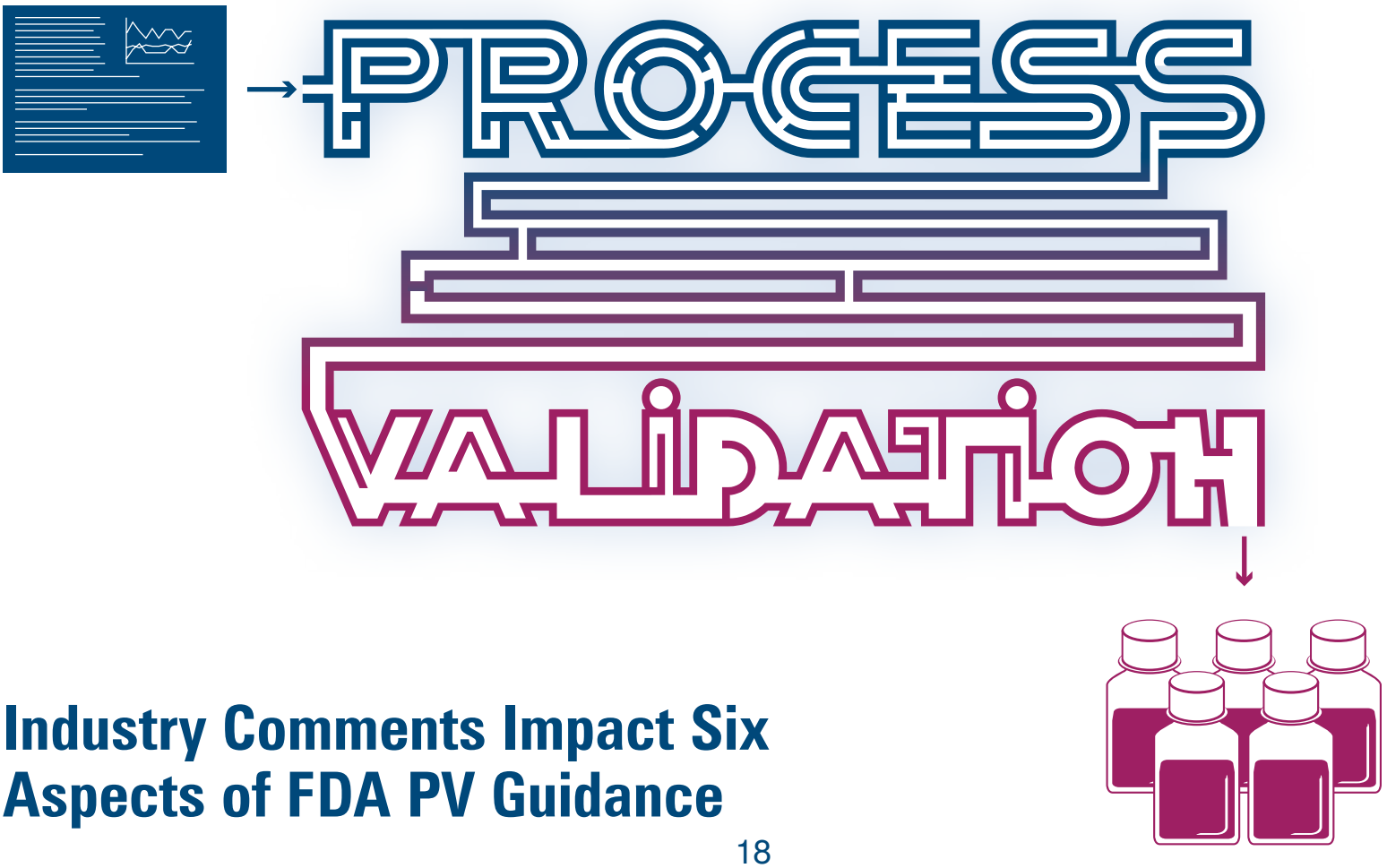
People • Science • Regulation

PDA Letter

Volume XLVII • Issue #4 www.pda.org/pdaletter April 2011



Industry Comments Impact Six Aspects of FDA PV Guidance

18

Register by April 26th and save up to $400!

The Parenteral Drug Association presents the...

2011 PDA/FDA Pharmaceutical Supply Chain Conference and TRI Course

End-to-End Supply Chain Security

Co-sponsored by IPEC AMERICAS and Rx 360 Member

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

The *2011 PDA/FDA Pharmaceutical Supply Chain Conference* 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 challenge of securing and protecting the integrity of the vast, global pharmaceutical supply chain can be met through a variety of science- and risk-based approaches. New laws, regulations and guidance continue to evolve helping to stimulate innovation toward enhancing good manufacturing, distribution, and importation practices. Building on earlier PDA co-sponsored conferences and workshops on pharmaceutical supply chains, this meeting will provide a forum to further implementation of innovative approaches aiming to prevent illicit acts such as counterfeiting, diversion, and economic adulteration from threatening the safety of the drug supply.

Supply chain security is evolving into a global initiative as well as a cross-departmental initiative. Global regulators must partner, just as industry must partner to promote patient safety. By attending the *2011 PDA/FDA Pharmaceutical Supply Chain Conference*, 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.

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

PDA/EMA 2011 Conference

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

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

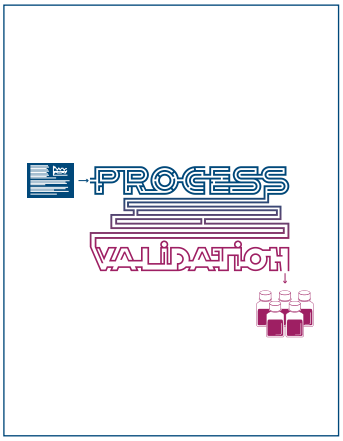
CONFERENCE, EXHIBITION
TRAINING COURSES

https://europe.pda.org/PDAEMA2011

PDA Letter

Volume XLVII • Issue #4 www.pda.org/pdaletter

Cover



Cover Art Illustrated by Katja Yount

Departments

News & Notes

People

Science

Regulation

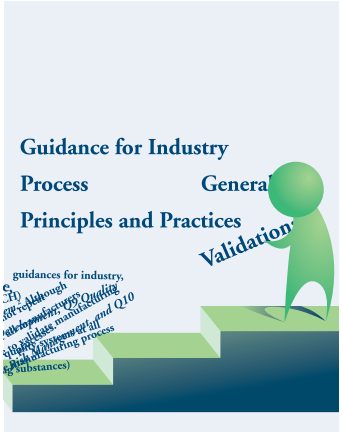
Programs & Meetings — North America

Programs & Meetings — Europe

TRI — Education

Contents

Features



PDA to Launch Newly Designed Website

Users of Internet Explorer need Version 7 or later starting April 15 to access new site

PDA is working on improving member engagement, and your satisfaction is at the forefront of our decision to invest in a new website (www.pda.org) with enhanced navigation.

"The website is a key area for all PDA activities and we are pleased to announce a new and improved www.pda.org. We think this new site will offer PDA members and non-members a chance to see all the opportunities that PDA has to offer. We look forward to hearing feedback on the new site," said **Richard Johnson,** PDA President.

The new PDA website is designed to work across a large range of browsers. However, if you use Microsoft's Internet Explorer, we recommend using Internet Explorer (IE) Version 7 or later. For a free download, visit the Microsoft website at www.microsoft.com/windows/internet-explorer/ie7 or contact your IT department to upgrade your browser, so you can optimize your interaction with the new PDA website.

PDA Contributes to the Red Cross Japanese Relief Effort

Katja Yount, PDA

In the wake of the devastating earthquake off the coast of Japan on March 11 and the catastrophic aftereffects, PDA has begun an effort to try to support those in the greatest need in that country. As we are a global community of members, we wish to support our colleagues, friends and family.

PDA has created a link on our homepage, www.pda.org, to the American Red Cross website to help with the Japanese relief effort. As of Thursday, March 24, our global members have generously donated $3,832 to the Red Cross, $750 of which came from our own PDA Midwest Chapter. Messages of hope, prayer and goodwill have also been included with donations.

The *PDA Letter* would like to take this opportunity to extend gratitude to anyone who has helped out and those who are in the process of doing so.

PDA Surveying Industry on Container Closures, TBA/TCA

PDA is conducting two surveys this spring to advance two important topics.

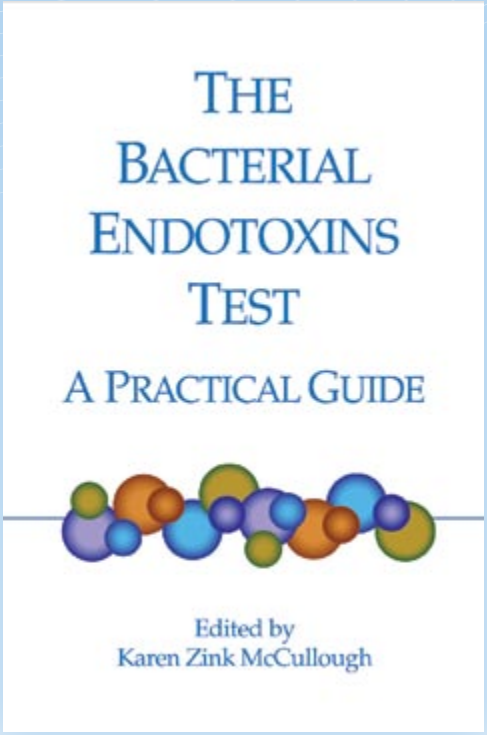
First, PDA will conduct a survey on "Pharmaceutical Container Closure Development." The questionnaire was created by **Duane Mauzey,** Manager, CMC Scientific Affairs of Pharmaceutical Development Compliance at Allergan, Inc. in cooperation with the University of Southern California, School of Pharmacy, Regulatory Science Program, directed by Dr. Frances Richmond. The survey is being conducted by PDA in collaboration with the PQRI team developing guidance for extractables and leachables in parenteral and ophthalmic drug product primary containers.

In the other survey, the PDA Task Force on Detection and Mitigation of 2,4,6-Tribromoanisole (TBA), and 2,4,6-Trichloroanisole (TCA) Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries will conduct a benchmarking survey in order to collect data about the TBA/TCA risk and actions which have been taken within the pharmaceutical industry to mitigate such risk. The survey content focuses on TBA/TCA contamination of packaging components, use of wooden pallets in the supply chain, understanding of consumer complaints relative to TBA/TCA contamination, investigation and analytical strategies, and risk mitigation strategies. The survey will be distributed to the "Top 50" pharmaceutical companies and to the members of the PDA TBA Task Force in order to collect feedback and publish general benchmarking information within the industry.

Keep an eye on the *PDA Connector,* the *PDA Letter* and www.pda.org for more information.

Pre-order Sale!
Save 10% by ordering your copy before April 20th!

New Release at the PDA Bookstore



The Bacterial Endotoxins Test: A Practical Guide

Edited by Karen Zink McCullough

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

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

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

www.pda.org/bacterialendotoxins

The PDA Bookstore's March Top 5 Best Sellers

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

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

3 Recent Warning Letters Review for Preparation of an Aseptic Processing Inspection
By Jeanne Moldenhauer
Item No. 17292
PDA Member $280
Nonmember $349

4 Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
By James L. Vesper
Item No. 17219
PDA Member $255
Nonmember $319

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

www.pda.org/bookstore | Tel: **+1 (301) 656-5900** | Fax: **+1 (301) 986-1361**

Volunteer

John Holmgren, Quality Systems Manager, Allergan

PDA Join Date: 2004

Areas of PDA Volunteerism: Membership Chair for Southern California Chapter

Interesting Fact about Yourself: I was born and raised in southern California. I attended UCLA and spent my entire career with local companies.

