET
Karen Z. McCullough, RMS, Principal Consultant, *MMI Associates*

PDA Web Seminars are hosted in real time and attendees are encouraged to engage in group discussions and ask their specific questions.

For more information on PDA web seminars please visit **www.pda.org/webseminars**

PDA Japan Chapter Celebrates 17th Annual Meeting

Izumi Saito, PhD, Shionogi

The main theme of the PDA Japan chapter's 17th Annual meeting in Tokyo on November 9-10 was *Moving from Quality Assurance to Quality Management.*

The phrase "quality by process" has been used in the past with the nuance that quality assurance is based on the correct quality control. However, an innovation occurring now with the introduction of ICH Q10, based on ISO-9000, is that quality is being considered as not only the activities by a factory or a single company but as involving the whole manufacturing organization, including companies responsible for design, raw materials, quality testing and so on. The movement has expanded globally with the increase in the number of PIC/S members and the implementation of ICH Q10. In particular, with the adoption of ICH Q10 for pharmaceutical quality management, the way of thinking about quality assurance for pharmaceutical drugs is going to change.

In view of this, the PDA Japan Chapter used the idea of *Moving Quality Control, Assurance to Quality Management* as the main topics of this meeting, and we decided to discuss it together with participants from Quality Management. We were fortunate to have the opportunity to receive three presenters from overseas, including PDA President **Richard Johnson,** who introduced the rapidly evolving trend of global quality management to us. We also had the opportunity to hear a presentation on Japanese inspection trends from PMDA in a special session.

The four lectures that were given at the meeting were:

- "Application of Principals of Quality by Design in Method Life Cycle Management" (**Imogen Gill,** PhD, Vice President, Head of Analytical Development, Pfizer)
- "Multipurpose Injection Manufacturing Site with Easy Validation Technology" (**Jorg Zimmermann,** PhD, Vetter Pharma-Fertigung)
- "Moving from Quality Assurance to Quality Management" (**Richard Johnson,** President, PDA)
- "Updated Japan GMP Inspection Trends by PMDA" (**Hiroshi Kato,** Principal Inspector, PMDA)

Each interest committee of the PDA Japan Chapter held a separate session for both days. They provided the discussion results with detailed examples to the attendees, useful information was provided, and productive discussions were held.

The following presentations were given by the various Committees at the Annual PDA Japan Chapter Meeting:

- "Toward the Movement of the Global Quality Assurance and the Practice in Japan" (QAQC Committee)
- "To Provide Effective Medical Treatment by the Medical Spot" (Medical Device Committee)

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PDA Korea Chapter Appreciates Visit by PDA President

Woo-Hyun Paik, Korea Pharm. Tech. Education Center

PDA's Korea Chapter celebrated its 13th Annual Meeting at the Seoul Education & Culture Center on December 13-14, with the support of a GMP consulting company, Bio-Support. With many participants from local pharmaceutical companies, the seminar was a great success.

Richard M. Johnson, President, PDA, attended the meeting and gave a presentation on business/regulatory influences on the pharma/biopharma industry. In addition, **Ingrid Walther,** PhD, GMP consultant, compared the requirements of the U.S. FDA's GMP to the EU's GMP.

Back in 2007, **Richard Levy,** PhD, Senior Vice President, PDA, attended the 10th Annual Meeting for the Chapter and gave a presentation on the 2007 revision of PDA's *Technical Report No. 1, Validation of Moist Heat Sterilization Processes.*

Woo-Hyun Paik, PhD, Chapter President, PDA Korea Chapter, said that he appreciated the visits over the years to his chapter meetings from the PDA Staff. "Attendance from PDA's staff to local chapter meetings is very important to PDA members," he said.

PDA President Richard Johnson stands outside of the PDA Korea Chapter Office with Woo-Hyun Paik, President of PDA's Korea Chapter

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PDA's Taiwan Chapter Plays Invaluable Role in Community

Chapter has provided support to the local pharma industry since 1997

Tuan-Tuan Su, Secretary General of Taiwan chapter

PDA's Taiwan Chapter has demonstrated its invaluable role as a provider of technical support and training for the pharmaceutical industry since it was founded in 1997. It currently has 579 local members.

When PDA President **Richard Johnson** visited Asia in November last year, he met with the TPDA board of standing directors to discuss PDA's strategic goals.

Due to the Taiwan FDA demanding that all pharmaceutical plants must comply with the PIC/S GMPs by January 2015, PDA is going to play a key role in the consultation for the plants and in the communication between industry and the Taiwan FDA. As for the future, PDA's Taiwan Chapter will focus on continual education providing the most current GMP information and developing training programs for pharmaceutical industries and Taiwan FDA inspectors.

PDA's Taiwan Chapter has also started to translate ICH, U.S. FDA and PIC/S GMP documents, which will be published in Chinese for the local community This will help the local industry gain a global perspective.

PDA's Taiwan Chapter will celebrate its 14th Annual Meeting on June 9, 2011 in Taipei. The one-day event will include government officials from the Taiwan FDA, who will give presentations. Additionally, an overview of PIC/S' GMPs will be given. There will be exhibits and demonstrations by major pharmaceutical vendors.

PDA President Visits Asia Chapters

Richard Johnson, PDA

In November and December 2010, I was fortunate to be able to visit our PDA Chapters in Japan, Taiwan and South Korea.

I would like to share with you some of the highlights of these visits:

Japan

On November 9 and 10, the PDA Japan Chapter (JPDA) held their Annual Meeting at the Tower Hall Funabori in Tokyo. The meeting was well attended with over 600 attendees listening to more than 25 presentations. There was a gala reception on Tuesday evening where many long-time and first-time attendees were able to meet and interact socially. The following day JPDA held an all-day training program, which was attended by almost 100 people. I felt very fortunate to be able to participate and to have the opportunity to meet with many members and JPDA's Board.

Richard Johnson speaks to the PDA Japan Chapter

Taiwan

On November 11 and 12, I met with the Board and staff of the PDA Taiwan Chapter (TPDA) at their offices in Taipei. The PDA Taiwan Chapter is very active in working with the Taiwan FDA in developing and translating technical guidances for the Ministry.

(l-r backrow) Steve Chang, China Chemical Synthesis Industrial; Sherry Hsiao; Tuan-Tuan Su, TPDA Secretary General; Lain-Tze Lee, Industrial Technology Research Institute

(l-r front row) Wayne Wu, Synmosa Biopharma Corp.; Richard Johnson, PDA; Frank Wu, United Biomedical

Korea

In December, our PDA Korea Chapter (KPDA) held their 13th Annual Meeting. On December 13 and 14, they held a two-day training event attended by almost 100 people.

(l-r) J.H. Oh, sureGMP; W.H. Paik, Korean Pharm. Tech. Education Center; Richard Johnson, PDA; Ingrid Walther; Manfred Poether, NNE Pharmaplan; W.I. Hong, Yuhon Chemical

It was inspiring to learn that we have a long history and active chapters in this region who are extending PDA's message around the world.

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Get Hired in an Overcrowded Job Market

Jim Kukral

If you've been looking for a new job, you've probably noticed that you are not alone. In fact, there are so many highly qualified people looking for jobs today that it can be really difficult not to feel like just another face in the crowd (or résumé in the pile!). Competition is certainly stiff. And that means that the job search techniques of yesterday—send out résumés, search the want ads and wait for a job to fall in your lap—won't even get your foot in the door. What you need in order to get a job today is the courage to put yourself out there and get the attention of employers by trying something no one else is doing.

It has never been more important to stand out and get noticed in the job market. No employer today is going to remember anybody who is just okay or who falls in the middle of the pack. If you're competing against fifty other applicants for a much-needed job, you have to ask yourself, what can I do to stand out and prove to them that I want it more than everyone else?

If you're trying to land a new job, but you're short on ideas for getting the attention of potential employers, don't worry.

Read on for five creative ways to use the power of the web and social media to land that new job.

1 Ramp Up Your Résumé

Potential employers have piles of résumés to look through—for the most part, they all look the same. Do something to make yours stand out in the crowd. For example, if you find out that the hiring manager at the company you're interested in loves Dunkin' Donuts, you should have a box of donuts delivered to her office every morning for a full week. Each box should have a picture of you on it and a reason why you're perfect for the job.

Ramping up my résumé helped me land a job right out of college. When I walked into the CEO's office for the interview, I noticed the walls were completely covered in post-it notes. The CEO told me he liked to keep his ideas and notes in this manner because it helped him to stay organized, and it kept the ideas in front of his face. Later that night an idea occurred to me: Why not use this guy's penchant for post-it notes to stand out to him? I bought a big piece of white posterboard and several packs of yellow post-it notes. Then I came up with fifty different qualities that I thought I represented and had my fiancée (who has fabulous handwriting) write down each quality on a post-it note. I arranged the notes on the posterboard one by one, emulating the CEO's office wall.

The next morning I arrived to his office early and left the board with his receptionist along with another copy of my résumé. About an hour later, I received a call from the CEO offering me the job. Out of all the people interviewing for the position, I was the only one who did something to stand out. This was an early and valuable lesson for me and has since helped shape my career and brand into what they are today.

2 Try Facebook Advertising

Facebook is a great way to network with friends and family, but what most people don't know is that it's a great way to network professionally as well. Many companies have Facebook pages that allow you to make contact with their employees. And what's even better, Facebook offers an advertising service (that few people actually even know about!) for very cheap. The service allows you to create your own target ad. It doesn't get much easier than that!

Create an ad on Facebook about yourself—include your skills and qualifications and what type of job you are looking for—and then target it to the companies where you want to work. Sound simple? That's because it is!

A great example of how this works is a woman named Miriam Schembari who was trying to get a job at one of the world's largest publishing houses. She had exhausted her efforts otherwise: She had sent résumés, called recruiters, posted on job boards, and, after six months she had nothing to show for it. She knew she had to do something different to get herself noticed—so she turned to Facebook. She created a Facebook advertisement that targeted only people who worked at the companies that she wanted to work for.

She ran the ad on the profiles of people who worked at HarperCollins and linked to her résumé. The entire ad run cost her only $6.00. A person who blogs for HarperCollins saw the ad and wrote a blog post with the headline "Why don't we hire more people like this?" and the blog post linked back to her ad and her résumé. A week later she had a contract gig with them.

3 Get Personal

Before you go on a job interview, find out everything you can about the people who are in charge of the hiring process at the company. Look them up on Facebook, LinkedIn, and Twitter, and get to know a little bit about them and their interests. This will help you to know what may impress them, annoy them or where you may share a common interest that will help you to connect. In the interview, make an attempt to connect—be friendly, honest and open to sharing a little about yourself as well. The more personal the connection you make and the more they like you as a person, the better chance you have at being chosen for the job.

Learning a little bit more about the decision makers in the hiring process will do nothing but help you. Learn as much as you can and then use some of those nuggets of information in the interview. Perhaps you discover that one of the interviewers is a huge Yankees fan or another has children the same age as your own, or one of them attended a local festival over the weekend. It's those details that will help you to break the ice and connect with them personally—and that will in turn make you more memorable.

4 Use YouTube to your Advantage

YouTube is a great resource—and not just for funny videos to forward to your friends. In fact, it's a cheap and easy way for you to show off your skills, and it can pack a big punch when it comes to setting yourself apart in the job search. You can use a video as a chance to follow up after an interview and say thanks. Or you could take the opportunity to send your potential employer something you've put together that displays your creativity or a skill that sets you apart. Send a link to your video via email to the people who conducted your interview as a way to follow up.

One great example is a man who used his kids' baby toys and made some funny videos about the public relations business and put them on YouTube. The videos started to get mentions in the media, and he leveraged that in his job search. He sent the videos, along with the media he had received, to potential employers with a note reading, "If I can get this much publicity from kids' toys and no budget, imagine what I could do for your clients." With very little investment, he was able to make a great impression and increase his chances for future employment.

5 Think Outside the Box—Then Go One Step Further

Doing things differently isn't exactly breaking news. Most people are at least somewhat aware of the fact that the job market is flooded with a surplus of talented and qualified people who are all vying for the same job openings. So you have to make sure you're thinking one step ahead of the rest. Advertise yourself in unexpected places, step out of your comfort zone, and, if you have to, invest a little money. You have to put some effort in if you want to see some results!

A great example of this is a woman named Pasha (HirePasha.com) who took her last bit of money and bought a billboard in a high-traffic area that read, "I'm ready and available for work, HirePasha.com." It worked so well that she ended up creating her own public relations firm because of all the attention she got for herself! The lesson here is to not limit yourself just because you think something is too outrageous or unexpected. In this case, it worked!

The job market, especially when it is as overcrowded as it is today, can be tough to navigate. But if you implement a few unique strategies, it can also be a lot of fun. Once you find the strategy that works for you, it will also become very fruitful. Good luck out there!

About the Author

Jim Kukral is the author of *Attention! This Book Will Make You Money: How to Use Attention-Getting Online Marketing to Increase Your Revenue.* For over fifteen years, Jim has helped small businesses and large companies like FedEx, Sherwin-Williams, Ernst & Young and Progressive Auto Insurance understand how to find success on the Web. Jim is also a professional speaker, blogger and Web business consultant. Find out more by visiting www.JimKukral.com. You can also follow Jim on Twitter @JimKukral.

PDA Annual Meeting Career Fair

Monday, April 11 and Tuesday, April 12

Attend the PDA Annual Meeting Career Fair and interact with employers from a variety of fields in the biopharmaceutical science and manufacturing industry. Ample time will be provided to find out about jobs, drop off resumes and interview on site.

Please Welcome the Following Industry

Ross Acucena, EMD Millipore
George Adams, EMD Millipore
William Aiello, MassBiologics
Aldwin Aldana, SIGA Technologies
Annabelle Alejar, Roche
Mauro Anglana, Merck
Ken Appel, Vaisala
Fabio Arenghi, CPC
Tom Armstrong, Merck
Atsushi Asakura, Asahi Kasei Finechem
Lawrence Atupem, Cold Chain Tech
Colin Baker, Septodont-Novocol
Haim Bangio, SciGen
Dan Beardslee, Ash Stevens
Vincent Beguin, Merck
Herve Berdou, AstraZeneca
Ken Betz, Eli Lilly
Sue Bocchicchio, Johnson & Johnson
John Boney, Genzyme
Jilla Boulas, Dyax
Annie Boyer, Pharmascience
Oliver Braendli, Sunstar
Debra Buxton, Complya Consulting Group
John Caldwell, Bayer Healthcare
Jacqueline Carew, Genentech
Misty Carlisle, Genzyme
Cheryl Carlson, Inspiration
Irene Chen, Baxter Healthcare
Maurice Chassagnoux, Merck Sharp & Dohme
Li Chen, Bristol-Myers Squibb
Vijay Chiruvolu, Amgen
Michael Clark, Commissioning Agents
Joe Como, Celgene Corporation
Mark Compo, Veltek Associates
Karl Cummins, Bausch & Lomb
Richard Day, Highland Biosciences
Corinne De La Foata, biomerieux
Brian Dean, GE Healthcare
Gina Deignan, Genentech
James Diamond, BioVigilant Systems
John Dobbins, Pfizer
John Dobiecki, JW Dobiecki Consulting
Kara Donovan, ARIAD Pharmaceuticals
Catherine Drach, Novartis Pharma SAS
Matthew Dunlavy, Bayer Healthcare
Philippe Dupont, VALDEPHARM
Elinor Erez, Bio-Technology General
Emiko Furukawa, Alcon
Masahiro Furukawa, Nissin Pharmaceutical
Navdip Ghai, Merck
Labranque Gilles, Sofrigam
Ashley Goldberg, Baxter Healthcare
Ondina Gondim, Johnson & Johnson
Carlos Gonzalez, AmSafe
Sheila Grant, Merck
Aimee Grosdidier, Pfizer
Angela Halvorson, Merck
Justin Harrell, Merck
Yoshitaka Hattori, Chugai Pharma Manufacturing
Wim Herings, Intervet International
Takahiro Higashibaru, Kawasumi Laboratories
Kuniko Hirota, Japan Poliomyelitis Research Institute
Yoshihiro Hishikawa, Dainippon Sumitomo Pharma
Daniel Hoch, Protocol Link
Naho Horie, Chugai Pharma Manufacturing
Klaus Hudel, Martin Christ
Travis Hudson, BioConvergence
Philip Humphrey, West Pharmaceutical Services
Takashi Ishihara, Sato Pharmaceutical
Toshihide Ishii, Ajinomoto Pharmaceuticals
Koichi Itadani, Maruho
Kana Iwamoto, Maruishi Pharmaceutical
Hiroshi Iwase
Nirdosh Jagota, Genentech
Charles Jeanblanc, Baxter Healthcare
Rick Jensen, GlobeImmune
Omkar Joshi, Bayer HealthCare
Chien-Yuan Kao, Immunogen
Yukari Kawaguchi, EN Otsuka Pharmaceutical
Taeko Kikuchi, Chugai Pharma Manufacturing
Asuko Kimura, Alcon
Masakazu Kitayama, Abbott
Hideyuki Konishi, Toyama Chemical
Yasuyuki Kumada, Yell Pharmaceutical
Diane Lane, Allos Therapeutics
Vincent Lapierre, Draxis Pharma
Lucy Lavallee, Genzyme
Deep Laxmi, ViroPharma
Wayne Lee, Pall
Helge Leibfritz, Novartis Pharma
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Brian Loeffler, Meridian Bioscience
Signe Lund, Johnson & Johnson
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John Mazzolla, Merck
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Kay McDonald, Shire
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Michael McMaster, Gerresheimer Glass
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Todd Mendelson, Abbott Vascular
Claudia Meyer, Amsterdam Molecular Therapy
George Michalakis, Celgene
Yuko Mihara
Diane Miskowski, EMSL Analytical
Hemant Misra, Prolong Pharmaceuticals
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Mark Moody, Merrimack Pharmaceuticals
Jeff Morgan, Merck
Fuyuhiko Mori, Fujifilm
Megan Morrison, Genentech
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Takako Nakanishi, Satoyakuhin

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Masako Ninokata, Irom Pharma
Yasushi Niwata, Kyorin Pharmaceutical
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Rieko Oishi, Toyobo
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Conor O'Rourke, Bioniche Pharma
Kwame Osea, Merck
Takayuki Otsuka, Dainippon Sumitomo Pharma
Tamar Oved-Gelber, TEVA
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Lalita Parimi, Genentech
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Katie Terry, Sunovion Pharmaceuticals
Barbara Thorne
Joseph Tirrell, West Pharmaceutical Services
Hirokazu Tokusho, Eisai
Hoshiko Tomonori, Eisai
Kazuyuki Uchida, Sysmex bioMerieux
Veerle Umans, Becton Dickinson
Vinay Valmiki, Roche
Eric Webster, Petnet Solutions
Theresa Willerup, PakSense
Andy Wirths, Merck
Lynda Wolfe, Johnson & Johnson
Amy Wyllie, PDA New England Chapter
Stephen Yang, Merck
Christopher Yessayan, Mork Process
Judy Zdanowicz, Dendreon
Jeff Zimmerman, Merck

2011 Chapter Election Results for New England, Southeast and Ireland

New England

President Rusty Morrison, Protein Sciences Corporation

President-Elect Roland Bizanek, Biogen Idec

Treasurer Position Open

Secretary Jonathan Morse, Complaya Consulting Group

Southeast

President Shelley Preslar, Hyde Engineering and Consulting

President-Elect Melissa Seymour, Biogen Idec

Treasurer Sherry Nelson, Vantage Consulting

Secretary Shannon Bellino, Doe & Ingalls

Ireland

President Brendan Cahill, Pfizer

President-Elect Alice Redmond, PM Engineers and Project Managers

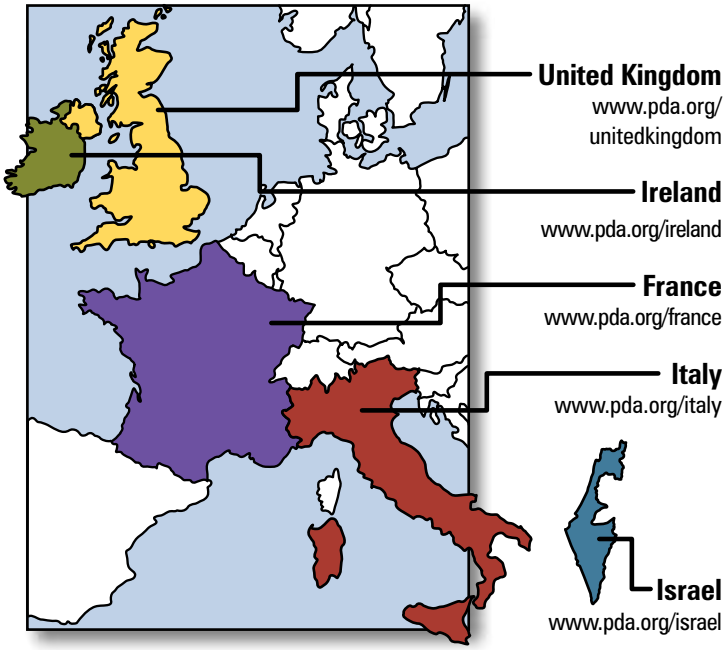
Treasurer Joan Fitzgerald, Allergan

Secretary Anne Greene, Dublin Institute of Technology

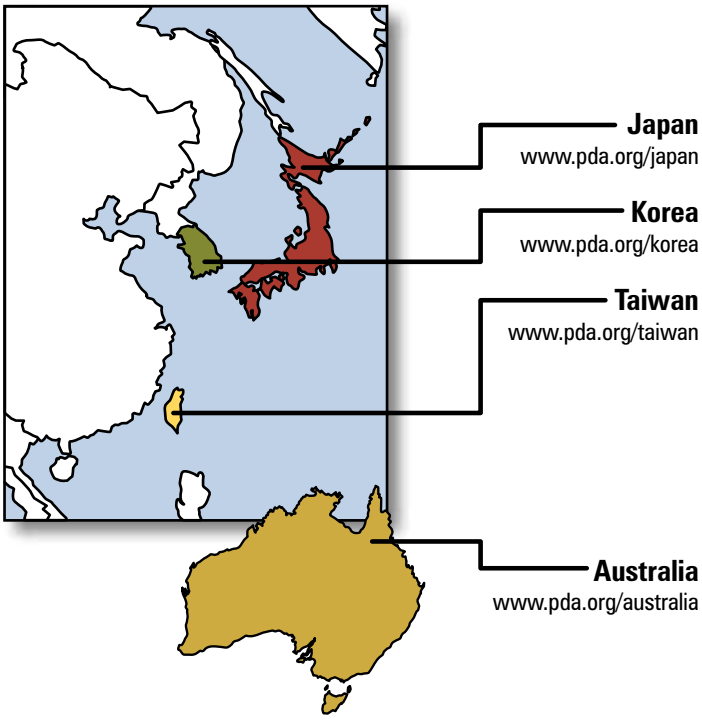
Chapter Contacts

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.