Why did you join PDA and start to volunteer? I felt it was time to get involved with industry colleagues and gain a broader perspective of the pharma landscape.

Of your PDA volunteer experiences, which stand out the most? Having the ability to suggest key issues and bring industry experts to a local venue and discuss resolutions to problems.

How has volunteering through PDA benefited you professionally? It helps me stay in tune with "hot topics" in the industry that can lead to enhancements for my company's systems.

Which PDA event/training course is your favorite? The 2008 annual conference in Colorado was memorable. It was a great location (Broadmoor Hotel), and I enjoyed the mountain scenery and snow.

What would you say to somebody considering PDA membership? It opens your eyes to a vast amount of resources (people, technical reports, publications, etc.) available to the entire industry and to a global point-of-view, so your access is no longer limited to one type of information.

Meet the Berlin Staff!

Emily Hough, PDA

PDA is known for excellence in developing scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership.

Founded in 1946 by a small group of pharmaceutical manufacturers who recognized the need for an organization to disseminate technical information within the industry, PDA has developed into a membership organization with about 10,000 members worldwide. Today, coordinated at its Global headquarters and its Training and Research Institute in Bethesda, Md., and through its subsidiary, PDA Europe, located in Glienicke, Berlin, PDA volunteers worldwide carry out PDA's mission of promoting the exchange of rapidly evolving information on the latest technology and regulations concerning high-quality pharmaceutical production.

PDA Europe stands out within the PDA organization as it is run by a staff of six, yet it is responsible for pursuing PDA's mission and vision in Europe.

The following people are members of PDA's European Staff:

Georg Roessling is the General Manager of PDA Europe. He represents PDA, communicates with the European health authorities, presents PDA to companies, develops new programs, and supports the organizing committees, interest groups and members.

Dirk Stelling is the Controller and takes care of all issues related to money, such as budget preparation and control as well as finance reporting. He deals with the special financial requirements in the European countries, takes care of contracts and with legal issues of the organization.

Nadine Gold is in charge of marketing, taking care of the printed and electronic mail, advertisements and the website.

Katharina Keisers-Engstfeld is responsible for exhibition management, which includes communication with the exhibitors and organizing exhibits.

continued on top of page 13

All staff members are responsible for giving on-site support, running conferences, trainings, workshops and other activities. (l-r) Dirk Stelling; Nadine Gold; Katharina Keisers-Engstfeld; Georg Roessling; Ailyn Kandora; Antje Petzholdt

"The Gold Sheet"

PHARMACEUTICAL & BIOTECHNOLOGY QUALITY CONTROL

Bulletproof guidance for the QA/QC professional.

In 2010, were you...

- **Ready for every single new development in FDA and other regulatory enforcement?**
- **Absolutely confident in your operation's GMP compliance?**
- **100% prepared for every inspection?**
- **Fully briefed on every promising new manufacturing, supply chain and documentation practice?**

It's a new year ... with new regulatory developments ... new problems ... and new chances for you to improve your performance over last year's with *"The Gold Sheet,"* the biopharma industry's most respected source for comprehensive QA/QC reporting, analysis and guidance.

GET ALL THIS FROM *"The Gold Sheet"*

- **Analysis of developments in FDA regulations and policies**

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

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

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

- **Trends in quality control practices**

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

- **Best practices in supply chain integrity**

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

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

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

- **Drug recall and warning letter data**

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

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

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

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

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

Special New Subscriber Offer!

http://pages.ElsevierBI.net/GS0211D

Elsevier Business Intelligence
Essential Insight for the Healthcare Industry

Agency Officials to Speak at Chapter's First Event

Kansas City, Mo. • April 25 • www.pda.org/missourivalleyregistration

PDA's Missouri Valley Chapter will hold its first meeting on April 25 at the Kansas City Airport Hilton Hotel and welcome two U.S. FDA presenters. **John Thorsky,** KC District Director, and **Nadine Johnson,** KC Investigational Supervisor, FDA will share with attendees updates on FDA District activities and initiatives.

The chapter will also welcome **Richard Johnson,** President of PDA, who will provide a brief update on the business and regulatory drivers of our industry.

For more information and to register, please visit www.pda.org/missourivalleyregistration

PDA Missouri Valley Chapter Officers

President **Thomas Pamukcoglu,** SAFC Biosciences

President-Elect **Ken Boone,** Covidien

Treasurer **Keith Koehler,** Certified Energy Laboratories

Secretary **Jeff Hargroves,** ProPharma Group

Please Welcome the Following Industry Leaders to the PDA Community

Kathryn Babcock, Steris

Keith Bailey, Merck

Julie Barker, Genzyme

Thaylon Barreto

W. Stephen Beversluis, Precision Medical Products

Anil Bhatoya, Coating Place

Angela Biernacki, Astellas

Joshua Bloom, Bausch & Lomb

Cladette Boulet, Health Canada

James Carmichael, Alexion Pharmaceuticals

Bong Jin Cha, Donga Pharm

Jerry Chapman, IPQ

Roberto Ciraolo, GF Spa

Silke Conrad, Ypsomed

Donald Dagen, Precision Medical Products

Jason Davis, Commissioning Agents

Alyce Deegan, W.L. Gore & Associates

Ted Dehaan, Gerresheimer Glass

Jacques Delisle, Macco Organiques

Sarah Deutscher, Genentech

David Dickerhof, Laureate Biopharma

Jesse Dill, Commissioning Agents

Carol Flynn, Gerresheimer Glass

Stephen Fournier, NNE Pharmaplan

Annett Girod, Elpro-Buchs

Sheri Glaub, RMC Pharmaceutical Solutions

Christopher Hanff, Ben Venue Laboratories

Catharina Hemström-Nilsson, GE Healthcare

Beth Hodges, Hodges Ventures

Rebecca Ingram, Pfizer

Hitoshi Ishichi, Schott

John Jasper, Molecular Isotope Technologies

Charles Jeanblanc, Baxter Healthcare

Hemant Joshi, Boehringer Ingelheim

Concepcion Kafka, Pfizer

Chung-Hyo Kim, Ildong Pharmaceuticals Co.

Michael Kril, AMRI

Janelle Lavoie, Pfizer

Francois Leduc, Alternatives Technologie Pharma

SangYoon Lee, Celltrion

Michelle Luebke, Baxter Healthcare

Wireko Manu-Tawiah, AMRI

Julie Marechal-Jamil, EGA

John Marr, CRB Consulting Engineers

Jason Melnick, Eli Lilly

Danielle Menniti, Forest Research Institute

Peter Mirabella, Q-Sales & Leasing

Vahid Mofidi, Amgen

Normand Mongrain, Macco Organiques

John Mosack, Bristol-Myers Squibb

Michele Myers, GlaxoSmithKline

John Nesvold, Gerresheimer Glass

Ruslan Nigmatullin, JSC Pharmstandard

Steve Nole, Pfizer

Janez Nosan, ABN

Werner Obexer, GlaxoSmithKline

Conor O'Rourke, Bioniche Pharma

R.J. Palmero, Reed Exhibitons

Manoj Pananchukunnath, Matrix Laboratories

Nevio Panzeri, Hospira

Ole Lien Pedersen, LEO Pharma

Tiffany Perry, PDA New England Student Chapter

Mark Petyak, AAI Pharma Services

Daniel Pond, W.L. Gore & Associates

Anoop Rajashekar, F. Hoffmann - La Roche

Saroj Ramdas, GlaxoSmithKline

Neil Reichel, Abbott

Robin Rist, Bausch & Lomb

Thomas Roberts, LifeConex

Robert Ruloff, Debiopharm

Matthew Rycyk, Dendreon

Petar Sale, Genentech

Fatimah Scott, Baxter Pharmaceutical Solutions

Carl Shoemaker, AMRI

Frank Sprinkel, Lachman Consultant Services

Bryan Stafford, Genentech

John Sweeney, Pfizer

Igor Tikhonov, GlaxoSmithKline

Michel van Musschenbroek, EMD Millipore

Gary Waller, Schott

Laura White, Pfizer

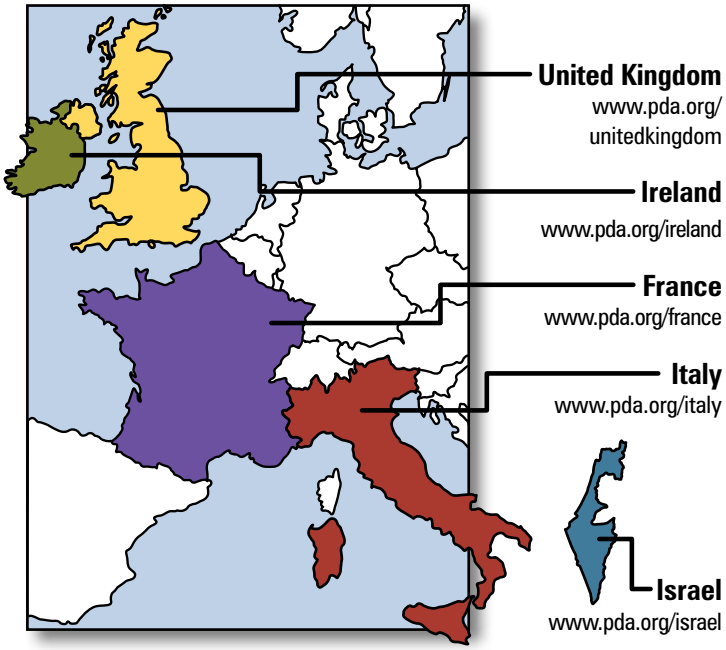
Rufus E Williams Jr.

Rachel Yi, Johnson & Johnson

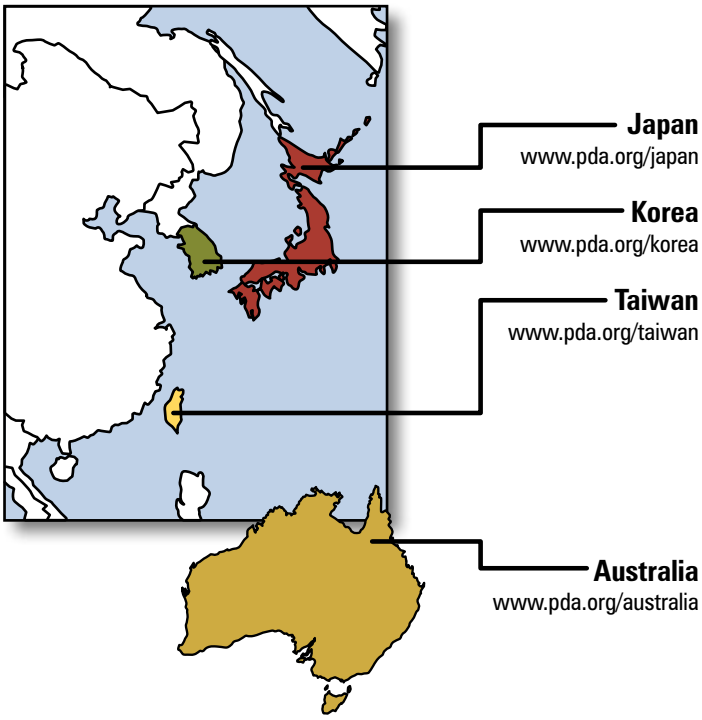
Chapter Contacts

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.