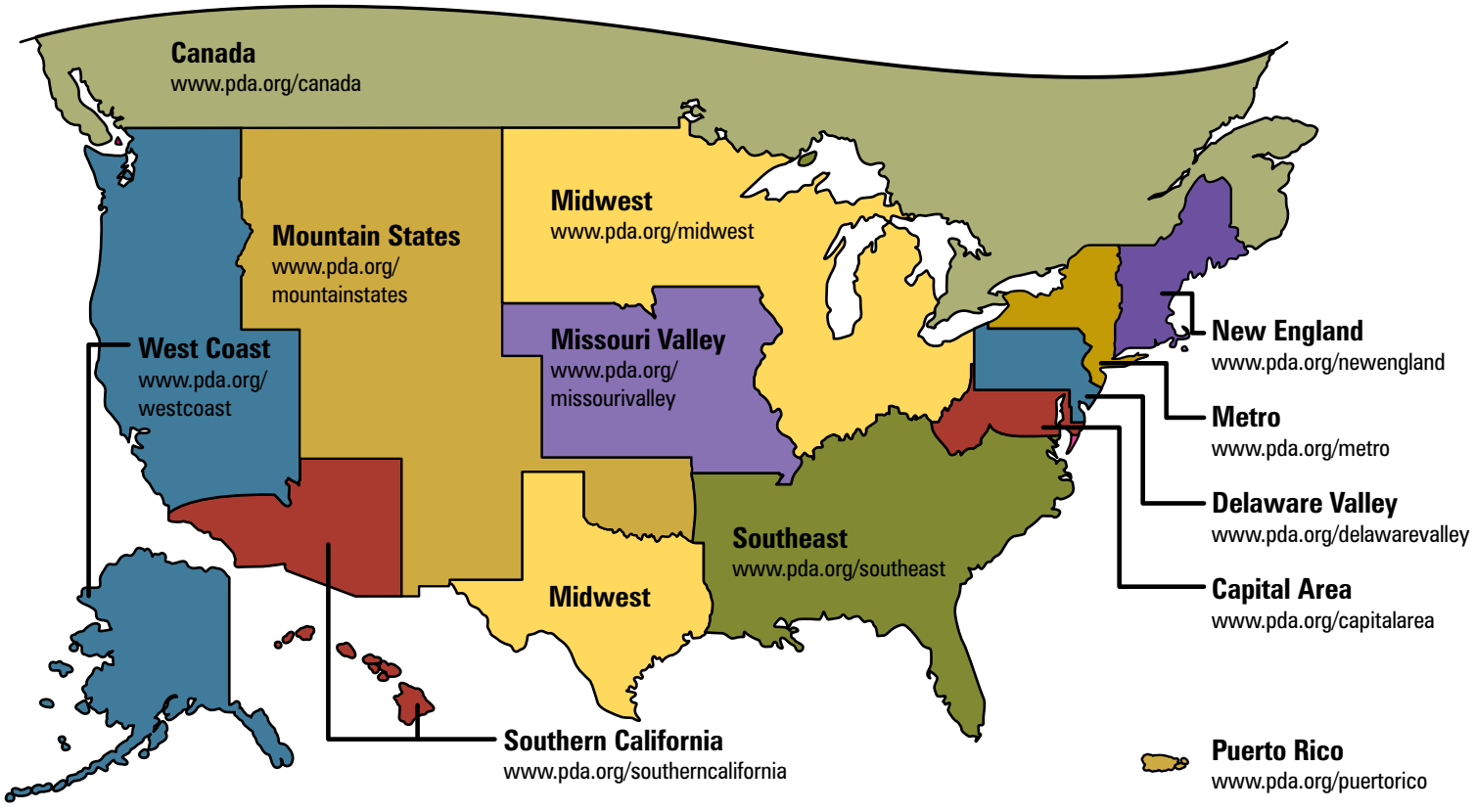
EUROPE



ASIA-PACIFIC



NORTH AMERICA



Faces and Places: Pharmaceutical Cold Chain Management

The 2010 PDA Europe Conference on Pharmaceutical Cold Chain Management took place in Berlin, Germany October 7-8.

PDA Japan Chapter Celebrates 17th Annual Meeting continued from page 9

- "Dealing Toward the Quality Improvement of the Bio-Pharmaceutical" (Bio-virus committee)
- "A New Proposal about the Insoluble Foreign Matter Inspection for Sterile Products" (Sterile product GMP committee)
- "The Selection of the Critical Quality Attributes of the API and Control Strategy" (API GMP committee)
- "Study about Deviation Management—the Prevention of a Deviation" (Kansai Study Group)

In parallel, an exhibition and luncheon seminar by pharmaceutical and pharmaceutical-related companies was also held.

A total of roughly 600 members participated and productive discussions were had on both days.

snapshot

Journal *Update*

A Number of Journal Enhancements Coming Soon!

Rich Levy, PhD, PDA

Among the many advantages of the electronic *PDA Journal of Pharmaceutical Science and Technology,* hosted by HighWire Press, is our ability to enhance the site to bring greater usability and value to the PDA membership. Members will see that we are doing that in 2011 with four upgrades, and each will be in place by mid-year.

The first upgrade is perhaps the most notable. In order to launch the e-Journal within a reasonable timeframe and budget in 2009, we elected to limit the archives to 10 years (1998-2008). This spring, we will expand the archives with 18 additional years: 1980-1997. As part of the PDA membership benefits, all members automatically receive free access to the current volume year of the e-Journal and the previous year. To access the archive, members can search and read the abstracts for free. To download full articles in the archives, members can pay-per-view or purchase the PDA 1-year license to access the full archive. For more information on these options, contact PDA's Membership Manager, **Hassana Howe** (howe@pda.org).

Ever read something in the Journal that you don't agree with? Or, something that you think was brilliant? Or, something that you have some additional knowledge about that you want to share? Well, starting soon, the e-Journal will have an online commenting tool available to all readers. The Journal Editors will monitor the comments, but it will represent a free forum for readers to interact and comment on the content of the *PDA Journal.*

Many PDA members are globe trekkers. They frequently travel to different corporate locations and to various suppliers. In addition, those active with PDA often need to travel for PDA business, and many members travel to our events. So, how do you keep up with an electronic Journal if you don't bring a laptop? Easy, access it on your smartphone! By July, PDA will launch a mobile interface for the e-Journal, providing a website that will render in a readable fashion on any mobile browser. This is a new feature just launched by HighWire Press at the end of 2010, and PDA will be among the first partner journals to launch a mobile interface.

Finally, we are working with HighWire Press's partner company, BenchPress, to launch an online article submission and review tool. Links to the tool will be easily accessible on the e-Journal site and at pda.org. This tool will make article submission a snap, and also help the editorial team manage the review process with modern information technology. These tools have been around for a while, and I know the editorial team, led by Dr. **Govind Rao,** is very excited to finally have one at their disposal. Look for this to be online by June.

Don't forget, particularly new members, to sign up for e-Alerts and RSS feeds at the website for the *PDA Journal of Pharmaceutical Science and Technology* (journal.pda.org). These help you stay on top of the latest content.

We are sure that PDA members will benefit greatly from these enhancements, and we are proud to bring them to you!

Technical Report *Watch*

In Board Review: Following technical editing, TRs are reviewed by PDA's advisory boards **(SAB, BioAB).** If/when approved, the PDA Board of Directors **(BoD)** makes the final decision to publish or not to publish the document as an official PDA TR. Balloting at each level can take several weeks or longer, depending on the questions posed or revisions required.

- *Technical Report No. 22: Process Simulation Testing for Aseptically Filled Products* **(BoD)**
- *Technical Report No. 3: Validation of Dry Heat Processes Used for Sterilization and Depyrogenation* **(SAB)**
- *Technical Report No. 13: Fundamentals of Environmental Monitoring* **(SAB)**
- *Guidance for Good Distribution Practices (GDPs) for Pharmaceutical Supply Chain* **(SAB)**
- *Good Guidance Practices for the Pharmaceutical Supply Chain* **(SAB)**
- *Guidance for Industry: Stability Testing to Support Distribution of New Drug Products* **(SAB)**
- *Steam In Place* **(SAB)**

Journal *Preview*

An Opportunity for Journal Readers

In the March/April issue of the *PDA Journal of Pharmaceutical Science and Technology,* Editor **Govind Rao,** PhD, writes about an opportunity for the readers of the Journal. Three reviews and five research topics also make up the issue.

Editorial

Govind Rao, "Author Redux: An Opportunity for Our Readers"

Reviews

Beth Junker, et al., "Design-for-Six-Sigma to Develop a Bioprocess Knowledge Management"

Dennis Jenke, "A General Assessment of the Physiochemical Factors That Affect the Leaching of Organic Substances from Plastic Materials into Aqueous Pharmaceutical Solutions"

Sia Chong Hock, Yan Mei Ying, and Chan Lai Wah, "A Review of the Current Scientific Regulatory Status of Nanomedicines and the Challenges Ahead"

Research

I. Kaesler, G. Haake, et al., "The Importance of Accurate Microorganism Identification in Microbial Challenge Tests of Membrane Filters – Part I"

Karunanidhi Santhana Lakshmi and Tirumala Rajesh, "Rosiglitozone Quantification in Rat Plasma Using High-Performance Liquid Chromatography with Mass Spectrometric Detection and Its Application to Preclinical Pharmacokinetic Studies"

Dipesh Shah, Jim Cronin, Molly Chacko, and Amy Gillum, "Impact of Formulation and Processing Parameters on Silicone Extraction from Cyclic- Olefin Copolymer (COC) Syringes"

H. Rachmawati, et al., "Intravenous Administration of Recombinant Human IL-10 Suppresses the Development of Anti-Thy 1–Induced Glomerulosclerosis in Rats"

Khushwant S. Yadav, et al., "Effect of Size on the Biodistribution and Blood Clearance of Etoposide-Loaded PLGA Nanoparticles"

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Annual Meeting *Preview*

IG Meeting Schedule at the Annual Meeting

PDA volunteers will dedicate some of their time at the *2011 PDA Annual Meeting* holding interest group meetings. All participants of the Annual Meeting are welcome to attend these discussions.

Monday, April 12: 4:00 p.m.– 5:30 p.m.

- Process Validation/Facilities and Engineering
- Packaging Sciences/Prefilled Syringes
- Vaccines
- Clinical Trial Materials
- Inspection Trends
- Quality Systems
- Microbiology/Environmental Monitoring

Tuesday, April 13: 4:30 p.m.– 6:00 p.m.

- Supply Chain Management
- Quality Risk Management
- Visual Inspection of Parenterals/Lyophilization
- Combination Products
- Blow-Fill-Seal/Sterile Processing and Parenteral Drug Manufacturing
- Filtration
- Biotechnology

Journal *POV*

Future of Consensus Standards in Biotechnology

Chris Watts and Kurt Brorson, U.S. FDA

[Editor's Note: The following is an editorial from the January/February 2011 *PDA Journal of Pharmaceutical Science and Technology.***]**

All government agencies, including the U.S. FDA, are mandated by law via the "National Technology Transfer and Advancement Act of 1995" to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. Accordingly, OMB circular A-119 sets forth policies necessary for reducing to a minimum the reliance by agencies on government-unique standards and provides guidance for satisfying the requirements of the Act. The FDA specifically encourages employee participation in these activities, and regulation guiding such participation can be found in 21 CFR 10.95 as well as FDA's Staff Manual Guide 9100.1, "Development and Use of Standards."

Acting on these mandates and in the public interest, the FDA and CDER have actively engaged in the development of consensus standards with a diverse range of stakeholders from ➤

the pharmaceutical community and, where relevant, other industrial sectors (e.g., ANSI, ASME, ASTM Technical Committees E11 and E55, ISO). Utilizing extensive collaboration, representatives from academia, consumers, regulators, industry (brand, generic, and biotech manufacturers) and suppliers (equipment and material) with multidisciplinary expertise have convened to form committees that offer an effective venue for the development of science-based consensus standards. Other industrial sectors (e.g., chemical and petrochemical) with significant experience in similar areas have a long history of standards development and further contribute to the depth and variety of expertise, integrating fundamental scientific, engineering, and statistical principles in order to develop relevant, science-based standards.

The FDA has a long history of working with consensus standard development organizations, most notably within CDRH. CDER has participated in several PDA task forces writing technical reports, including the PDA Virus Filter Task Force. This group wrote the first industry nomenclature standard for both small and large virus-retentive filters based on lab studies performed in-house at CDER.

The FDA...is willing to work as part of collaborative groups committed to building standards

As we progress with a 21st century drug quality system, consensus standards will continue to play an important role. Clearly there is/will be a need for standards to provide clarity, improve predictability, and encourage innovation. In this issue of the *PDA Journal,* **William Huitt**, W.M. Huitt Co., presents an excellent overview of ASME standards for Pharmaceutical Facilities, specifically those for Bioprocessing Equipment. These standards are very useful for industry to design and select appropriate piping to ensure quality of biotechnology active ingredients, for example. The FDA has neither the resources nor expertise necessary to alone develop these kinds of standards but is willing to work as part of collaborative groups committed to building standards.

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Poster Presentation

Library Databases for Microbial Identification: Critical Aspects and Recommendations

The Power of Knowledge

Thomas Peither, Halfmann Goetsch Peither and Maas & Peither GMP Publishing

Knowledge is already one of the most precious commodities in the pharmaceutical industry.

Information is not knowledge.
— Albert Einstein

According to the *Oxford English Dictionary,* knowledge is defined as "expertise, and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject." The competition to get the most knowledgeable people has already started and companies are spending a lot of time and money to find, attract and hire subject matter experts. This seems to be in conflict with the recent layoffs in the pharmaceutical industry, but both are parts of a picture to become more efficient and to reach operational excellence.

[Editor's Note: This article is a precursor to a detailed presentation on the topic which will be given at PDA's Annual Meeting in San Antonio, Texas.**]**

To stay ahead, it is necessary to develop a strategy for an organizational memory, which retains and preserves knowledge and makes the memory accessible to all employees. Other industries have made great strides from which the pharmaceutical industry could learn. While it might look simple at first, careful evaluation uncovers a sizeable challenge, which needs deeper thoughts and discussions.

Other industries have made great strides from which the pharmaceutical industry could learn

The Paradigm Change in Manufacturing Operations (PCMO[SM]) Task Force on Knowledge Management (KM) during Commercial Manufacturing is developing a technical report on one way to implement KM in an organization.