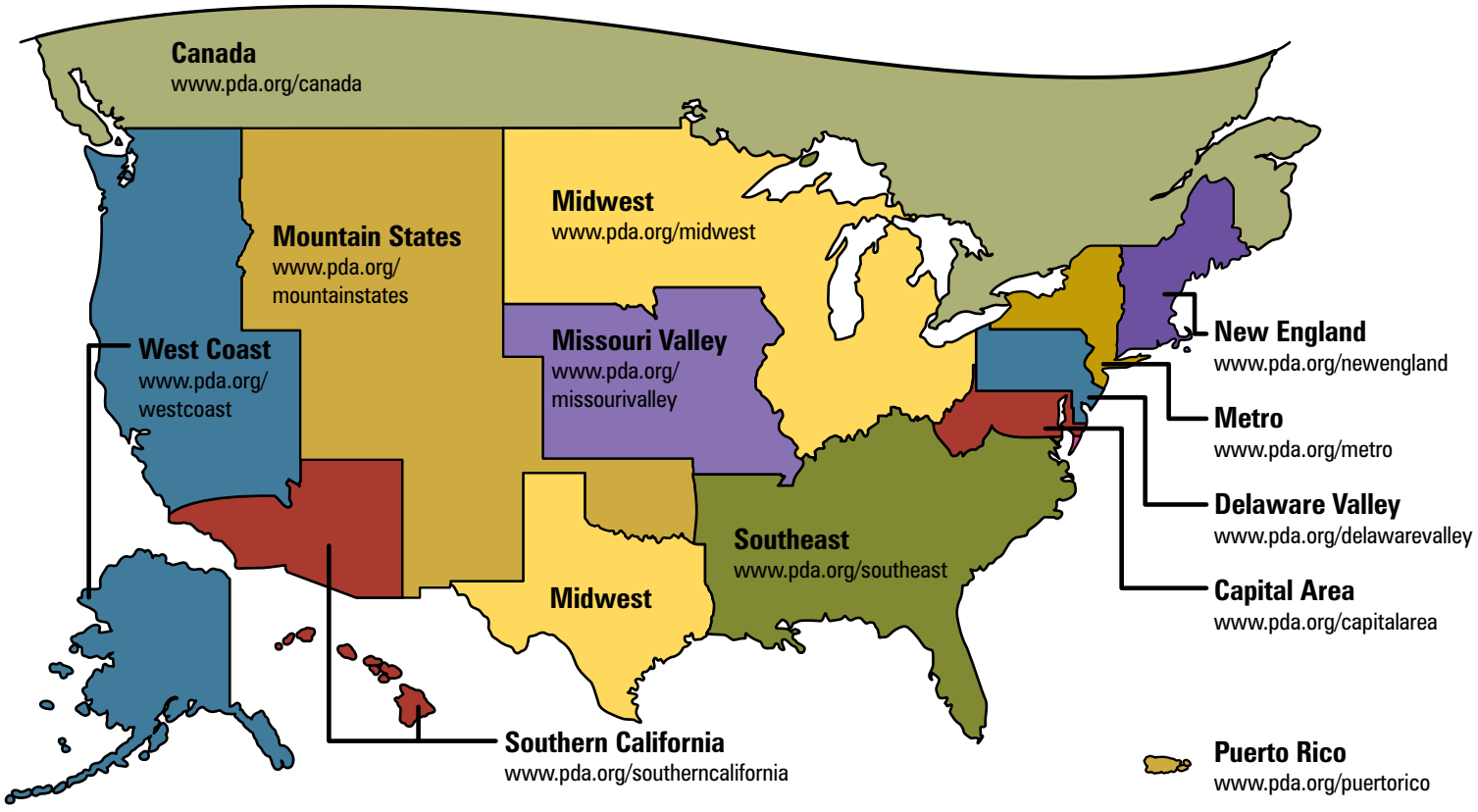
EUROPE



ASIA-PACIFIC



NORTH AMERICA



PDA Tools For Success

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

Do's and Don'ts of Keeping Your Job

Randall S. Hansen, PhD

Whether you love your job, hate your job or simply see it as a means to an end, there are times when your focus is less on job satisfaction and more on job preservation. When your profession or industry is on the decline or when the economy is in the tank and employers are cutting jobs at a dizzying pace, it's time to hunker down and focus more on protecting your position within the organization.

With this goal of job preservation in mind, here are some crucial do's and don'ts for keeping your job—and these techniques can be used both in good times, as well as in bad times.

Do your Job Well

Too obvious? Perhaps, but if you generally aren't happy with your job, it shows in your job performance, so now is the time to step it up and show that you can excel in your job (whether you love it or hate it).

Don't Stand Out for the Wrong Reasons

Now is not the time to complain about the snacks in the breakroom, argue over the temperature in the office or otherwise act as if you are entitled to things your employer doesn't currently offer.

Do Keep your Boss Informed of Your Activities, Especially as you Finish Major Projects

If your boss isn't aware of all your accomplishments, it makes it much easier for him or her to see you as expendable when budgets are cut. And do listen to what your boss says—and try and find ways to make his/her job easier. Keep a "paper" trail by emailing your boss with weekly updates or progress reports.

Don't Even *Think* About Gossiping

It's best to stay as far away from the office water cooler and any of the regular gossipers because the easiest workers for management to cut are the ones perceived to be the unhappy (and ungrateful) bunch. But *do* keep an ear to the ground (and an eye toward Google alerts about your employer) so that you are not blindsided by bad news.

Do Volunteer for New Projects or to Help Complete Tasks Previously Done by Others Who Have Already Been Laid Off

Showing your care and concern, even if it makes your job harder and longer, goes a long way to securing your spot with the organization.

Don't be Negative About Anything

You don't have to walk around the workplace as if you have popped some happy pills, but you don't want be perceived as Doug the Downer, so no trash-talking or bad-mouthing about work, the economy, the climate crisis and so on.

Do Focus on Maintaining Current Skills and Certifications and Obtaining New Ones That Make Sense for your Career

Even if these skills and certifications are not appreciated by your current employer, you'll want to be prepared to show your next employer that you are on the cutting edge for your field.

Don't Grab the Limelight

While it's important for your boss (and his or her boss) to know that you are performing great work, you don't want to be seen as a prima donna who does not recognize the work of others. Make sure the boss knows of the accomplishments, but make sure the team also gets the credit. Don't bad-mouth or backstab of any team members.

Do Continue Networking—Both Within And Outside your Employer

Building relationships is the name of the game in job-hunting and career success. You can build your reputation and better protect your position with a strong internal network. By increasing your network outside the organization, you increase your chances of succeeding in your job-search should you lose your job.

Don't Forget About Developing a Back-Up Plan

Your employer is in trouble, your industry is shrinking, and you can't just go to work and pretend that everything is fine. Develop a plan for dealing with a potential layoff, including a job-search strategy and a savings and budget plan.

Do Keep an Open Mind

You may be asked to work two jobs or take on responsibilities you never imagined or that you know you won't like, but now is the time to be open to new job duties and responsibilities, especially if it means securing your position for at least the short-term.

Don't Ask for a Promotion or Raise

If the organization is struggling and workers are being laid off, you'll look like either a fool or an egomaniac in asking for a promotion or raise.

Do Become a "Company Man" or "Company Woman"

Now is the time to arrive to work early and stay late and work hard all day long. Face time is especially important, so don't telecommute or don't telecommute as often as you did in the past.

Don't Give Up

If it appears as though your job is in serious trouble, you may be able to negotiate with your employer to keep your job by working fewer hours, by taking a temporary pay cut or by becoming an independent contractor.

Do Keep Your Resume Current

While it's a good practice to always to keep your resume regularly updated with your most recent accomplishments, it's especially important in times when your current position is not very secure.

Don't Lose Sight of Your Goals

While you may feel stuck in your current job, with no short-term options for escape, stay focused on your long-term job and career strategies. While you may need to adjust your timetable, do your best to keep building toward your goals.

Do Look for Opportunities to Build Your Brand and Possibly Land a Better Job

While you may need to be more conservative about saying how great you at the office, it's still important to build your brand both within your company and within your profession. Consider writing position papers or other articles for your professional association, developing or enhancing your personal website and maximizing the use of social networking sites—all with the idea of strengthening your digital presence.

Don't Stop Job-Hunting

Even in a horrible economy, some employers are still hiring. Job-hunting will take much more time, energy, patience and persistence, but you can find a new job in any economy if you have the right plan and execute it well. Just don't advertise the fact that you are looking for a new job.

Final Thoughts

Most of us will face times in our lives when we have to maximize our efforts to protect and keep our jobs, even for jobs that we may not particularly like or enjoy. By following the advice in this article, you'll use proven techniques for helping you fight for your current job while also keeping a foot in the job market so that you are ready to find a better job when the opportunity arises.

About the Author

Randall S. Hansen, PhD, is the founder of Quintessential Careers, one of the oldest and most comprehensive career development sites on the Web, as well CEO of EmpoweringSites.com. He is also founder of MyCollegeSuccessStory.com and EnhanceMyVocabulary.com. He is the publisher of Quintessential Careers Press, including the Quintessential Careers electronic newsletter, *QuintZine*. Hansen is also a published author, with several books, chapters in books and hundreds of articles. He's often quoted in the media and conducts empowering workshops around the country. Finally, Hansen is also an educator, having taught at the college level for more than 15 years. Visit his personal website at www.randallshansen.com or you can reach him by email at randall@quintcareers.com.

Questions about some of the terminology used in this article?

Get more information (definitions and links) on key college, career and job-search terms by going to Quintessential Careers Job-Seeker's Glossary of Job-Hunting Terms at www.quintcareers.com

Latest Hot-Job Postings

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

New jobs posted daily to PDA's Career Center!

Medimmune, Mountain View, Calif.
Associate Scientist II – Vaccine Research, Proteins

Medimmune, Gaithersburg, Md.
Scientist II- Infectious Disease/Vaccines

Bristol-Myers Squibb, Syracuse, N.Y.
Quality Analyst

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

Meet the Berlin Staff! continued from page 8

Antje Petzholdt spends her time at PDA working at the registration desk and helping out with membership queries as well as with PDA's European Chapters.

Ailyn Kandora is in charge of event and program management. She deals with the event and the logistics of the meetings and supports the organization committee and speakers to develop the program agenda.