We all have a wealth of data stored in various IT systems, SOPs, databases, etc., but this is not yet knowledge. Turning this data into information and, from there, applying the information as useful knowledge is the task at hand. The PCMO Task Force developed a KM Function Model which describes step by step implementation that is intended to help pharmaceutical companies build their own KM system.

Knowledge Management Function Model

1. Acquisition of data
2. Data evaluation
3. Filtering information from the data
4. Understanding product/process information
5. Review process of knowledge
6. Storage & sharing of knowledge

Data and Information

Pharmaceutical companies have terabytes of data and information stored in IT systems. Data evaluation can transform raw data into useful information about procedures, processes and products. Turning this information into knowledge still requires the expert mind to apply the information. Differentiations have to be made and we have to distinguish between relevant and irrelevant information.

Knowledge

Usually experts or expert teams decide which information is needed to reach decisions, and these decisions are often based on a combination of prior experience and the outcome of analysis of a series of experimental results. It is challenging to gather this kind of information and transform it into applied knowledge, since it often involves tacit knowledge. Tacit knowledge is the large part of individual wisdom that the person is not aware of but which frequently influences decision making. One can imagine that it is very difficult to transfer knowledge of this type into a repository system.

For more than 500 years, experts have used books as a repository system for knowledge. In this age, we search for immediate answers to our questions. It is a challenge to design processes with the ability to answer these questions reliably.

Part of knowledge is the understanding of processes, products and procedures. When somebody understands all the correlations and interrelations, he or she is an expert. Experts, the owners of knowledge, are highly respected in our society, and KM will only be a success when they identify with knowledge management within the organizations. Since the general framework of companies and knowledge is becoming increasingly complex and finding experts is increasingly difficult, sharing of knowledge throughout a company is the key to knowledge retention and success.

Peer Review

When implementing knowledge management, it is essential to plan and incorporate a review process. Discussions between experts will often result in differences of opinions. For this reason, it is important to only share proven or applied knowledge. In science-based publications, peer review is an established procedure. Every organization can benefit by adopting similar procedures and applying knowledge only once there is a consensus that the filtered information can be usefully implemented within the specific organization.

IT Systems

Knowledge management systems must support business processes. Therefore IT systems (e.g., repository systems), designed in a later project phase, are defined in an earlier phase, through development of system requirements. IT systems themself should not trigger knowledge management projects but rather support knowledge management procedures.

Today there are countless data and information technology systems in place (ERP, LIMS, CAPA, etc.). It is important to sort, arrange, classify and merge the data and information collected by these different systems. Just adding another system to the already existing ones will not do any good. IT systems will not help where the procedures for data entry, collection and analysis are inadequate. The procedures are definitely more important in KM projects.

Knowledge Sharing

Knowledge management does not support the organization when the knowledge is:

- not used
- too difficult to find
- not handed over/communicated
- not supported by senior management

Key Points from the Article

- Clarify differences between data, information and knowledge
- Evaluate and filter information
- Understand process, product and procedures

Knowledge becomes obsolete as time goes by. It is vital that it is being used—the more the better. When a KM project is launched, everybody can tell if it works and if it was done right. Knowledge management systems without acceptance of the employees are a waste of time and money. Currently, the Task Force is identifying and looking for case studies supporting the acceptance of KM projects in organizations.

Implementation with Success

After discussion of the *Knowledge Management Function Model,* the PCMO Task Force realized that there are high hurdles for implementation in a typical pharmaceutical company. Often there are too many restrictions in quality and IT systems. The systems may be inflexible, rigid and documentation driven. The PCMO group found that certain factors must be in place for the success of knowledge management projects, such as:

- Employee training, involvement and empowerment
- Removal of organizational constraints
- Knowledge-friendly culture
- Information systems infrastructure
- Top management leadership and commitment

The presentation about the results of PCMO Task Force at the Annual Meeting will give an overview of the milestones of knowledge management projects. The Knowledge Management Function Model will be discussed, and success factors leading to pharmaceutical excellence will be shown. Success of KM implementations also depends on knowledge-based performance measurement and benchmarking, as already stated by Albert Einstein: *"Not everything that can be counted counts and not everything that counts can be counted."*

Harnessing Knowledge Management is one of the challenges of our days and can guide us to a prosperous and profitable future. Come to San Antonio and learn about the power of knowledge.

Be sure to check out Thomas Peither's presentation at PDA's Annual Meeting at 9:30-10 a.m. on Tuesday, April 12

About the Author

Thomas Peither is the co-founder of the three-year-old consulting company HGP and has been with the publishing company, Maas & Peither since 1999. With more than 15 years consulting experience, he is an international expert in cGMP issues in the pharmaceutical industry. Peither is responsible for the GMP consulting business at HGP and the international business of Maas & Peither. Additionally, he is member of the PDA Taskforce PCMO℠ Sec. 2.1 "Capture Knowledge Management during Commercial Manufacturing." Peither is the editor of the comprehensive GMP knowledge source the *GMP Manual* and is the author of several books and articles.

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A Look into the Future of Parenteral Manufacturing: Part 2

Volker Eck, PhD, PDA

[Editor's Note: The following is the continuation of Volker Eck's report of the 2010 Parenteral Conference. The first installment published in the January *PDA Letter*.**]**

Future of Parenterals

The first to give a flavor of where the industry comes from, what has been achieved, what is still an issue and where it is heading was **Tor Gråberg,** Chief Pharmaceutical Inspector, Medical Products Agency, Sweden. Gråberg elaborated on globalization and harmonization needs and projects, big versus small pharma positions and potentials, information and trust building, role and implications of contract manufacturing and environmental impact.

His message to the participants was that, most probably, the EU GMP Guide will be split into three parts and into Annexes. The first two parts we already know and deal with—Drug Substances and Drug Products—and the Annexes are well established elements of the current EU GMP Guide. The plan is to introduce a Part III which will contain miscellaneous, general guidance on topics like Quality Systems, Risk Assessment and Risk Management. Also, the validation concept might change and become a verification concept, based on a Quality by Design approach and supported by a solid knowledge background. "One main barrier is probably the uncertainty of regulatory consequences," he stated.

Another topic of interest was the goal of harmonizing inspections, their quality and interpretation of rules, regulations and requirements. Here, Gråberg emphasized the role and impact of the PIC/S scheme that has as its objectives "to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products." PIC/S is therefore providing training to inspectors of adhering agencies and facilitating joint assessments and audits. To this end, "PIC/S will aim for a deepened cooperation with PDA and ISPE," he stated. The interest in joining this organization is increasing and there are seven agencies under assessment, including the U.S. FDA. **[Editor's Note:** The U.S. FDA has since become a member of PIC/S.**]**

Another area of concern is the traceability of pharmaceutical product. Here a focus is set on inspections and audits of API manufacturing by following the history path of the product and thus creating traceability.

Gråberg's talk was echoed by the lecture of **Jens Friedrich Haefele,** VP, Bio-Pharma Operations, Boehringer-Ingelheim, who highlighted aspects like the impact of inspections of manufacturing operations by as many as 14 regulatory authorities from outside the EU. In the specific case for his company, which markets its locally manufactured products globally, the time spent for inspections more than doubled from 2000 to 2009. As this trend continues, any training and harmonization efforts are welcomed, as they might contribute to a reduction in the variance in expectations and requirements.

Concerning parenteral products in particular, Haefele pointed out that in 2016, the revenue from biopharmaceuticals, also known as New Biological Entities (NBEs), is expected to grow by more than 30% compared to 2009. As NBEs are primarily offered as parenteral formulations, this will have impact on capacities, techniques and technologies used in development, manufacturing, fill/finish and analytics. But not only the volume, at the same time their formulation and packaging options will be broader and include facilitating application devices like cartridges, prefilled syringes and others. Manufacturing technologies that can easily accommodate such wide format changes will be most sought.

Another trend in steady growth, he continued, is that "processes of pharmaceutical manufacturing are transferred upstream in the supply chain to component suppliers. For example, ready to use quality components are sterilized by ethylene oxide at the vendor's site, as are ready to fill quality components sterilized by gamma-irradiation." This has impact on the way suppliers to the pharmaceutical industry manufacture and operate in future and introduces GMP aspects into a completely new area.

Trends in Parenteral Manufacturing

The following talks were aimed to go into more detail on current trends in parenteral manufacturing. **Hal Baseman,** COO, ValSource, gave an overview on the use and issues involved with isolators and restricted barrier access systems (RABS) in aseptic manufacturing. An important consideration often difficult to address are media fill frequency with respect to a multiple shift process and the environment this process was performed in. This can be best answered on a risk-based approach. The frequency will depend on the number of shifts and whether the equipment and environment involved where closed. Automated systems would require the least number of aseptic process simulations. However, "lower numbers of media fills would be based on risk rationale and would be subject to reevaluation, if contamination issues occur," he stated. In the discussion following his talk, it emerged that it would be beneficial to the industry if a PDA task force of experts could give some points to consider for the validation of the diverse systems of isolators and RABS. **James Drinkwater,** Senior Scientist, Bioquell, pointed out that there was a white paper published by the Pharmaceutical and Healthcare Science Society (PHSS) on the use of hydrogen peroxide vapor in sterilizing non-direct surfaces specifically in RABS. The link to this document can be found on the PDA UK Chapter **(1)** and PHSS websites.

Mike Sadowski, Director, Sterile Manufacture Support, Baxter Healthcare, gave an overview of the work of the PDA Task Force on the revision of the Technical Report No. 30 on parametric release. The obvious trend is to extend parametric release, which was once limited to terminally sterilized processes by moist heat, ethylene oxide and irradiation, to other manufacturing areas like aseptic processing. In his view, it was "time to eliminate the sterility test-based release program to waive or be exempted from the scientifically sound or best demonstrated practices that are fundamental to a parametric release sterilization program." Revised PDA Technical Report No. 30 will be published soon.

Building new facilities also offers the opportunity to reduce energy consumption

Klaus Haberer, Managing Director, Compliance, Advice and Service in Microbiology, presented the ongoing work of the PDA Task Force on Post Aseptic Filling Lethal Treatment. The goal of this Task Force is to develop a Technical Report that will illustrate how to assess a combined sterilization/aseptic manufacturing process. The idea being that in case a terminally moist heat sterilization is not feasible and an aseptic process needs to be used, potential microbial contamination can be reduced by a sub-sterilization moist heat treatment of 60°C or 80°C combined with an aseptic process. So "to expose an aseptically filled drug product to a lethal process sufficient to destroy microorganisms that might be introduced during aseptic filling" would be beneficial, he said, adding that "the treatment must consider the maintenance of material properties." He continued, "The resulting combined process is safer than either the aseptic process or the terminal sterilization process alone." The technical report will introduce a decision tree to facilitate the choice of post aseptic fill lethal treatment conditions.

Innovative Plants

Alexander Sterchi, Head of Support & Infrastructure, F. Hoffmann-La Roche, gave some insight into innovative concepts put into operation at the new facility at Kaiseraugst, Switzerland. For the complete production suite, isolators, RABS and CIP/SIP technology were installed. Additionally, collision free transport was implemented throughout. In-line NIR spectrometry to monitor lyophilization processes was only one example of an innovative technology that was selected. But apart from technology solutions, organizational innovations are as important, he underlined. Kaizen Tools had been used from the beginning. These resulted in designing new and improved processes, and also the process maps were redesigned to improve understanding and enhance compliance. Verification and simulation of the processes allowed to identify potential gaps at interfaces and made potential improvements visible. In an example, he demonstrated that such improvements resulted in a significant reduction of environmental monitoring findings in the personnel locker area.

Building new facilities also offers the opportunity to reduce energy consumption, added **Jens Frederik Studstrup,** Area Specialist, Novo Nordisk. As an example he showed the solutions implemented in a new facility in Tianjin, China. He emphasized that NovoNordisk had over 400 projects in existing production facilities to reduce the CO_2 emission by 28,000 tons or 80 million kWh. More than half of them had a return of investment by energy cost savings of less than 12 months and that came mainly from projects involving cooling and ventilation systems. By very simple ad-

justments like going from fixed set points to larger intervals, increased use of recirculated air, better balancing of differential pressures gained them a reduction by 47% and more in heating, cooling and dehumidifying costs. Also, water savings were realized in the process. Sanitary water and irrigation by reuse of process water, reuse of reversed osmosis eject water and other technological solutions returned a 20% saving in water consumption. "Start doing the mapping, speak with facts, data and money," he recommended. "Prioritize the efforts and set targets. Do not run for everything possible. Be careful with prejudice and eliminating saving opportunities too early. Involve consultants, subcontractors and vendors and challenge their 'we usually do' answers.

"Do not forget to install meters for energy and water consumption and establish an energy management system from start, so you can monitor progress and identify future saving opportunities."

Innovations are also relevant in the monitoring of aseptic process areas. Trends and progress was illustrated by **Lorenzo Fumagalli,** Manager, Business Dev., Copan Italy; **Vincent Beguin,** Design Validation Manager, Millipore; and **Bruno Vallayer,** Director NRBC, Biotechnology Health, Bertin Technologies. Fumagalli illustrated the use and benefits of a new swab that allowed a better than usual recovery for environmental isolates. Beguin detailed the efforts of technology suppliers in validating modern microbiological methods. Vallayer introduced a new air monitoring system that is based on a cyclone technique. Air is pulled into a cone and produces a cyclone airflow and intimate mixing of any airborne particle with the fluid phase. The volume sampled can reach 3 m^3 in 10 min, the sample can be split and an aliquot submitted to rapid microbiological analysis. The efficiency for recovering microbiological contaminants range from 78% biological efficiency for *S. epidermidis* to 85% for *E coli.* Techniques applied thereafter include solid phase cytometry, bioluminescence, and PCR.

In a very detailed presentation, **Kathryn King,** Staff Scientist, Office of Biotechnology, U.S. FDA, gave an overview on molecular methods for virus detection in biologics. Virus contamination is a concern, as some biologics may be contaminated by rotavirus for example. "In addition to exogenous viruses, endogenous viruses are of concern with rodent cell lines," she stated. "Despite extensive purification steps, freedom from contaminating agents like bacteria, fungi, mycoplasma, viruses and TSE must be assured," she continued. New molecular cell substrates are in development and well characterized cell substrates still can become contaminated.

The response from the audience was such that the organizers decided to hold the next conference in two years time for another 360° overview

CE is an official certification that a device complies with the pertinent European law on consumer health, safety and environmental impact and, hence, may be sold in the entire EU region (and additionally in the EEA countries as well as Switzerland). The major document produced is called Conformity Assessment and, for some products, like medical devices, competent authorities will be scrutinizing it before granting approval.

New molecular testing methods are being used. In addition to extensive microbial agents testing, the safety profile of biologics can be strengthened by implementing new molecular testing methods. PDA has put together a task force to draft a technical document on molecular methods for virus detection. The document will cover all available technology, its advantages and limitations, as well as a section on traditional viral assays.

Application Devices

Application devices are a trend within the industry. They are aimed to increase compliance by patients, increase safety and reduce administration resources. The overall trend seems to include application devices already in the development phase rather than as a life cycle option. Also they span from single dose to repeated and multi-dosing regimes. The general trend also seems to support devices that are tailored to the application and the patient group rather than platform families. "My recommendations are to start early with a partner and evaluate suitable devices; to work in a strong team, as the auto injector is a system with many facets; to work with experienced experts in the field; and to adapt the system to the target group and the local regulations," **Mats Persson,** VP, Executive Management, SHL Group, concluded.

Silke Conrad, Manager, Regulatory Affairs, R&A, Ypsomed, elaborated further on the regulatory requirements and environment for application devices. Depending on the jurisdiction, it may be seen as a "combination product" in the United States and fall under the GMP rules for medicines, however, at the same time be viewed as a medical device in Europe and, hence, fall under the CE mark* approval and oversight regime. She highlighted the requirements in Europe to be seen either as a medical device or a medicinal product, however, she warned, that there was the notion of "borderline products," where such a clear cut sorting would not apply and guidance from the European Medicines Agency should be sought. For any applicant it would be very important to be clear on the diverse requirements and prepare for the respective consequences on registration strategies as well as on manufacturing facility and operations.

Looking Forward to 2012

The conference gave a broad overview and hit on several hot topics in parenteral manufacturing. The response from the audience was such that the organizers decided to hold the next conference in two years time for another 360° overview on achievements made and challenges to meet.

References

1. PHSS–RABS, Development of Definition and Specifications, 2010, www.pda.org/mainmenucategory/chapters/united-kingdom/chapter-resources.aspx

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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

Workshop to Discuss Future of Medical Products

An industry exchange workshop on *The Future of Medical Products Regulations: Ensuring Safety and Integrity in a Global Market* will be held June 20 and 21 at the Marriott Dallas/Plano at Legacy Town Center in Plano, Texas.

Co-sponsored by the Association of Food and Drug Officials, the Mid-Continental Association of Food and Drug Officials and the FDA Medical Device Industry Coalition, the workshop will include discussions on:

- Globalization, Imports and Supplier Controls
- Medical Product Theft and Criminal Investigations
- Proposed changes to the 510(k) review process
- Health fraud
- Streamlining the FDA Enforcement Process
- The future of medical products regulation
- Medical Devices in Canada
- The Freedom of Information Act
- Medical Product Complaint Investigations
- Writing Corrective and Preventive Actions procedures and documents to reflect compliance initiatives
- Top Ten FDA483 objectionable observations

FDA's Draft Guidance on Positron Emission Tomography(PET) Available

The U.S. FDA's *PET Drug Applications–Content and Format for NDAs and ANDAs* draft guidance is now available.

The draft guidance is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications or abbreviated new drug applications.

Comments on the new draft guidance are due by April 4.

Agency Issues Process Validation Guidance

The U.S. FDA has issued the Process Validation: General Principles and Practices guidance. The guidance replaces the previous guidance on the subject that was published in May 1987.

The guidance provides information for the pharmaceutical industry on the elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients.

Key Regulatory Dates

Comments Due:

April 4 — FDA's Draft Guidance on Positron Emission Tomography

Europe

EMA Launches Public Access to EudraGMP Database

In early February, the European Medicines Agency launched the long awaited "public access" version of its EudraGMP database.

This version allows public access to authorization and GMP certificates from all countries in the EU plus Iceland, Liechtenstein and Norway. It eliminates the need to submit applications in paper form; and will facilitate sharing inspection outcomes with other authorities.

The Agency expects around 3,000 new certificates to be imported into EudraGMP every year. The database will grow rapidly following the introduction of inspections in countries outside the EU and new GMP requirements for active substances.

Regulatory Authorities to Speak at Annual Meeting

The *2011 PDA Annual Meeting* held in San Antonio, Texas on April 11-13 will feature some important speakers from the European Medicines Agency and the U.S. FDA.

On Monday, April 11, at 8:45 a.m.-9:15 a.m., **Piotr Krauze,** Scientific Administrator/Compliance and Inspection Sector, European Medicines Agency, will give a presentation on Knowledge Management from the EMA perspective. At 11:15 a.m.-11:45 a.m., **J. David Doleski,** Team Leader, CBER, FDA, will speak about regulatory expectations for biologics applications submitted to FDA.

On Tuesday, April 12 at 7:30 a.m.-8:00 a.m., **Kurt Brorson,** PhD, Staff Scientist, Monoclonal Antibodies, CDER, FDA, will give an analysis of glycoform characterization within monoclonal antibody regulatory submissions.

To see what other speakers will be presenting, visit www.pda.org/annual2011.

Grace McNally, Consumer Safety Officer, CDER, *FDA,* will give the opening plenary session address and will take part in the closing panel discussion of the *PDA Process Validation Guidance Workshop.* The workshop will be held immediately following the Annual Meeting.

The Parenteral Drug Association presents the...

2011 PDA/FDA Joint Regulatory Conference

Quality and Compliance in Today's Regulatory Enforcement Environment

September 19-23, 2011

Renaissance Hotel | Washington, D.C.

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

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

PDA TRI courses include:

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

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

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Don't Miss an Informative Event: Attend the Annual Meeting!

San Antonio, Texas • April 11- 15 • www.pda.org/annual2011

Vice Chair Annual Meeting Planning Committee Marsha Hardiman, Dendreon

On behalf of the Annual Meeting Program Committee, I would like to invite you to attend the *2011 PDA Annual Meeting*, April 11-15 at the JW Marriott in San Antonio, Texas. The program planning committee is very busy working with the excellent panel of presenters we have selected as we put the finishing touches on the conference and events which we have planned for you. This year's PDA Annual Meeting theme is *Knowledge Management*. Information and knowledge of our processes are corporate assets and we need to better develop strategies, tools and policies for managing these assets.

Whether you are an experienced veteran or a novice new to our industry, I encourage you to attend this extraordinary meeting. Are you (or is one of your employees or colleagues) new to the industry or have you recently changed jobs? For the first time, we have added a one day Fundamentals track to the meeting which is aimed at novices and will feature fundamental sessions in Validation, Operations, Microbiology, Quality and Regulatory Affairs as well as Aseptic Processing.

We believe this year's annual program has the perfect blend of education, excellence in science and fun for all levels of employees in your organization! This is PDA's "flagship" event and continues to be considered the years' most valuable networking opportunity. Come share best practices among colleagues in industry, regulatory agencies and academia. We look forward to seeing you there. Come network with old friends and meet new ones.

Today's economic environment has put pressure on our organizations to optimize performance. From ICH Q10 to guidance documents like the finalized FDA Process Validation Guidance, we are being reminded of what should be a good business practice—*that we need to know and understand our processes!* Our presenters and interest groups as well as workshops will be focusing on the theme of the 2011 Annual Meeting—harnessing the power of knowledge to drive world class science and technology. Coupled with the presentations will be state of the art technology options which you will explore in the exhibition hall as you mingle with the vendors.

The meeting will be conducted in the traditional format with three parallel conference tracks with additional time added in each session for questions and answers. We really want this conference to be as interactive as possible. The exchange of thoughts and ideas creates the drive to influence change as we move forward in science and technology. We encourage you to not just come to this year's meeting, but to come and engage in this exchange and influence someone! This year's tracks include:

We encourage you to not just come to this year's meeting, but to come and engage in this exchange and influence someone!

- Manufacturing Process Science
- Development Science
- Quality Science
- Microbiology/Environmental Monitoring/RMM
- Supply Chain/Outsourcing
- Fundamentals

This meeting will be a dialogue on the ways and means to manage information in R & D and the laboratories; transfer knowledge in manufacturing and how to harness and manage the power of knowledge. With three plenary, 24 concurrent sessions (including the Fundamentals Track and 14 interest group meetings) and Training and Research Institute courses offered on Wednesday–Friday, this event has much to offer everyone.

At the opening plenary session on Monday, April 11, the committee is excited to present a keynote presentation from **Piotr Krauze**, Scientific Administrator, Compliance and Inspection Section, EMA, to speak about EMA initiatives and compliance issues. In addition, we will have two excellent keynote presentations from the Dean of the College of Pharmacy at the University of Texas, **Lynn Crismon** and the Director of the Drug Dynamics Institute, Professor **Janet Walkow.** They will be speaking about private academic collaborations and product development. On Wednesday, April 13, we will enjoy a closing plenary session from U.S. FDA.

In addition to the formal conference proceedings, we have put together an impressive choice of optional and fun events beginning with the PDA Annual Golf Tournament and the 5th Annual Fun Walk/Run on Sunday, April 10. I have personally taken part in these events in the past and I can attest to how much fun they are. I have been bringing my family along to the PDA Annual Conference for years, and I encourage you to do the same. There will be a spouse and guest activities orientation breakfast on Monday and Tuesday. There is so much to do around the resort and in the area. Family members can participate in the Fun Walk/Run and Golf Tournament. On Tuesday, April 12, don't miss the San Antonio River Cruise. Make your conference experience a well rounded one by taking part in these networking activities.

The committee appreciates your continued commitment to this meeting, and in return, we are committed to presenting you with a valuable, highly informative and fun program.

We all look forward to seeing you in San Antonio in April. Please visit www.pda.org/annual2011 for more information and to register!

Meet New Friends and Exchange Ideas at the Annual Meeting's Networking Events

It's all about exchange, so make your conference experience a well-rounded one by participating in networking activities at the *2011 PDA Annual Meeting*. There are a handful of opportunities to choose from for you and your family!

Sunday, April 10: 5th Annual PDA Golf Tournament at the AT&T Canyons Golf Course

TPC San Antonio opened in 2010 and has 36 holes, designed by two of golf's most respected and innovative architects and World Golf Hall of Fame members, Pete Dye and Greg Norman. Network with colleagues while playing on this course that sits on a beautiful piece of land which provides panoramic views of an adjacent 750 acre nature preserve. The design, which measures more than 7,500 yards, is true to nature and the flow of the land. The dramatic elevation changes and hill country views make this course not only challenging, but breathtaking as well. This event is $190 per person and includes tee time, bag valet, cart, range of balls, tournament management and lunch. Sign up for your foursome today!