Two consultants also devote their time to helping the PDA Europe staff. **Volker Eck** and **Jim Lyda** help support the development of meeting programs and special meetings. Lyda also looks at the regulatory news and supports writing regulatory comments on the draft regulations from Europe.

snapshot

Task Force *Corner*

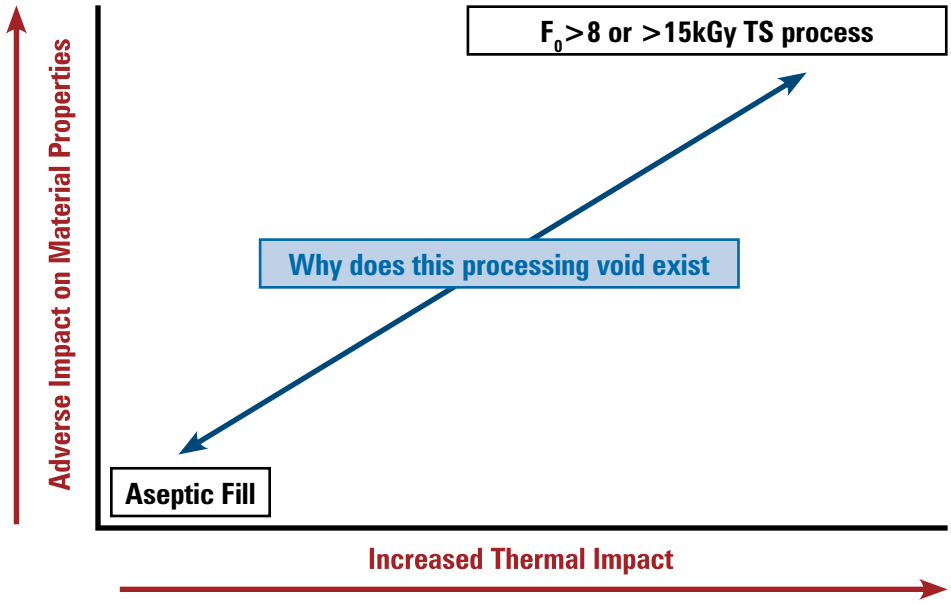
Post-Aseptic Fill Lethal Treatment TF Looks at Safety and Operational Improvements in Injectable Drug Manufacturing

James Agalloco, Agalloco & Associates

The production of sterile products in the global healthcare industry has devolved into two distinct approaches: aseptic processing and terminal sterilization. In the first, individually sterilized components, containers and equipment are deployed in extremely clean environments and assembled into a finished sterile container. In the second, the assembly process is completed with lesser controls and the finished container is subjected to a sterilizing process.

To a large extent, the industry has adopted an either-or approach as depicted in **Figure 1** in which an aseptic process or one using a minimum F_0 of 8 minutes (or >15 kGy) or more is utilized. There are a limited number of products currently approved globally with lower F_0 or kGy values; however, these are very much the exception.

Figure 1 Current Sterile Processing Continuum



The apparent reason for this processing void appears to be related to an earlier desire to utilize biological indicators as worst case surrogates for the bioburden that might be present in a container. Biological indicators by intent are substantially more resistant than the majority of expected microflora in a processing environment. Establishing their destruction as the basis for all terminal sterilization processes is seemingly very conservative, but actually it creates situations where the safest possible process from the patient's perspective are not used.

Sterility, as it is understood today, is an absolute situation. Regrettably no amount of testing can establish it regardless of the underlying process: aseptic or terminal. Neither process enables the attainment of the absolute condition that is sterility. Terminal sterilization processes are considered acceptable if they deliver a minimum PNSU of $1x10^{-6}$, while aseptic processing capability is established by contamination rates on not more than 0.1% (1 non-sterile unit in a 1,000). Conventional practice is to establish processes that exceed these minimum targets; however, no process can assure sterility in the absolute sense.

The goal of making something sterile is really one of making it safe. Where a terminal process cannot be used because of formulation or container issues, firms typically default to aseptic processing, accepting the less certain exclusionary process as the best they can do.

Given the uncertain nature of aseptic process whose conventional controls lack the definitive metrics of a sterilization process, the patient is potentially exposed to some measure of added risk however minute.

Changing the processing paradigm from aseptic processing or terminal sterilization to one where they are performed sequentially offers safety and operating advantages. This would be accomplished by the use of a range of lethal conditions to materials that are already aseptically processed.

The Post-Aseptic Fill Lethal Treatment Task Force has reached a consensus on the desirability of these processes to fill the processing void. The future processes that we envision would likely be developed as extensions of those already in use. Terminal sterilization with some to be determined additional controls could be utilized at lower F_0's or lower dose conditions. Aseptic filling followed by a lethal process could enhance patient safety. As a group, we have considered the benefits of what new thinking in this area might provide to patient and producer. Our next activities will focus on outlining potential processes, identifying the appropriate process controls and defining the benefits to all concerned. Before doing so, we'd be interested in feedback on the potential impact of a changed paradigm with respect to sterile product manufacturing.

Please send your comments (positive and negative) to Task Force leader **James Agalloco** at jagalloco@aol.com. We will consider your comments as we move towards the development of the position paper we are charged with developing.

continued at top of page 16

Interest Group *Corner*

Transparent and Engaging Dialogue Shapes PDA Process Validation Interest Group

Hal Baseman, ValSource and Scott Bozzone, Pfizer

Participating in PDA technical Interest Groups (IGs) is an excellent way to become more involved, more informed and more engaged in this industry. The PDA encourages its IGs to solicit suggestions for technical initiatives, reports, conferences, and other activities as well as to form task forces, working groups and committees to plan and conduct these activities.

The PDA Process Validation Interest Group (PVIG) is among the most active IG at PDA. They now have over 200 members. The objective of the PVIG is to *provide an on-going forum for the exchange and dissemination of information and ideas for the purpose of education, innovation, and compliance related to the validation of critical processes and those activities which support the validation of critical processes. The interest group should be a forum for presenting and discussing issues and trends in validation. These discussions should result in a better understanding of PDA member needs. This in turn results in better programs, more useful publications, and appropriate areas of advocacy.*

The PVIG objective is divided into three core elements:

1. Provide a forum for members to discuss current issues and matters related to process validation
2. Present industry best practices and approaches for the planning and performance of process validation
3. Engage members of PDA in Interest Group activities which enhance the practice of process validation

To accomplish these objectives, the PVIG provides a number of services to its members and the industry. One important service the PVIG provides is holding regular meetings twice-a-year, usually at the PDA Annual Meeting in April and again at the PDA/FDA Joint Regulatory Conference in September. The meetings are designed to be interactive, exchanging ideas and discourse on subjects of immediate interest. The meetings are typically divided into four parts:

1. Update on current industry issues
2. Presentation on a hot topic or process validation method
3. Review of current PVIG activities and plans
4. Open forum to discuss items of interest to member attendees

In addition, the PVIG is particularly active in supporting industry and PDA initiatives. In 2005, members of the PVIG recognized the need to develop programs for the planning, training and implementation of quality risk management principles. This eventually led to *PDA Technical Report No. 44: Quality Risk Management for Aseptic Processing.*

The PVIG has helped to organize and conduct several process validation workshops, meetings, and presentations, including notable workshops presenting the 2008 draft FDA Process Vali-

continued at middle of page 16

In *Print*

QbD Complement Process Validation

Paul Pluta, Advanstar

The following has been excerpted from the chapter, "QbD and Process Validation – Complementary Lifecycle Approaches," by Paul L. Pluta, Journal of Validation Technology *and* Journal of GXP Compliance. *The chapter appears in the PDA/DHI book,* Quality by Design: Putting Theory into Practice, *edited by Siegfried Schmitt, PAREXEL Consulting, which was published in February 2011.*

Pharmaceutical Quality by Design (QbD) is a systematic and proactive approach to pharmaceutical development based on scientific and technical understanding of product and process. The QbD process begins with defining objectives, determining interrelationships, identifying potential sources of variation and emphasizing ongoing controls. The QbD approach should be maintained throughout the product commercial lifecycle to facilitate ongoing quality in manufacturing and continuing product and process improvements. QbD became widely known during the 2000s and has evolved to clarify the most important elements of product development. Various statistical methods in QbD such as strategy of experimentation and Design of Experiments (DoE) have been used for many years. The QbD effort has successfully integrated these established methods with newer concepts such as Critical Quality Attributes (CQA), Critical Process Parameters (CPP) and design space in an organized, risk-based and focused approach. The principles of QbD are now being applied to other aspects of pharmaceutical manufacturing, including analytical methods and quality systems.

Simultaneous with the development of QbD has been a concurrent evolution of process validation and its associated components. Validation was originally mentioned in the FDA GMPs in the 1970s. FDA issued *Guideline on General Principles of Process Validation* in 1987. While this guidance and other subsequent related documents mentioned the importance of product development and ongoing commercial post-validation manufacturing, the emphasis of validation was on the "validation lots." Successful manufacture of the three validation lots was considered to be the entirety of validation through the 1990s and thereafter. Concepts presented in the 2000s culminated in the publication of a new draft validation guidance published in November 2008. The guidance was finalized (Revision 1) in January 2011.

Process Validation: General Principles and Practices clearly expanded the scope of process validation from a one-time "three-lot" event to a continuum extending from initial product and process design through the ongoing commercial manufacturing lifecycle. This guidance incorporated QbD, Process Analytical Technology (PAT), risk management, and other evolving concepts into the lifecycle approach to process validation. The life-

continued at bottom of page 16

snapshot

Task Force Corner continued from page 14

Post-Aseptic Fill Lethal Treatment Task Force Members

James Agalloco, Agalloco & Associates
James Akers, PhD, Akers, Kennedy & Associates
Kris Evans, Amgen
Klaus Haberer, PhD, Compliance Advice and Services in Microbiology
Deborah Havlik, Hospira
Doerthe Feuersenger, B. Braun
John Kowalski, PhD, Sterigenics International
Rich Levy, PhD, PDA
Len Mestrandrea, Mestrandrea Consulting
Roger Miller, B. Braun
Mike Sadowski, Baxter

Interest Group Corner continued from page 15

dation Guidance, conducted in San Francisco, Calif.; Las Vegas, Nev.; Chicago, Ill.; Bethesda, Md.; Munich, Germany; and San Juan Puerto Rico throughout 2009. The workshops were designed to present the draft guidance, obtain and communicate feedback from industry to the FDA and discuss challenges and solutions to implementation of the recommendations contained in the Guidance. The PVIG should be pleased to note that the 2011 finished version of the Guidance appears to have addressed many if not all of the concerns raised by the PVIG in their report.

The most recent PVIG activity is the formation of the PCMO Process Validation Task Force. The Task Force is in the latter stages of preparing and issuing its Technical Report on Process Validation. This comprehensive document will present approaches and recommendations for implementing a program based on the principles of the 2011 FDA Process Validation Guidance and ICH international guidance.

During the PDA Annual meeting in San Antonio on April 11, the PVIG will hold a joint interest group meeting with members of the PDA Facilities and Engineering IG. The purpose of this meeting is to highlight the synergy and interdependence of qualifying systems and processes. We are planning on holding an open forum of any questions or problems you may be experiencing with the new paradigm on the lifecycle concept of process validation.

Later that week, on April 13 and 14, the PVIG will host a special workshop on the interpretation and implementation of the new *2011 Process Validation Guidance* featuring industry and FDA experts.

Process validation is an evolving and challenging concept in our industry. As new technologies, processes and regulatory expectations emerge the need to keep up-to-date will be more important than ever. We can set the path forward for many years to come. Interest groups such as the PVIG provide a valuable way to continue to obtain knowledge, develop understanding and provide input.

In Print continued from page 15

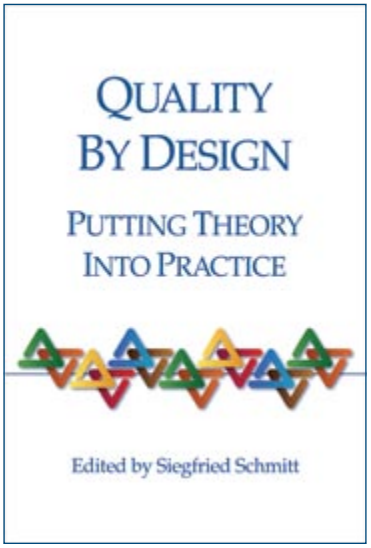
cycle approach is now being applied to other areas of validation such as analytical, equipment/facilities/ utilities, computer systems and other areas.

QbD and process validation are complementary approaches to assure quality throughout the lifecycle of a pharmaceutical product. Their objectives are identical. Their language is consistent. Strategies, approaches and language used in QbD and process validation guidances are consistent with current pharmaceutical development, risk management, quality systems and associated documents. The work of QbD is vital to process validation. The emphasis of QbD is on pharmaceutical development—Stage 1 of process validation. QbD work then extends into Stage 2 process qualification and into maintaining ongoing quality in the Stage 3 validation commercial product lifecycle. New applications of QbD to related areas are consistent with new applications of validation/qualification.

[Editor's Note: Following this introduction to the chapter, Pluta addresses the following major topics:

- QbD basics
- Process validation basics
- Basis and current expectations for process validation
- Process Validation Stage 1: Process Design
- Process Validation Stage 2: Process Qualification
- Process Validation Stage 3: Continuing Process Verification

Additional process validation considerations, including equipment, analytical, statistics, and documentation.**]**



Environmental Monitoring **Simplified.**

Real-Time Microbial Monitoring

Microbial Sampling

Integration and Validation

Particle Counting

Viable and Non-Viable. Together. **VALIDATED.**

PARTICLE MEASURING SYSTEMS

Without measurement there is no control.
www.pmeasuring.com • 1(303) 443-7100

Industry Comments Impact Six Aspects of FDA PV Guidance

PDA Task Force analyzes final guidance and implementation challenges

Since the new U.S. FDA *Guidance for Industry on Process Validation: General Principles and Practices* was published as a draft in Nov 2008, the pharmaceutical industry has asked many questions and voiced concern about implementation challenges. FDA refined the document based on the comments that were received from industry.

Impact of Industry Comments

Industry comments were addressed in the following areas:

- Wording and Terminology
- Approach and Assurance for Commercial Distribution
- Viral and Impurity Clearance
- Concurrent Release
- Scope and Legacy Systems
- Qualifications, Documentation, Organization and Regulatory Impact

Below is a summary of the refinements added to the document.

Wording and Terminology: The final guidance has added a glossary of terms, which had been requested by industry. The ten terms include continued process verification, process qualification and state of control. These terms will help industry understand the concepts of the document and be more uniform in application of the guidance concepts.

Additionally clarification of the document was added in several key places. In Stage 2, the process design is "evaluated' instead of "confirmed" This change is consistent with actual industry practice. The word "drift" was replaced with "undesired process variability." The new wording is in keeping with a scientific approach. Given that there was confusion on the steps of Stage 2, the guidance has introduced the term Process Performance Qualification for Stage 2B.

Approach and Assurance for Commercial Distribution: The use of risk assessments throughout the lifecycle was clarified and a reference to ICH Q9 was added. Quality risk management was expanded on pages 7 and 9 of the FDA guidance to describe attributes, criticality, parameters, risk-based decisions and controls. The guidance recognizes that the type and extent of controls are enhanced and improved as experience is gained in commercial distribution. Also added to the guidance is the concept of a continuum of criticality. Each parameter should have control commensurate with the risks to patients that are inherent with the parameter. This differs from current practice in many firms where a binary system (critical and non-critical) is in use. The document also eliminates the need to demonstrate commercial manufacturing conditions that pose high risk of process failure.

Viral and Impurity Clearance as Requested by Industry: The guidance was toned down on performing these studies under cGMP. The final document clarifies that quality oversight is maintained, which is current industry standard. These studies are also not considered as early process design experiments.

Concurrent Release: The guidance was significantly reworded in this area, including two new paragraphs. The guidance maintained that concurrent release is for infrequent use. Stability requirements were updated to an evaluation for inclusion in the stability program from automatic inclusion. The Process Performance Qualification (PPQ) protocol should include a rationale for concurrent release and individual lot release. Additionally, the guidance includes provision for careful oversight of the released batches to accommodate rapid customer feedback.

Scope and Legacy Systems: The guidance scope was clarified that it does not include clinical trial manufacturing. Legacy products are included in the scope, but the guidance recognizes that for most of these products efforts will start with Stage 3, continued process verification.

Qualification: The guidance expanded considerations for continuation of heightened sampling in PPQ consistent with the volume of production, process complexity, level of process understanding and experience with similar products and processes.

Analytical Methods: The guidance clarified that validated methods are not required for characterization. Rather, the methods must be scientifically sound and provide reliable results, which is current industry standard.

Implementation Challenges: Stage 1

The PDA Process Validation Task Force has identified the following challenges associated with Stage 1 (Process Understanding):

Resources: The allocation of resources to carry out stage 1 activities will be challenging to many firms. Defining process and formulation variables to obtain a thorough understanding takes efforts of scientific resources, materials, equipment and time. To design a predictable process for future commercial scale also takes management commitment to invest in resources early in the lifecycle. This is difficult without knowing the clinical efficacy of a new product.

Scale-up and Technology Transfer: In stage 1, evaluating the process parameters and attributes as to their importance in the process is also a challenge. Numerous factors during formulation, scale-up, transfer to the manufacturing site(s) are involved, which may complicate the evaluation with multiple interactions of the factors.

Firms have been challenged to define the documentation deliverables from stage 1 (process design) into stage 2 (process qualification)

The importance of these parameters and attributes can change during the lifecycle. New ones may be identified and the importance of others may be reduced as more data is generated on both the product and process. The lifecycle approach shows how consistent the importance of these parameters and attributes will be throughout.

Data can be limited at this beginning point in the lifecycle. Thus, it can be challenging to define the degree of significance of parameters and attributes that will hold true for the subsequent stages 2 and 3.

Predictable Controls: Establishing controls for the manufacturing process, having limited scale data at this point of the lifecycle, can present a dilemma. Again, scale factors, equipment, raw materials, site and the necessary efforts can be complex. In addition, the need to produce clinical supplies can take priority to experimental non-clinical studies to establish these process controls.

Knowledge and Documentation: The transfer of knowledge gained during process design, maintenance and the future use of that knowledge is pivotal to successful commercial manufacturing. It is incumbent on firms to have a means of using and capturing stage 1 data and document it before moving on to stage 2 and 3.

A frequently asked question is how to generate, maintain, and transfer that knowledge base to minimize dealing with problems during commercial manufacturing. It is essential to document the specific design experiences and justification of decisions that may be needed years later. Mechanisms for knowledge transfer between process development and manufacturing are of paramount importance so that this information is preserved

Deliverables: Firms have been challenged to define the documentation deliverables from stage 1 (process design) into stage 2 (process qualification). This could vary from firm-to-firm, but will typically include definitive scientific studies, process characterization and development reports, design of experiments studies and analytical methods reports.

Implementation Challenges: Stage 2

Stage 2 (Process Qualification) challenges include:

Amount of Data: Determining the information required to assure that processes are adequately controlled and qualified will take considerable knowledge of process inputs, outputs, process parameters and attributes. Some examples of questions that have been asked and need to be answered are:

- How much and what type of data needs to be generated by the PPQ?
- How do we determine a confidence level for process controls, as mentioned in the FDA Guide?

Article at a Glance

This article will discuss the refinement of the document and summarize industry implementation challenges. Note that these challenges can overlap and occur in the multiple stages described in the guidance.

- With the PPQ results in hand, are we convinced it is representative of the commercial material that will be subsequently produced? If not, what is the strategy for heightened sampling past the PPQ or beyond stage 2?
- What are some possible statistical uses of data generated in stage 2 for later use in stage 3 commercial manufacturing?
- How much data from stage 1 do we need in stage 2 when processes vary considerably from case to case?

These questions will need to be addressed by firms prior to release for commercial manufacture of the PPQ batches.

Implementation Challenges: Stage 3

Continued Process Verification (Stage 3) presents the following challenges, in the view of the task force:

Length of Stage and Data Monitoring: The commercial phase of a product lifecycle is generally the longest, hopefully spanning many successful years for the firm as well as for the patients. Having an extensive knowledge base at the start of commercial production is a challenge since significant numbers of lab, pilot or commercial scale batches may have not been manufactured up to this point in the lifecycle. Thus, developing an effective data monitoring program for acquiring and evaluating post licensure commercial manufacturing information is vital to understanding the process. Typical questions are:

- What type of information do we need to look for?
- How do APRs (annual product reviews) relate to monitoring evaluations?
- How to handle legacy processes in stage 3?
- Which statistics to use and how to address less-than-desired results?

Use of Statistics: This topic can be asked for at any stage but the FDA Guide does emphasize the use of statistics such as trending performance data and acceptance criteria setting. This can be quite challenging if only a few batches or data points are available.

Knowledge Management: Capturing Stage 2 and 3 process knowledge and linking it with Stage 1 knowledge is considerably challenging. Keeping an updated database of all relevant information associated with the process can be difficult.

Having an extensive knowledge base at the start of commercial production is a challenge

Other questions on knowledge management throughout the process lifecycle have been asked. Such as what documentation of inputs and outputs do we need between the stages? How much process knowledge is sufficient and how do I transfer it? It is difficult to maintain the documented knowledge as "evergreen," with "real-time" updating of the process design database by commercial manufacturing.

Preliminary Industry Actions: Some firms have begun to implement the principles through their company inter-site or intra-site systems. Some have conducted gap analysis, created templates for site use of guide recommendations, written company standards, made presentations and have discussed at their company forums.

Furthermore, it is important to maintain an influence with regulators on the developing expectations of process validation and to stay up to date with peers in the industry. This can be accomplished by participating with peers, at conferences, discussion groups, and sharing amongst ourselves, with regulators, both in the United States and internationally.

Moving Forward

Industry initiatives by PDA and other groups are addressing the challenges, such as by preparing technical reports, good practice guidances, conferences and webinars.

The path along the process validation lifecycle will face some challenges. The hurdles and roadblocks will need to be surpassed in order to provide a process that benefits both the firm and the patients. The ultimate reward for industry to this additional upfront work should be more robust processes, minimizing problems both internally and externally.