Sunday, April 10: 5th Annual Walk/Run Benefiting the American Cancer Society

Get your heart rate up and feel energized for the week with a 3k walk or a 5k run during this optional event with colleagues, family and friends. The proceeds of this event will go to the American Cancer Society. This event is $15 per person and includes a race bib and healthy refreshments.

Monday, April 11 & Tuesday, April 12: Spouse & Guest Activities Orientation Breakfast

Your spouse and family members can attend these orientations to plan a pleasant and memorable experience in San Antonio, Texas. There is so much to do at the resort and in the area so make sure your family and friends are aware of all that San Antonio has to offer!

Monday, April 11 and Tuesday, April 12: PDA Annual Meeting Career Fair

Attend the PDA Annual Meeting Career Fair and interact with employers from a variety of fields in the biopharmaceutical science and manufacturing industry. Ample time will be provided to find out about jobs, drop off resumes and interview on site.

Tuesday, April 12: San Antonio River Cruise

You can't visit San Antonio without experiencing a River Cruise down the famous San Antonio River! This is a delightful trip that will take you past some beautiful rustic old world accents, lush landscapes, quaint pathways all the while being pampered. This event is $55 per registered attendee or guest and includes round trip transportation, cocktails, hors d'oeuvres and the cruise.

Learn more about these networking events by visiting www.pda.org/annual2011networking.

Last year at the *2010 PDA Annual Meeting,* PDA members and staff participated in the Walk/Run event

Workshop to Review Agency Process Validation Guidance

San Antonio, Texas • April 13-14 • www.pda.org/processvalidation2011

Workshop Organizers Hal Baseman, ValSource and Scott Bozzone, Pfizer

In November 2008 the U.S. FDA issued a draft revision of the General Principles of Process Validation Guidance. The draft guidance introduced a three stage program incorporating *process design, process qualification and continued process verification* into an overall life cycle approach to process validation.

A PDA Committee reviewed the draft guidance, collected industry and member comments, and issued a response to the FDA. Over 400 industry comments were organized into major categories. The categories included:

1. Wording and Terminology
2. Approach and Assurance for Commercial Distribution
3. Viral and Impurity Clearance
4. Concurrent Release
5. Scope and Legacy Systems
6. Qualification, Documentation, Organization and Regulatory Impact

Joint workshop sessions were held throughout 2009 with the FDA and PDA in San Francisco, Calif.; Las Vegas, Nev.; Chicago, Ill.; Munich, Germany; Bethesda, Md.; and Puerto Rico.

On January 24, 2011 the FDA released a final version of the revised Process Validation Guidance. The 2011 version appears to have taken note and addressed many of the PDA/industry comments. There are changes to the guidance related to all of the major categories. If you liked the 2008 draft version, we suspect you will be pleased with the finished version. However, as would be the case with any attempt at change, implementation of the guidance presents challenges and questions the industry must now be prepared to face and answer. Many of these challenges were articulated at a recent meeting in Bethesda, Md. of the PDA PCMO Process Validation task force.

These include:

Stage 1: Process Design Process Understanding

- How to allocate resources to determine variables and understanding
- How to define the continuum of criticality
- How to establish an effective Control Strategy

Technology Transfer

- How to set up mechanisms for knowledge transfer between process development and manufacturing ➤

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- How to identify process variables and designing adequate control strategies

Stage 2: Process Qualification

- How to best link the information generated in Stage 1 to Stage 2
- How to determine the information required to assure that processes are adequately controlled prior to release for commercial manufacture.
  - How many batches in PPQ protocol?
  - How much and what type of data is needed?
  - What are the correct confidence levels for process control?
  - How much sampling and monitoring is needed beyond Stage 2?

Stage 3: Continued Process Verification

- How to develop an effective program for acquiring and evaluating post commercial manufacturing information.
- What type of information should we look for?
- How should the information be presented?
- How should legacy processes be addressed?
- How should less-than-desired results be addressed?
- What statistical models and risk assessments methods should be used?
- How should all of this be documented?

On Wednesday, April 13 and Thursday, April 14, PDA will host a workshop on the Process Validation Guidance in San Antonio, Texas at the conclusion of the *PDA 2011 Annual Meeting and Conference*. The workshop will bring together validation industry professions and regulators to review the finished guidance and discuss ways to meet the expectations and recommendations in the guidance, as well as meet the challenges and begin to answer the questions listed above.

An example of the session topics are:

- FDA Perspectives
- Industry Perspectives
- International Perspectives
- Implementation Sessions for each of the 3 stages (Process Design, Process Qualification and Continue Process Verification)
- Breakout and Panel discussions on What's missing from the guidance and the Path Forward

This is a great chance to meet with regulators, listen to the experience and plans of your colleagues, hear what other companies are doing, and to perhaps influence the approaches, which will form the basis of Process Validation in our industry for years to come. Please do not miss this important meeting. If you wish to attend—sign up soon. If you wish to participate—attend. We promise that you will have every opportunity to be heard.

For more information or to register, visit www.pda.org/processvalidation2011.

Risk-Based Approaches Showcased at Disposables Workshop

Bethesda, Md. • June 22-23 • www.pda.org/singleuse2011

Morten Munk, CMC Biologics and Robert Repetto, Pfizer

The PDA Single-Use Systems Task Force is completing a technical report on the implementation of single-use systems and will host a conference that showcases and encourages the philosophies championed in the report.

One of our key messages for successful single-use system implementation is a transparent partnership between the single-use system supplier and the end user by encouraging an open science and risk-based dialogue.

The workshop will be organized to highlight this partnership theme demonstrating the science and risk-based values we encourage in the document.

If you can attend only one conference this year, the *2011 Single-Use Systems Workshop* is clearly the meeting you should attend. The workshop will be structured around the PDA technical report on implementing single-use systems and will showcase the concepts and themes in the report.

PDA's Single-Use Systems Workshop offers a different approach, presenting science and risk-based concepts which are flexible and can be applied in many different situations and organizations.

The Single-Use System Task Force was strategically designed as a partnership between end users, suppliers, industry enablers and regulators. During the workshop, it will be possible to interact with regulators from the EMA and U.S. FDA. This unique mix of skills and expertise provides a balanced, well-vetted, consensus viewpoint that ensures the educational value of the conference.

Presentations at competing conferences are often focused on specific case studies with a "single organization" viewpoint. These "war story" presentations may outline what that organization did for their specific situation, but this provides little educational value that an audience can apply in their own organization. PDA's Single-Use Systems Workshop offers a different approach, presenting science and risk-based concepts which are flexible and can be applied in many different situations and organizations.

The Task Force's close relation with Bioprocess System Alliance and single-use systems suppliers offers PDA a unique opportunity to host a hands-on technology

continued on the bottom of page 47

The Parenteral Drug Association presents the...

2011 Single Use Systems Workshop

June 22-23, 2011

Hyatt Regency Bethesda | Bethesda, Maryland

Single-use (disposable) technology is a proven alternative solution for the biopharmaceutical industry offering several significant advantages over standard reusable stainless steel systems, by reducing cross contamination risk, cleaning and associated cleaning validation, capital investment, lead times and the number of connections to enhance sterility assurance.

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

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

Register before March 28, 2011 and save up to $200!

www.pda.org/Singleuse2011

Photos courtesy of Sartorius Stedim Biotech

Overview of AMD, Validation Standards Offered at Workshop

Bethesda, Md. • June 20-21 • www.pda.org/analyticalmethods2011

Program Planning Committee Co-chairs Stephan O. Krause, PhD, Medimmune and Dwayne Neal, SAIC-Frederick

The program planning committee requests your attendance at *PDA's 2011 Analytical Methods Development & Validation Workshop*. It will be held on June 20–21 in Bethesda, Md. The theme of this year's meeting is *The Complete Method Life Cycle*. This workshop offers an excellent opportunity to interact with fellow Analytical Development and Validation professionals, regulatory representatives and leaders from around the world in the pharmaceutical and biopharmaceutical industry.

The workshop will provide participants a wide overview of the laboratory and documentation standards expected during the development, qualification, and validation of analytical methods. An update from last year's meeting will be presented in context to current recommendations for appropriate development and validation of methods in accordance to ICH, Pharmacopoeia, PDA Technical Reports and other relevant regulatory documents.

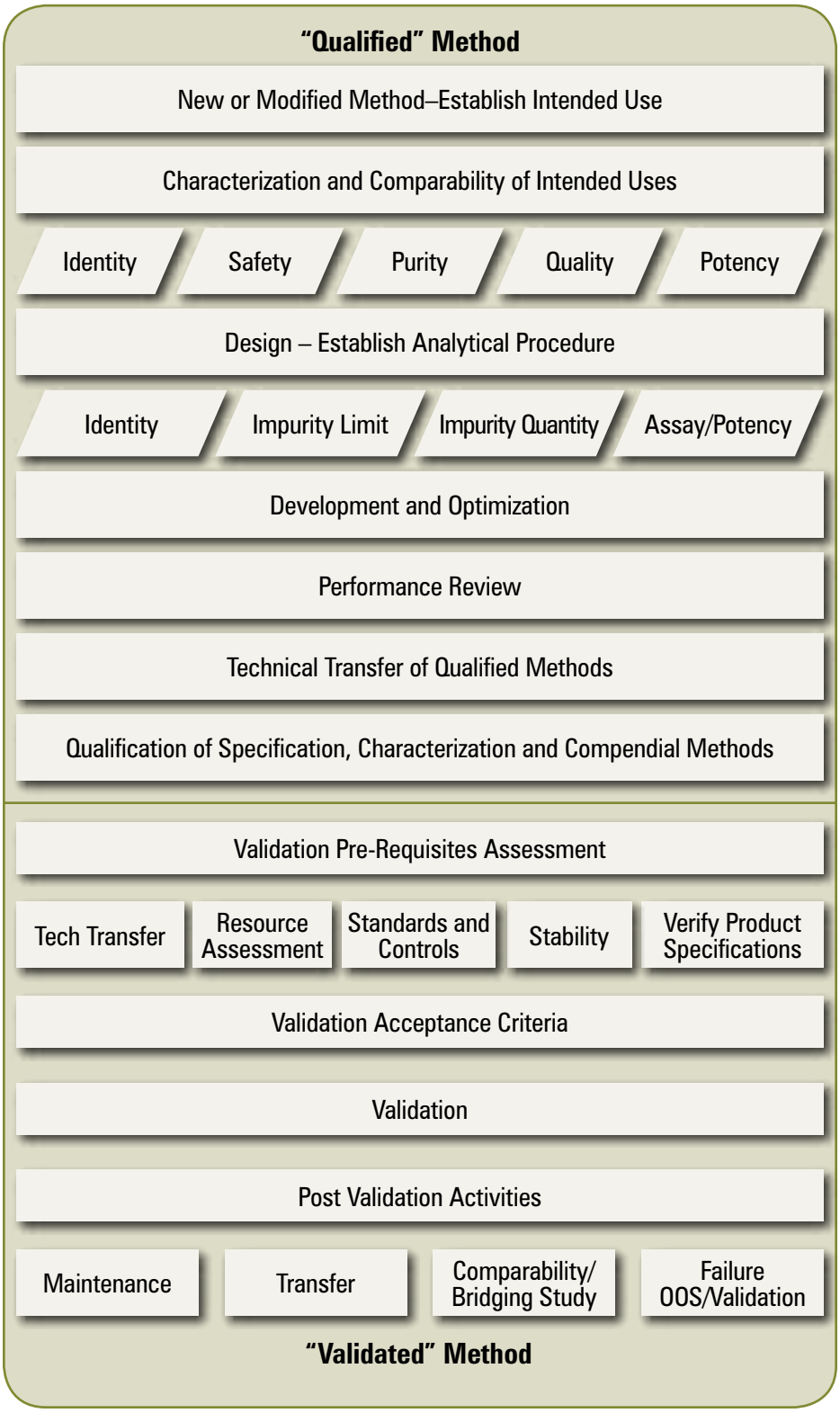
A case study of a representative method life cycle (shown in **Figure 1**), will be one of the featured presentations. In addition, regulatory-approved strategies and case studies to demonstrate analytical method comparability of replacement assays will be presented and discussed.

Attendees at this workshop will gain practical information on regulatory expectations and current industry best practices for the development and validation of analytical methods for biopharmaceutical products.

PDA will host an exhibition of leading bio/pharmaceutical companies who will highlight new technologies and trends.

We look forward to seeing you at this exciting and informative workshop. Visit www.pda.org/analyticalmethods2011 for more information about the meeting, abstract submission and registration.

Figure 1 Example of Method Pathway from Development to Ongoing Maintenance (from Draft PDA Technical Report, Analytical Method Validation for Biotechnology Products)



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The Parenteral Drug Association presents the...

2011 PDA Pharmaceutical Ingredient Supply Chain Workshop

End-to-End Supply Chain Security

Co-sponsored by IPEC and RX-360 Member

June 6-7, 2011

Bethesda North Marriott | Bethesda, Maryland

The *2011 PDA Pharmaceutical Ingredient Supply Chain Workshop* co-sponsored by IPEC-Americas and RX-360 will expound upon how **high quality, safe and effective drug products and drug ingredients depend upon a consistent supply of high quality ingredients and starting materials.**

The recent surge in global cooperation and efforts toward harmonization of Good Manufacturing and Distribution Practices (GMPs and GDPs) and controls pertaining to the Supply Chain stresses the need to secure the entire ingredient manufacturing and distribution chain to ensure quality and safety of medicines for our patients.

Through a series of plenary sessions and breakout sessions, the program will provide participants the opportunity to:

- Hear directly from senior FDA personnel on current regulatory situations
- Share improvements in programs and technology
- Identify any barriers and associated actions to enable implementation of good solutions

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

www.pda.org/supplychain2011

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

The Parenteral Drug Association presents the...

2011 PDA/FDA Glass Quality Conference

Best Practices to Prevent and/or Detect At-Risk Glass Packaging

May 23-26, 2011

Key Bridge Marriott | Arlington, Virginia

Register before March 11, 2011 and save up to $400!

FDA Participation Confirmed

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

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

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

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

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

www.pda.org/glassquality2011

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

Advancing the Fight for Patient Safety

Supply Chain Conference Looks at Supply Chain Security

Bethesda, Md. • June 6 – 7 • www.pda.org/supplychain2011

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

Supply chain security is evolving into a global initiative as well as a cross-departmental initiative. Global regulators must partner, just as industry must partner to promote patient safety. By attending the *PDA/FDA 2011 Pharmaceutical Supply Chain Conference,* co-sponsored by IPEC-Americas and Rx-360, you will hear from US and EU regulators as well as industry experts

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

An audience response system will be used to engage all participants during each plenary session. This will provide a unique speaker and audience interaction as well as real-time benchmarking information. Plenary sessions will cover:

- Supply chain security
- Immediate solutions
- How to create an end-to-end approach
- And much more

This promises to be an excellent conference, be sure to be part of it!

Glass Quality Conference to Discuss Issues, Solutions

Arlington, Va. • May 23-24 • www.pda.org/glassquality2011

Co-Chairs Martin Van Trieste, Amgen and Joyce Bloomfield, Merck

Appropriate 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 life cycle of sterile injectable pharmaceutical and biopharmaceutical products. Due to recent glass packaging quality issues and recalls related to defects and and/or incompatibilities with finished product over the shelf life, pharmaceutical manufacturers and glass suppliers have recognized that improvements are needed in glass packaging and glass handling practices throughout the product life cycle.

During this two-day 2011 Glass Quality Conference, industry and global regulatory authorities will discuss issues that resulted in product recalls, results of an industry survey on glass packaging supplier quality, and global regulatory perspectives and expectations of both the glass supplier and product manufacturer.

Participants at the completion of the conference will know more about:

- Current Issues with Glass Packaging
- Best Practices on Glass Handling
- Current Expectations for Incoming glass and Pharmaceutical Product Packaging
- How to establish an effective Glass Supplier Relationship for Product Improvement
- Improvements in glass manufacturing, characterization, handling or packaging

All attendees will have the opportunity to be involved in discussions on what are we going to do to assure that the highest quality products and packaging are made.

Rx-360 will be hosting a half-day workshop immediately following the conference at the same location to further the discussion on glass delamination.

Conference on Quality Requirements Garners Local Interest

Japan Conference has more than a 100 attendees

Markus Kirchner, Vetter Pharma International

Under the theme of *Primary Packaging and Drug Delivery Trends for Injectables* with the key focus on quality requirements, more than 100 experts from the Japanese and European pharmaceutical and biotech industry met last November at the Westin Hotel in Tokyo for the 2010 Japan Workshop.

"A conference designed exclusively for the sharing and comparing of the latest information on state-of-the-art prefilled injection systems with colleagues from across Japan and Europe is a unique event," said **Brigitte Reutter-Haerle,** who supported the conference.

This year's conference comprised an agenda of nine speakers from representative companies including the PDA Japan Chapter, Nuova Ompi and Vetter as well as Pharma Solutions, Skan, Ypsomed, Bausch & Stroebel and Schreiner MediPharm. One of the conference highlights was a lecture by **Daikichiro Murakami,** co-Chair of the event. His presentation provided the latest information on newly developed contamination technology for clean rooms. Presentations on self-injection trends, track and trace for syringes and the latest news in Japanese regulatory issues rounded out the workshop.

The conference, sponsored jointly by Nuova Ompi and Vetter, was organized in close collaboration with the Japanese and European chapters of the PDA. It represented the fifth time that the group assembled in the Japan capital. "Increasing enrollment and widespread interest in the conference by companies throughout Japan necessitates that planning for next year's event begins immediately," said Daikichiro.

"We hope to welcome many new participants also in 2011, and eagerly look forward to an even greater number of highly qualitative presentations and discussions that help enlighten us on the continuing evolution of prefilled injection systems on the Japanese market," added **Fabio Nicoletti,** co-Chair of the Japan conference.

PDA's Who's Who

Daikichiro Murakami, PhD, Advisor, Taikisha and Director, PDA Japan Chapter

Fabio Nicoletti, President of International Commission on Glass and Co-chair of the 2010 Japan Workshop

Brigitte Reutter-Haerle, Director Corporate Marketing, Vetter Pharma International, and PDA European Prefilled Syringes Interest Group Leader

More than 100 industry experts attended last year's conference, as they did not want to miss the numerous high level presentations and discussions.

Volunteer Opportunities

2011 PDA Europe Workshop on Advanced Therapy Medicinal Products

Call for Papers and Posters

Poster Abstracts due April 15

2011 PDA Europe Virus & TSE Safety Forum

Call for Papers and Posters

Poster Abstracts due May 2

PDA
Parenteral Drug Association

Register by 2 May 2011 and SAVE!

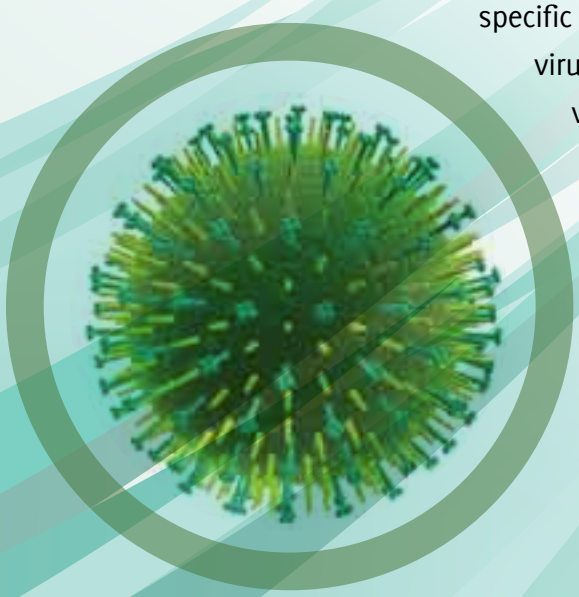
2011 PDA European

Virus & TSE Safety Forum

27-30 June 2011

Barcelona, Spain

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



PRE-CONFERENCE WORKSHOP 27 JUNE

CONFERENCE/EXHIBITION 28-30 JUNE

https://europe.pda.org/VirusTSE2011

PDA Interviews TRI Instructor Anne Marie Dixon

Clean room consultant **Anne Marie Dixon** has been actively engaged in the field of contamination control with extensive experience in the areas of training, technical writing, strategic consulting, facility start-up, construction protocols and process optimization.

She has used that knowledge to teach courses for TRI for the last 25 years.

PDA Letter: You've had a lot of firsts in your career. You were the first recipient of the James P. Agalloco award, and you were the first woman elected to the Institute of Environmental of Science and Technology as the President. How do you think those awards have shaped your career?

Anne Marie: I think, in looking back over the 30+ years of training and education for people who work in clean rooms and controlled environments, that these have been important milestones in my career. There have been actually additional firsts. Last year, I received the exceptional woman award, and I'm the first recipient of that as well.

PDA Letter: Where did you receive that from?

Anne Marie: The IEST started a new award in May of 2010. I received the exceptional woman contributor award in the field of contamination control.

PDA Letter: How does this feel when you receive all these firsts?

Anne Marie: Wonderful. Outstanding. I think it is important on various levels. One, I think it is important that the field of contamination control is recognized. Second, I think it is exciting and critical today that awards are presented to women who have careers in this field for a long time. But first and foremost, it is for the industry—for the science.

PDA Letter: And does it help in the training?

Anne Marie: I think anytime our field of science is recognized, it adds value to training.

PDA Letter: I know you said 'anytime the field of science of contamination control is recognized, it is great.' Do you feel the field of contamination control is not recognized a lot?

Anne Marie: I think it has taken years to become recognized, and I think when we look back, especially after the 30+ years I've been involved with it, it was acknowledged in the very beginning as something people had to do. They did this as a reaction—the technology required this attention. Something would go wrong and, people would say, 'Oh it's a contamination issue. We have to fix it.' We are now becoming very proactive and we perform risk assessments to prevent contamination. We review design, operational controls, personnel training, qualifications, validation, maintenance and environmental monitoring. The system's approach for cleanroom management has improved and matured. This approach has helped to create the paradigm shift in contamination control.

PDA Letter: How did you get involved with the teaching aspect of PDA?

Anne Marie: PDA corporate headquarters at the time came to me to teach courses in the field of contamination control as it was evolving. Because I was teaching in the field, they asked me if I would participate, and I was delighted to do so.

PDA Letter: How long have you taught for PDA?

Anne Marie: I've been an active member at PDA for 25 years. I became involved during my first year as a member.

PDA Letter: That's a long time.

Anne Marie: Yes, I've been with PDA for a long time in the field of education and training. I was involved with PDA when it established the first Institute. It has evolved into the great center it is today.

PDA Letter: How do you feel TRI has changed since it first started in Baltimore to when it moved to Bethesda?

Anne Marie: The center has refocused its attention on very specific areas from its original concept. I think that redefining and realignment with what the industry needs is absolutely critical. I think PDA is an organization that has the ability to do that and to look both to the current needs and what is needed for the future. I think that this is what keeps PDA as a vital leading organization.

Anne Marie Dixon has been involved with PDA TRI for over 20 years

PDA Letter: What do you think the driver is behind that? Is it teachers or PDA staff?

Anne Marie: I think it is all of the above. I think first and foremost it is the leadership of PDA—the board, committees, teachers and staff. But, all non-profit societies need the membership—and the headquarters staff must be able to listen to the needs of the membership and respond.

PDA Letter: How have you seen the students and the issues you have to address with them change over time?

Anne Marie: Because I have been in the field of training for so long, I'm seeing things revert back to the issues of basic contamination control that were in question when I started training. The knowledge base for incoming professionals has changed. They do not have that historical perspective of cleanrooms and associated controlled environments. We have lost so many senior people in

industry through retirement. Some of the mentors that we had within organizations are gone. So companies are going to be looking at groups like PDA to help fill that gap.

PDA Letter: Being someone who is naturally inclined to teach, how does TRI and other organizations fit into your efforts?

Anne Marie: I support PDA and other organizations like IEST. I chair international and national committees, and I feel strongly about the need to support the industry through these efforts.

PDA Letter: As a consultant, is that a big part of what you do?

Anne Marie: Training and education is a part of what I do as my day-to-day work. But, cleanroom operations and assessments is a larger part of my work.

PDA Letter: I want to mention that I had the opportunity to sit in on one of your classes in Orlando back in 2004. You were doing a session on gowning, and you were wearing the clean room outfit. You were very engaging with the students, I could tell the students were getting a lot out of the course. What do you get out of teaching? It's your job, it's part of what you do as a consultant. But what do you get out of all the opportunities to meet with students and teach them something new. What have you gotten out of it over the years?

Anne Marie: My main focus, and I only have one focus, is to educate people to a level that they do not need me. Companies must be able to recognize and solve problems in the area of cleanroom management and contamination control.

PDA Letter: There is a lot of flux in the industry—companies merging, people with a lot of experience let go, reduced staffs and a lot of new people coming in. If I were a new professional in the field, how would I keep up with all of this? How do they go about their daily jobs as well as keeping up with all of the standards and understanding all of them?