PCMO PV Task Force

Chris Ames, Hospira
Kristopher Barnthouse, Centocor (Johnson & Johnson)
Harold Baseman, ValSource
John Bennan, ComplianceNet
Michael Blackton, ImClone Systems
Scott Bozzone, PhD, Pfizer
E.J. Brandreth, Althea Technologies
Rebecca Devine, Consultant
Stephen Duffy, Covidien
Panna Dutta, PhD, The Medicines Company
Kurtis Epp, BioTechLogic
Irwin Hirsh, NNE Pharmaplan
Norbert Hentschel, Boehringer Ingelheim Pharma
Pedro Hernandez, Consultant
Raj Jani, Baxter Healthcare
Peter Levy, PL Consulting
Rich Levy, PhD, PDA
Richard Love, Stiefel Labs
Anthony Luttrell, LCG
Victor Maqueda, Consultant
John McShane, Genentech
Taiichi Mizuta
Morten Munk, CMC Biologics
Jose Luis Ortega, PharmaMar
Elizabeth Plaza, Pharma-Bio Serv
Michael Popek, FDA/CVM
Praveen Prasanna, Shire
David Reifsnyder, Genentech
Markus Schneider, Novartis
Abhinav Shukla, PhD, Bristol-Myers Squibb
Julie Spyrison, BioTechLogic
Cerlinde Storer, Becton Dickson
Iolanda Teodor, Baxter
Mark Varney, Abbott
Alp Yaman, Biotech, Pharma & Device Consulting
Wendy Zwolenski-Lambert, Abbott

sartorius stedim biotech

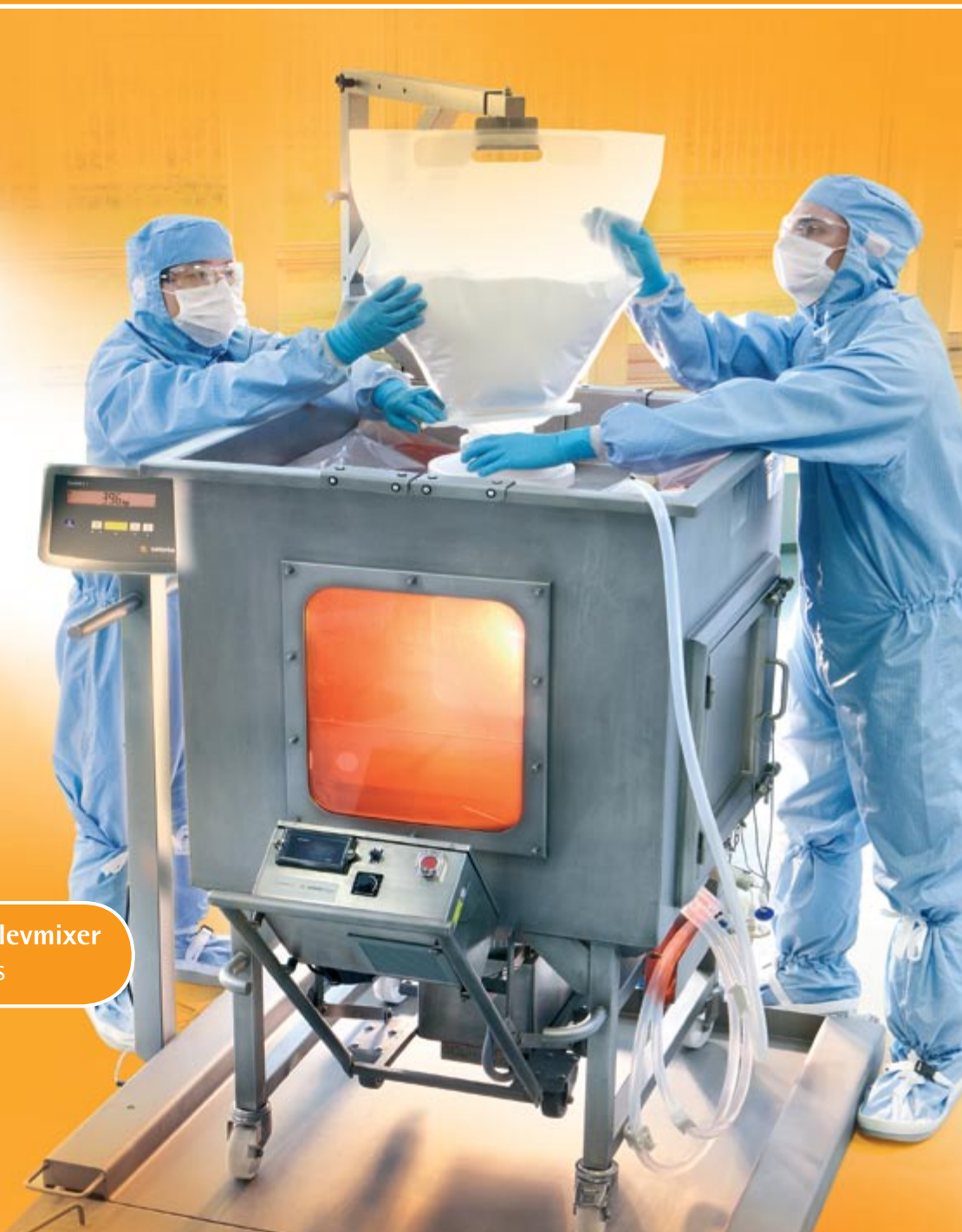
SINGLE-USE TECHNOLOGY

New Flexel® 3D for LevMixer® System.
Higher mixing efficiency up to 2,000 L.

Flexel® 3D for LevMixer® systems offer a wide range of standard and custom-design, single-use mixing systems for liquid/liquid and solid/liquid applications using ATMI patented mixing technology.

The combination of a levitating impeller with the sophisticated Flexel® 3D bag geometry secures both excellent mixing efficiency and full scalability of the mixing performances.

Flexel® 3D for LevMixer® systems ensure:
- Easy and time-saving installation and operation
- Maximum protection of the bag during mixing and shipping
- Highest sterility assurance level
- Usage of one drive unit for different tank sizes
- Security of supply through multiple manufacturing sites



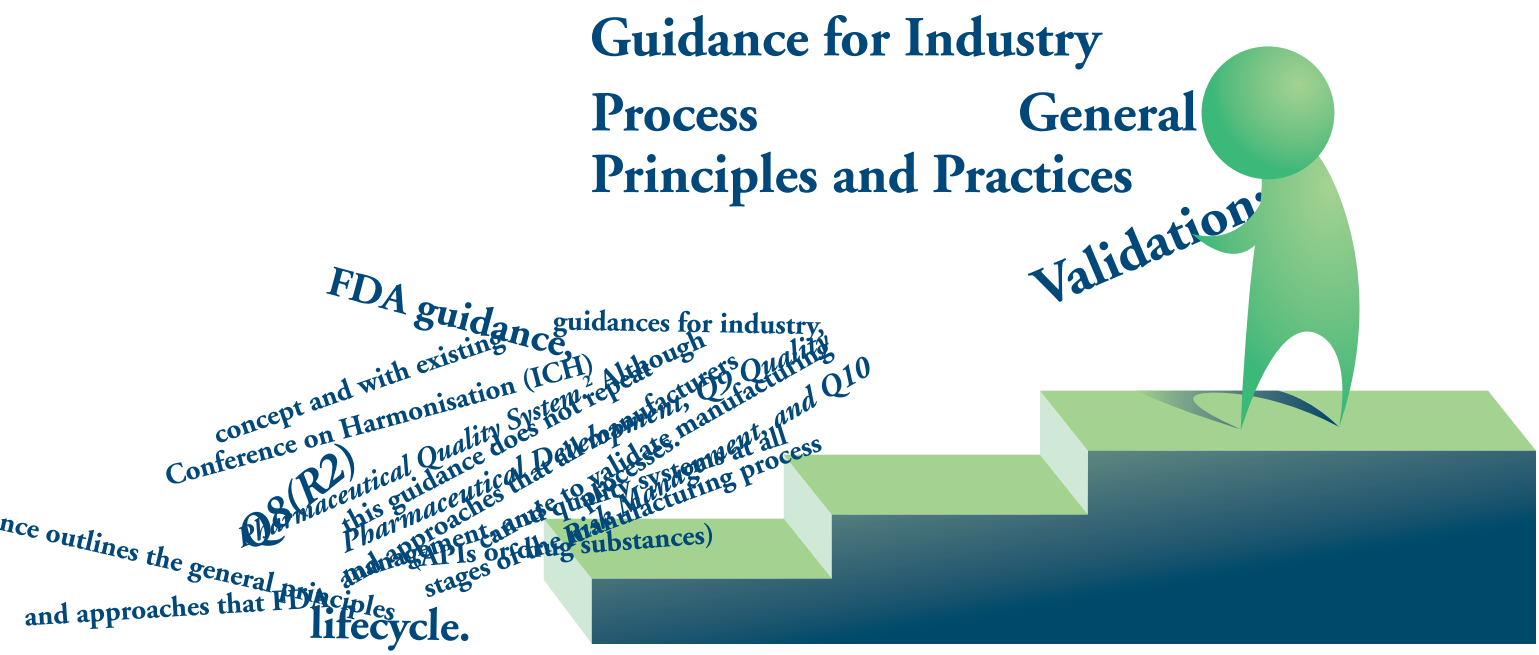
www.sartorius-stedim.com/levmixer
turning science into solutions

Sartorius Stedim Biotech
USA +1.800.368.7178
Europe +49.551.308.0

Process Validation: FDA has Guidance, Industry has Questions

Process validation discussion forum in Berlin, Feb. 17 generates dialogue between industry and regulators

Walter Morris, PDA, with contribution from Karen Ginsbury, PCI Pharmaceutical Consulting



The U.S. FDA's final *Guidance for Industry on Process Validation: General Principles and Practices* (a revision of the 1987 guideline) is sure to raise a lot of questions as industry works to implement new principles.

As this process unfolds, FDA officials are committed to helping clarify the recommendations in the guidance and to quickly dispel any myths that might arise. FDA is participating in an upcoming PDA workshop (April 13-14) on the guidance following the Annual Meeting in San Antonio, Texas. This comes just a few months after the Agency participated in a "Validation Discussion Forum" in February in Berlin, sponsored by PDA Europe. During the latter workshop, FDA fielded a number of questions, and its answers helped bring clarity to the new guidance. The discussion set the stage for what promises to be an informative event in April.

The questions from industry participants focused on several key concepts in the process validation guidance.

One questioner asked about which statistical models and procedures FDA expects to see in product licensing applications (NDA/ANDA), and specifically, sampling and acceptance criteria expectations. The FDA official replied that the guidance does not cover regulatory submissions, nor was it intended. Rather, the guidance addresses GMP expectations and what an FDA investigator would look for during an inspection. Sponsors and applicants should contact the reviewing officials in the Center to determine what information should be submitted in the ANDA or NDA application.

A question touched on the tenuous balance between too much and too little "how to" language that should be included in FDA guidances. The questioner asked if there are particular statistical tests that would be considered appropriate or if that decision is entirely up to the firm. FDA's representative clearly stated that the Agency is not advocating the use of any particular statistical tool. Selection of the statistical model hinges on its purpose, i.e., sampling and testing of starting materials, initial performance assessment or Phase 2 to reach certain assurance levels. The tool selected should be appropriate to the firm's process and justified.

The key is for firms to have objective measures to assess process performance over time. There should be a target, and variability should be contained within a reasonable range. A company needs to get results and then analyse them to formulate an understanding about the batch and the inherent variability of the process—normal output—so it knows when it can identify special-cause incidents.

Concurrent release* was discussed in detail prompted by a long inquiry. The questioner wondered if concurrent release is appropriate even for products ➤

Concurrent release: *Releasing for distribution a lot of finished product, manufactured following a qualification protocol, that meets the lot release criteria established in the protocol, but before the entire study protocol has been executed.*

Biotest

From Nature for Life

NEW

APC SmartTouch

Smart system with an easy touch

- World's first airborne particle counter with a dual flow rate
- Intuitive software on color-touch screen
- Flexibility through high-capacity batteries
- On-screen visual representation of sample locations

Biotest Microbiology Corp.
400 Commons Way
Rockaway, NJ 07866
USA

Tel.: +1 973.298.8596
Fax: +1 973.625.9454
CustomerService: 877.210.5103
CustomerService@biotestusa.com
www.biotestusa.com

2011 PDA UPCOMING EVENTS

APRIL 2011

6-7

Stoppers & Elastomers
Rennes, France
europe.pda.org/stoppelasto2011

11-15

2011 PDA Annual Meeting and Course Series
San Antonio, Texas
www.pdaannualmeeting.org

13-14

PDA Process Validation Post Conference Workshop
San Antonio, Texas
www.pda.org/processvalidation2011

26-28

Environmental Mycology Identification Workshop
Bethesda, Maryland
www.pdatraining.org/mycology

MAY 2011

3-4

Assessing Packaging and Processing Extractables/Leachables
Bethesda, Maryland
www.pdatraining.org/extractablesandleachables

3-6

PMA/EMA Joint Conference
London, England
europe.pda.org/pdaema2011

9-13

Aseptic Processing Training Program Session 3 Week 1
(Week 2: June 6-10)
Bethesda, Maryland
www.pdatraining.org/aseptic

17-19

Cleaning Validation
Bethesda, Maryland
www.pdatraining.org/cleaningvalidation

23-26

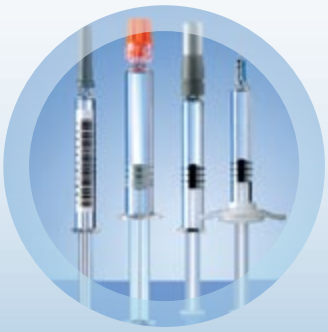
2011 PDA/FDA Glass Quality Conference and Course Series
Arlington, Virginia
www.pda.org/glassquality2011

24-25

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments
Bethesda, Maryland
www.pdatraining.org/dvcd

26-27

An Introduction to Visual Inspection
Berlin, Germany
europe.pda.org/visual2011



www.pda.org

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

Save these dates!