I think it is very critical that people belong to an organization such as PDA

Anne Marie: I think it is very critical that people belong to an organization such as PDA. People can attend networking sessions, read the technical reports and journals, network with colleagues and stay current in the technology. In these economic times, many companies have travel restrictions. Many people can't leave their offices. Another concern is the control on staffing. Most people do not have any extra time. The twenty-four hour clock has already expired before they can even look at participating.

PDA Letter: Do you have anything else to add to the interview?

Anne Marie: We all get involved with the day-to-day paperwork: SOPS, batch records, operational issues, change control issues, CAPAs, investigations, etc. At the end of the day, if we can take a brief second to see the benefit of what is done at the facility, the benefit of our final products and the patients who relay on us, I think it can give all of us a sense of pride and contribution to the science and technology.

About The Instructor

Anne Marie Dixon is the Principal of Cleanroom Management Associates, a consulting firm that specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management. She has been certified as an ISO 9000 Internal Auditor. She has authored over 200 technical articles, 10 books, and publications including the definitive text book for undergraduates in the field of semiconductor cleanroom technician training.

Below are a sampling of courses Anne Marie has taught for TRI:

"Risk Mitigation Solutions: The Response to Risk Assessment"

"Cleanroom Management"

"Methods of Reducing Costs for Cleanroom Operations"

"Compliance Auditing of Cleanrooms and Controlled Environments"

Risk-Based Approaches Showcased at Disposables Workshop continued from page 38

showcase at the conference. Participants will see hands on technology demonstrations for key single-use systems technologies, including: bioreactors, connectors, mixers, etc. This showcase will be unique where specific technologies are grouped and suppliers work together to present their technology, not products.

Single-use (disposable) technology is a proven alternative solution for the biopharmaceutical industry offering several significant advantages over standard reusable stainless steel systems, by reducing cross contamination risk, cleaning and associated cleaning validation, capital investment, lead times and the number of connections to enhance sterility assurance. Disposables, or single-use technology/systems, are still in an early stage concerning the industrial use. Indeed, we have a lot of experience with the traditional way of running processes using e.g., steel vessels, containers, separation systems and filling lines connected by steel tubing.

If you would like to learn more about single-use systems, be sure to register for this event! Visit www.pda.org/singleuse-2011for more information.

Great Education Opportunities at 2011 Annual Meeting

Three brand new courses offered at conference!

San Antonio, Texas • April 13-15 • www.pda.org/annual2011

Stephanie Ko, PDA

We are excited to present a selection of seven training courses specifically chosen to be held in conjunction with the *2011 PDA Annual Meeting* in San Antonio, Texas. The courses are intended to help a variety of professionals, no matter their experience level, with interests in aseptic processing, biotechnology, microbiology, quality/regulatory affairs and validation.

While these courses are being offered directly after the annual meeting, anyone is welcome to sign up for them regardless if they attend the Annual Meeting or not.

For beginners, and especially for those following the Fundamentals Track at the Annual Meeting, we are scheduling a half-day course on April 13. "GMP 101" is an introductory course, taught by **Gregory Meyer,** President and Principal Consultant, Compliance Media. It focuses on parenteral pharmaceutical and biopharmaceutical manufacturing basics that touch upon essential elements of the US and EU GMP requirements. Topics include testing and documentation, levels of personnel cleanliness, equipment maintenance and an introduction to calibration and validation.

Six full-day courses are scheduled April 14–15. Three of those courses are being presented for the first time offering those that are coming to the Annual Meeting fresh topics to choose from.

The first new course, "Steam Sterilizers: Getting It Right From the Beginning," will provide you with an understanding of the steam sterilization process and will give you greater clarity to ensure successful and cost effective qualification and validation of steam sterilizers. Instructors **Matt Hofacre,** Director Application Project Manager, Steris Life Sciences, and **Christopher Smalley,** Associate Director BioSterile Validation, Merck, will teach you how to design sterilization cycles for optimum performance and qualification success.

Jason Orloff, Statistical & Engineering Consultant, J. Orloff & Associates, teaches the second new course, "DoE Basics for Validation by Design," and uses group activities and individual exercises to give participants a practical introduction to experimental design basics with applications to Quality by Design and Validation. You will learn specific techniques such as the five basic steps to designing a study, three experimental methods and when to use them, and fractional factorials to save time and money.

Anyone is welcome to sign up for TRI courses offered during the Annual Meeting regardless if they attend the meeting or not

The third new course, "Six Sigma in Process Validation" will allow participants to review the fundamental steps in the Six Sigma process. **Mike Long,** Director, Consulting Services, ValSource, and **Harold Baseman,** Principal, ValSource, will introduce Six Sigma DMAIC tools and explain how they can be used in commissioning, qualification and validation.

The three other courses have been brought back to the schedule based on the popularity of the subject matter, industry needs and outstanding evaluations from previous students.

Learn how to assess a cleanroom training program, manage the daily requirements of the cleanroom, evaluate cleanroom supplies and garments, and assess the efficiency and frequency for aseptic and non-aseptic cleaning methods in "Cleanroom Management," taught by **Anne Marie Dixon,** Managing Partner, Cleanroom Management Associates. This course will give extensive guidance for the critical daily aseptic maintenance and housekeeping functions necessary to maintain the cleanliness levels required.

In "CMC Regulatory Compliance of Biopharmaceuticals," **John Geigert,** PhD, President, BioPharmaceutical Quality Solutions, discusses the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move products through clinical development into the marketplace. The course emphasis will include U.S. FDA, EMA and ICH guidances.

Finally, we have "Rapid Microbiological Methods: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment," taught by one of the industry leaders, **Michael Miller,** PhD, President, Microbiology Consultants. This course will give participants a complete review of current RMM technologies, validation strategies, applications, regulatory expectations and much more. You will be able to develop your own qualification and implementation plans for a variety of microbiology applications and discuss the US and EU regulatory environment in implementation and testing expectations.

We look forward to seeing you in San Antonio, Texas, but, if you cannot attend these courses, and there are several others in your company who require the same training, consider having the course brought to you as in-house training. Check out our online course catalog at www.pda-training.org for a listing of other training topics that will suit your needs.

Parenteral Drug Association Training and Research Institute (PDA TRI)

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals

April 2011

The 2011 PDA Annual Meeting Course Series
April 13-15, 2011 | San Antonio, Texas | www.pdaannualmeeting.org/courses

- GMP 101 – Of special interest to participants in the Annual Meeting Fundamentals Track
- Steam Sterilizers: Getting It Right from the Beginning – *New Course*
- Rapid Microbiological Methods: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment
- DoE Basics for Validation by Design – *New Course*
- Cleanroom Management
- CMC Regulatory Compliance of Biopharmaceuticals
- Six Sigma in Process Validation – *New Course*

Environmental Mycology Identification Workshop
April 26-28, 2011 | Bethesda, Maryland | www.pdatraining.org/mycology

May 2011

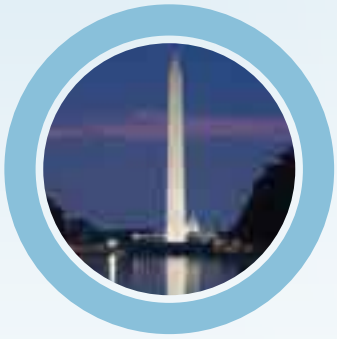
Assessing Packaging and Processing Extractables/Leachables
May 3-4, 2011 | Bethesda, Maryland
www.pdatraining.org/extractablesandleachables

Aseptic Processing Training Program Session 3
Week 1: May 9-13, 2011; Week 2: June 6-10, 2011
Bethesda, Maryland | www.pdatraining.org/aseptic

Cleaning Validation
May 17-19, 2011 | Bethesda, Maryland | www.pdatraining.org/cleaningvalidation

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments
May 24-25, 2011 | Bethesda, Maryland | www.pdatraining.org/DVCD

2011 PDA Glass Quality Conference Course Series
May 25, 2011 | Arlington, Virginia | www.pdatraining.org/glasscourses



June 2011

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

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

Lyophilization Week (Special pricing applies - call +1 (301) 656-5900, ext. 151 for details)
June 20-24, 2011 | Bethesda, Maryland | www.pdatraining.org/lyophilizationweek

- Fundamentals of Lyophilization (June 20-21)
- Economical Design of Lyophilization Experiments Workshop – *New Course* (June 22)
- Validation of Lyophilization – *New Course* (June 23-24)

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

Laboratory Courses

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

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

Editor's Message

Busy Year for PDA

This month the *PDA Letter* Editor, **Walter Morris,** has been busy working on a history of PDA for the Association's 65th Anniversary, so I volunteered to write this month's Editor's Message.

Walt isn't the only one that is busy around here. In this month's issue, PDA President **Richard Johnson** provides PDA's plan for the year in his President's Message (page 6) and if the list of projects, conferences, TRI courses and technical reports are any indication, 2011 will keep more than a few staff and member volunteers very occupied. Richard has also provided us with a "Tales from the Trail" about his visit to the PDA Korea, Japan and Taiwan Chapters late last year.

Walt and I have worked on expanding the PDA Editorial Committee to get more diverse comments and ideas. While we would have liked to accept all our volunteers (we received a record number of applicants), we could only take a limited number. However, I'd like to thank all those who applied and give a special mention to those that were picked:

Winston Brown, Baxter Healthcare

José A. Caraballo, Amgen

Doris Conrad, Conrad Consulting

Robert Darius, GlaxoSmithKline

Martha Folmsbee, Pall

Anastasia Lolas, U.S. FDA

While 2011 is already proving to be a successful year on our end with the expansion of the PLEC and the new look for the Letter, we will not rest on our laurels. We have big plans for future issues. Next months issue will include analysis of the new U.S. FDA guidance on process validation. One of the articles is currently being written by the PDA Process Validation Task Force that commented on the draft guidance; their analysis will look at how their comments influenced the final guidance. In future issues, we will publish articles on "Quality Near Hits," regulatory intelligence, and a review of warning letters under FDA's new enforcement posture.

This month's feature story on Knowledge Management by **Thomas Peither** is an article that will be sure to peak your interest. Incidentally, if, after reading the story, you would like to learn more about Knowledge Management, you should travel to San Antonio in April and attend our Annual Meeting. Also, be sure to check out articles about the Annual Meeting in the Programs and Meetings North America, Science, and TRI departments to get more of an idea of what is going on at the event, or visit www.pda.org/annual2011.

We are also running the second part of **Volker Eck's** article about the future of parenteral manufacturing. We published the first piece back in January. We hope you find his article as insightful as we did! (By the way, tell us what you think! Email me at hough@pda.org) **— Emily Hough**

PDA Letter

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

Subscriptions are not available.

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Recommended Reading for the 2011 PDA ANNUAL MEETING

1946 65TH ANNIVERSARY 2011

April 11-15, 2011

JW MARRIOTT SAN ANTONIO HILL COUNTRY RESORT & SPA | SAN ANTONIO, TEXAS

www.pdaannualmeeting.org

Cleaning and Cleaning Validation, Volume 1
Edited by Paul L. Pluta, PhD

Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 1 and 2
By Destin A. LeBlanc

Environmental Monitoring: A Comprehensive Handbook, Volume I, II, III, IV and Protocol CD
Edited by Jeanne Moldenhauer

Laboratory Design: Establishing the Facility and Management Structure
Edited by Scott V. W. Sutton, PhD

Quality By Design: Putting Theory Into Practice
Edited by Siegfried Schmitt

Recent Warning Letters Review for Preparation of an Aseptic Processing Inspection
By Jeanne Moldenhauer

Recent Warning Letters Review for Preparation of a Non-Sterile Processing Inspection, Volume 2
By Jeanne Moldenhauer

Validation by Design: The Statistical Handbook for Pharmaceutical Process Validation
By Lynn D. Torbeck

Water Activity Applications in the Pharmaceutical Industry
Edited by Anthony M. Cundell, PhD and Anthony J. Fontana, Jr., PhD

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

The PDA Bookstore's February Top 5 Best Sellers

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

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

3 Validation by Design®: The Statistical Handbook for Pharmaceutical Process Validation
By Lynn D. Torbeck
Item No. 17266
PDA Member $265
Nonmember $329

4 Environmental Monitoring: A Comprehensive Handbook, Volume IV
Edited by Jeanne Moldenhauer
Item No. 17291
PDA Member $335
Nonmember $419

5 Cleaning and Cleaning Validation, Volume 1
Edited by Paul L. Pluta
Item No. 17288
PDA Member $335
Nonmember $419

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