JUNE 2011

1-2

Sterile Pharmaceutical Dosage Forms
Bethesda, Maryland
www.pdatraining.org/sterilepharma

6-8

2011 PDA/FDA Pharmaceutical Supply Chain Conference
Bethesda, Maryland
www.pda.org/supplychain2011

7-8

Advanced Therapy Medicinal Products (ATMPs)
Helsinki, Finland
europe.pda.org/atmp2011

7-8

4th Monoclonal Antibodies Workshop
Basel, Switzerland
europe.pda.org/monoclonal2011

20-24

Lyophilization Week at TRI
Bethesda, Maryland
- Fundamentals of Lyophilization (June 20-21)
- Economical Design of Lyophilization Experiments Workshop – *New Course* (June 22)
- Validation of Lyophilization – *New Course* (June 23-24)

www.pdatraining.org/lyophilizationweek

20-21

2011 PDA Analytical Methods Development & Validation Workshop
Bethesda, Maryland
www.pda.org/analyticalmethods2011

22-23

2011 Single Use Systems Workshop
Bethesda, Maryland
www.pda.org/singleuse2011

28-30

Virus/TSE Safety Forum
Barcelona, Spain
europe.pda.org/virustse2011

28-30

Fermentation/Cell Culture Technologies Training Workshop
Bethesda, Maryland
www.pdatraining.org/fermentation

JULY 2011

11-12

Biotechnology: Overview of Principles, Tools, Processes and Products
Bethesda, Maryland
www.pdatraining.org/biotechnologyoverview

25

A Risk Based Approach to Technology Transfer
Bethesda, Maryland
www.pdatraining.org/riskbasedapproach

26

Practical Applications of Risk Management
Bethesda, Maryland
www.pdatraining.org/practicalapplications

not falling into the categories outlined in the guidance, e.g., orphan drugs, radiopharmaceuticals, and medically necessary therapies. This question relates to section IV.C.2: Process Performance Qualification, or PPQ. The FDA representative explained that all drug processes are expected to prospectively qualified, i.e., that manufacturers achieve a high level of assurance in the process before commercial distribution begins. That is viewed as reasonable protection to the consumers and patients. Concurrent release may be justified when the public health benefit of having some drug immediately available is greater than the risk of inconsistent or poor quality drug, an undesirable outcome that good process design and prospective process qualification, in part, helps prevent.

This question caused the FDAer to pause and ask the audience why a firm would want to release product before completing their initial assessment. The ensuing discussion turned to products with varying batch sizes, which prompted the official to advise that if the process is different for the different batch sizes each unique process must be validated.

It was also emphasized that the new guidance does not mention the number of batches that should be included in the validation work. FDA's concern is what firms know about the batches studied, no matter how many.

The discussion turned to the recommendation to continued enhanced sampling and monitoring for some period after the initial process qualification. The questioner wanted to know if it is appropriate to identify unit operations of special concern that would receive enhanced sampling while reducing sampling for unit operations The FDAer said such an approach could be justified. The purpose of continuing the higher level scrutiny is to measure the normal, inherent variability in the process. Once "normal" performance at commercial scale is known, a monitoring program to detect special cause variation can be established. Firms with demonstrated process understanding and knowledge about the normal variability of the different operations have opportunity to justify different monitoring levels. The choice of sampling and monitoring should be based on the capability of the process.

Reference in the guidance to ASTM E2500 and the absence of the three types of qualification (IQ, OQ, PQ) in place of the term "verification" was discussed. FDA's expects manufacturers to focus on the activities that must occur, not the terminology. Terminology, it was noted, can change over time, but the goal is to have relevant guidance with staying power.

There were other questions during the session, and industry will continue to have questions as implementation proceeds. For this reason, PDA thanks FDA for willingly participating in our workshops to engage the membership. We look forward to another strong session of dialogue in April.

vai

Veltek Associates, Inc.

One Wipe, MULTIPLE SOLUTIONS



For more than 30 years, VAI has pioneered the design and manufacture of hundreds of clean room solutions.

- **Cleanest wipe in the industry**
- **Asepti-Fill® closed filling system**
- **Laundered in Class 1**
- **Saturated wipes are made with WFI**
- **Lot Specific Documention for all wipers**
- **Laser cut sealed edges**

Quadruple Bagged using the ABCD Introduction System®

No other company offers this broad a range of wipers…

WIPEDOWN	PROCESS 2 WIPE	STERI-PEROX® WIPE	HYPO-CHLOR® Wipe	DECON-Clean® Wipe	ALCOH-Wipe®	STEEL-BRIGHT® Wipe	DAS-Wipe®
Dry cleaning wipe	70% USP IPA in Water for Injection saturated wipe	Saturated Hydrogen Peroxide Wipe	Saturated Sodium Hypochlorite Wipe	Removes residue from disinfecting agents	Saturated with DECON-AHOL® WFI 70% USP Isopropyl Alcohol	Stainless Steel Cleaning wipe	Stainless Steel cleaning and lubricant wipe

www.sterile.com

1-888-4-STERILE

snapshot

Advisory Board *Update*

RAQC Renamed to RAQAB; Still Connecting People, Science and Regulation

An interview with the RAQAB co-chairs

The Regulatory Affairs and Quality Advisory Board, or RAQAB (formerly called the Regulatory Affairs and Quality Committee) is one of the oldest standing PDA volunteer committees. While always at the level of an official PDA "advisory board" (one step below PDA Board of Directors), it has finally been renamed to reflect its status.

Stephan Rönninger

Since it has always functioned as an advisory board, the name change is just a formality. The group's mission—to track regulatory and GMP developments in the major pharma markets and to support excellence in regulatory guidances and regulations—remains unchanged.

In recent years, RAQAB has been more strategic in fulfilling its mission by recruiting participants to be "regional leaders" to represent markets of strategic interest (North America, Canada, China, Europe, Asia Pacific, and Australia). The committee also has connected with other PDA areas of interest through liaisons from the Science Advisory Board, the Biotechnology Advisory Board and PDA's Training and Research Institute (TRI).

The RAQAB co-chair and European Regional Leader, **Stephan Rönninger,** Head of External Relations, Europe/Japan, External Relations and Collaboration (PTQR), Hoffmann-La Roche, explained that the regional leaders were important to the advisory board.

Sue Schniepp

"We have given different responsibilities to the regional leaders. These individuals have input and keep everyone up-to-date and network. Each one of them is providing a piece of the regulatory puzzle in support of RAQAB as a whole."

RAQAB co-chair, **Sue Schniepp,** VP, Quality, OSO Biopharmaceuticals Manufacturing, agreed. "The world is small in terms of regulatory authorities and it is more efficient to have members watching varying regulations in different parts of the world." As an active instructor for TRI, Sue also serves as RAQAB's TRI liaison.

The RAQAB is best known for preparing consensus based comments on proposed regulatory guidance or regulations on behalf of the Association. However, due to limited resources (including volunteers' precious time), the group is selective regarding which guidances will be subject to RAQAB review.

RAQAB members and the PDA staff routinely circulate and discuss new regulatory guidances. When a regulatory document worthy of scientific comments is identified, a volunteer leader is selected and a Task Force is formed to study the document and prepare written comments. When a list of recommendations is approved by the full RAQAB, they are sent to the PDA Board of Directors for approval and only then submitted to the originating agency/organization (e.g., U.S. FDA, EMA, etc.) for consideration. If asked, PDA will facilitate informal discussions in workshops, forums and conferences to facilitate communication between industry and regulators.

When asked to identify the most challenging, recent regulatory policy on which to formulate recommendations, both Sue and Stephan agreed that it was the "recent draft on process validation," which is now final (see p. 18 for the commenting task force's analysis of the final document).

Unfortunately, sometimes the appetite of the group exceeds its ability to prepare comments, said Sue. Because of that, the group needs to be selective on what it chooses to focus on. "It's very stimulating to do this collaborative work. We all donate a lot of time, but feel the importance of participation in this activity. However, it is very time-intensive, and takes a minimum of two months, usually more, to prepare the comments and secure internal PDA approval."

Historically, PDA has been recognized for the business-like, science-based comments that are useful for regulators. The RAQAB co-chairs mentioned that agencies also put a lot of value on PDA's technical reports and frequently use them as training documents.

Since January, RAQAB has been focusing on PDA's five-year strategic plan, which included items to enhance the Association's regulatory activities. RAQAB will provide input to achieve the following goals:

- Provide science and technology based input on regulations and guidelines related to PDA strategic areas, utilizing PDA's volunteer and membership base
- Bring sound scientific and technical information to the regulatory process, maintain valuable and effective relationships with global regulators, and educate members on current expectations

continued on bottom of page 38

Regulatory Compliance

It's critical to keep your ducks in a row

BD

Helping all people live healthy lives

Microbiology Media Solutions for USP <1116> Compliance

WIth BD Prepared Environmental Monitoring Media, you'll find it a lot easier to stay in line with regulatory compliance.

- Validated SAL (Sterility Assurance Level) to minimize the risk of false positive results and the introduction of contamination into critical environments
- Wrapped in Tyvek®/Polyethylene for moisture-control and sterility assurance
- Compatible with various air sampling instrumentation
- Over 170 years of combined Difco™ and BBL™ microbiology experience

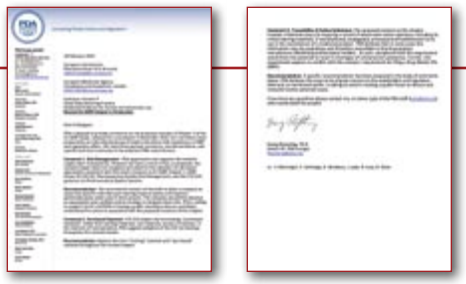
Microbiology – it's what we do.

Find out what we can do for you.
Visit us on the web at **www.bd.com/ds**

BD Diagnostics
800.638.8663
www.bd.com/ds

PDA Provides General Comments on Ch. 5 of the EU GMP Guide

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



28 February 2010
European Commission
Pharmaceuticals Unit, Brussels
SANCO-gmp@ec.europa.eu

European Medicines Agency
Compliance and Inspection, London
ADM-GMP@ema.europa.eu

EudraLex, Volume 4
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Revised EU GMP Chapter 5: Production

Dear Colleagues,

PDA is pleased to provide comments on the proposed revision of *Chapter 5 of the EU GMP Guide,* released for consultation in November 2010. Our comments were prepared by an international group of expert volunteers with experience in GMP and regulatory affairs. We have three general comments, mentioned below, and specific technical comments in the attached EMA matrix format.

Comment 1, Risk Management: PDA appreciates and supports the need for supply chain transparency. However we have a concern that, as proposed, the revised chapter does not recognize and allow for the adoption of risk-based approaches consistent with the recent revisions to EU GMP Chapter 1, GMP Annex 20 (ICH Q9, Pharmaceutical Quality Risk Management), and the ICH Q10 guidance on Pharmaceutical Quality Systems.

Recommendation: We recommend revision of the draft to allow a company to assess the specific risks that each starting material (active and inactive) potentially poses when used in their process. The company would then develop an appropriate and justified control strategy to mitigate those risks. PDA is willing to support the EC and EMA in hosting a public meeting to discuss and better understand the concerns associated with the proposed revisions of the chapter.

Comment 2, Purchased Materials: ICH Q10 adopts the terminology "purchased materials" rather than starting materials, raw materials, actives or inactives. In the interests of harmonisation, PDA suggests adoption of the ICH terminology throughout the revised chapter.

Recommendation: Replace the term "starting" material with "purchased" material throughout the revised chapter.

Comment 3, Traceability of Active Substance: The proposed revision to this chapter includes a footnote (see p.5) requiring a record of where each active substance, including its critical starting materials, is manufactured, propagated, processed and handled prior to its use in the manufacture of a medicinal product. PDA believes that in some cases this information may be proprietary and therefore unavailable to the drug product manufacturer (Marketing Authorisation Holder). As such, compliance with the requirement would have the potential to result in shortages of critical active substances. Further, this requirement appears to conflict with the concept/requirement for filing a Drug Master File (DMF).

Recommendation: A specific recommendation has been proposed in the body of comments below. PDA believes this issue to be of great concern to the stakeholders and regulators alike and, as mentioned earlier, is willing to assist in hosting a public forum to

continued on bottom of page 35

PDA Commenting Task Force

Karen Ginsbury, PCI Pharmaceutical Consulting Israel
Stephan Rönninger, F. Hoffmann-La Roche
Paul Ellis, GlaxoSmithKline
Scott Self, Aptuit
Robert Caunce, Hospira
Siegfried Schmitt, Parexel
Steven Mendivil, Amgen
Susan Schniepp, OSO BioPharmaceuticals Manufacturing
Barbara Zinck, Zinck Consulting

Your Product is Unique, so is our Sterile Collection.

Custom Sterile Solutions

At Texwipe, we understand what you have invested in your product. We protect your investment by helping you produce the safest medicines for your patients.

Have a specific size, solvent or packaging in mind for your dry or prewet sterile wipers? Need additional testing for your IPA?

Call us - Texwipe is here to serve your needs.

North America
336 996 7046
info@texwipe.com

Europe
+45 87 400 220
info@itw-cc.com

Asia
+65 6468 9433
asia@texwipe.com

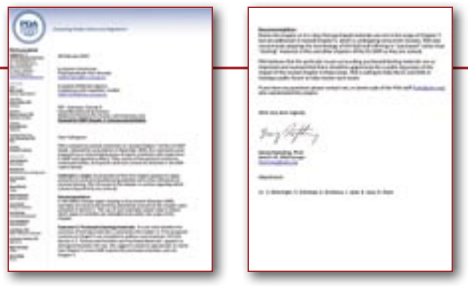
ITW Texwipe®

The Next Level of Clean™

www.texwipe.com

PDA Concerned Over Scope of Ch. 7 EU GMP Guide

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



28 February 2010
European Commission
Pharmaceuticals Unit, Brussels
SANCO-gmp@ec.europa.eu

European Medicines Agency
Compliance and Inspection, London
ADM-GMP@ema.europa.eu

REF : EudraLex, Volume 4
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Revised EU GMP Chapter 7: Outsourced Activities

Dear Colleagues:

PDA is pleased to provide comments on revised *Chapter 7 of the EU GMP Guide,* released for consultation in November 2010. Our comments were prepared by an international group of expert volunteers with experience in GMP and regulatory affairs. They consist of two general comments, mentioned below, and specific technical comments attached in the EMA matrix format.

Comment 1, Scope: As presently written the chapter appears to apply primarily to contract manufacturing activities with a few references to contract testing. The full scope of the chapter is unclear regarding which outsourcing activities are covered.

Recommendation: In the EMEA concept paper relating to this revision (October 2009), examples of outsourced activities potentially covered by the chapter were provided in Section 2. The use of such examples would make it clearer which types of activities are intended to be within the scope of the chapter.

Comment 2, Purchased (starting) materials: It is not clear whether the purchase of starting materials is covered by this chapter or if the proposed revisions to Chapter 5 are intended to address such materials. ICH Q10, Section 2.7, 'Outsourced Activities and Purchased Materials', appears to distinguish between the two. We suggest it would be appropriate to clarify that Chapter 5 covers GMP aspects for purchased materials, and not Chapter 7.

Recommendation: Revise the chapter so it is clear that purchased materials are not in the scope of Chapter 7, but are addressed in revised Chapter 5, which is undergoing concurrent revision. PDA also recommends adopting the terminology of ICH Q10 and referring to "purchased" rather than "starting" materials in this and other chapters of the EU GMP as they are revised.

PDA believes that the particular issues surrounding purchased/starting materials are so important and nuanced that there should be opportunity for a public discussion of the impact of the revised chapter in these areas. PDA is willing to help the EC and EMA in hosting a public forum to help resolve such issues.

If you have any questions please contact me, or James Lyda of the PDA staff (lyda@pda.org), who coordinated this project.

With very best regards,
Georg Roessling, Ph.D.
Senior VP, PDA Europe

PDA Commenting Task Force

Karen Ginsbury, PCI Pharmaceutical Consulting Israel
Stephan Rönninger, F. Hoffmann-La Roche
Paul Ellis, GlaxoSmithKline
Scott Self, Aptuit
Robert Caunce, Hospira
Siegfried Schmitt, Parexel
Steven Mendivil, Amgen
Susan Schniepp, OSO BioPharmaceuticals Manufacturing
Barbara Zinck, Zinck Consulting

The Parenteral Drug Association presents...

PDA 2011 Analytical Methods Development & Validation Workshop

The Complete Method Life Cycle

June 20-21, 2011 | Hyatt Regency Bethesda | Bethesda, Maryland

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

Here's a look at highlighted sessions and speakers:

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

www.pda.org/analyticalmethods2011

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

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

Collection of Information Available on Reports of Corrections and Removals for Medical Devices

There is an opportunity to comment on a proposed collection of information related to Reports of Corrections and Removals for Medical Devices.

The information collected will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market.

Comments should be submitted by April 14.

Guidance on Potency Tests for Cellular and Gene Therapy Products Finalized

A U.S. FDA guidance about potency tests for cellular and gene therapy products has been finalized. The guidance provides manufacturers of cellular and gene therapy products with recommendations for developing tests to measure potency.

The recommendations are intended to clarify the potency information needed to support an IND or a BLA. Because potency measurements are designed specifically for a particular product, the guidance does not make recommendations regarding specific types of potency assays or propose acceptance criteria for product release.

U.S. FDA Collection of Information Pertaining to Electronic Records and Signatures is Ongoing

A collection of information related to electronic records and electronic signatures is now underway.

The Agency is looking for comment on:

1. Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility
2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used
3. Ways to enhance the quality, utility, and clarity of the information to be collected
4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Comments should be submitted by April 18.

CDER's Regulatory Project Management Site Tours and Regulatory Interaction Program Ongoing

A recent Federal Register announcement indicates pharmaceutical companies who are interested in participating in CDER's Regulatory Project Management Site Tours and Regulatory Interaction Program still have time.

This program was initiated to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide firsthand exposure to the industry's drug development processes and a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

Proposed agendas should be submitted to the CDER office by April 18.

Draft Guidance Available on Fermentation-Derived Intermediates, Drug Substances and Related Drug Products for Veterinary Medicinal Use

A draft guidance is now available on Fermentation-Derived Intermediates, Drug Substances and Related Drug Products for Veterinary Medicinal Use.

The purpose of the draft guidance is to provide recommendations on what documentation to submit to support the Chemistry, Manufacturing, and Controls Information-information for fermentation derived intermediates, drug substances and related drug products for veterinary medicinal use.

Comments on the draft guidance should be submitted by May 30.

User Fee Waivers, Reductions and Refunds for Drug and Biological Products Draft Guidance Available

A revised draft guidance on User Fee

Key Regulatory Dates

Comments Due:

April 14 — Collection of Information Available on Reports of Corrections and Removals for Medical Devices

April 18 — Guidance on Potency Tests for Cellular and Gene Therapy Products

CDER's Regulatory Project Management Site Tours and Regulatory Interaction Program

May 30 — Draft Guidance Available on Fermentation-Derived Intermediates

May 31 — EMA Helps Pharma Comps Standardize Biopharmaceutical Data

June 12 — User Fee Waivers, Reductions and Refunds for Drug and Biological Products Draft Guidance Available

June 30 — Changes to Part I, III of EU GMP Guide

July 1 — India to Protect Supply Chain by Adding a UID to Products Sold Domestically

March 2014 — FDA, EMA Announce Pilot for Parallel Assessment

Waivers, Reductions and Refunds for Drug and Biological Products is now available.

The draft guidance provides recommendations for applicants considering whether to request a waiver or reduction in user fees. It is a revision of a July 1993 draft guidance addressing the same topic.

For consideration as the final guidance is developed, comments on the draft should be submitted by June 12.

FDA, EMA Announce Pilot for Parallel Assessment of QbD applications

The U.S. Food and Drug Administration and the European Medicines Agency have launched a new, voluntary pilot program that will allow parallel evaluation of relevant development and manufacturing data components (known as QbD) of new drug marketing applications that are submitted to both agencies.

Reviewers from both agencies will separately assess the quality/chemistry, manufacturing and control section of the NDAs submitted to the FDA and marketing authorization applications submitted to the EMA. However, there will be regular communication and consultation between European regulators and their U.S. colleagues throughout the review process relevant to QbD aspects of the applications.

This pilot program began out of concern that certain ICH guidelines were being interpreted differently in Europe and the United States.

Goals of the pilot program include:

- Helping to ensure consistent implementation of ICH guidelines for manufacturing quality in the application evaluation process
- Increasing awareness of these regulatory concepts by staff that review marketing applications and inspect manufacturing facilities as part of the approval process
- Defining the reviewer and inspector interaction for QbD applications
- Creating a further way for EMA and FDA assessors/reviewers to share full knowledge about these applications
- Developing and harmonizing regulatory decisions to the greatest extent possible.

The pilot will end on March 31, 2014.

Europe

Changes to Part I, III of EU GMP Guide Posted to EC Website

On its website, the European Commission has posted the latest revisions of the European Union Guide to Good Manufacturing Practice, Eudralex Vol 4.

Part I: Basic Requirements for Medicinal Products

- Revised Introduction to the GMP
- Revised Chapter 4, Documentation (effective June 30)
- Revised Annex 11, Computerized Systems (effective June 30)

Part III: GMP Related Documents

- New guidance on the Site Master File
- ICH Q9, Quality Risk Management, has been moved from GMP Annex 20, to Part III
- ICH Q10, Pharmaceutical Quality Systems, has been named as a Note for Guidance

EMA Helps Pharma Comps Standardize Biopharmaceutical Data with Module 2.7.1

The European Medicines Agency has published Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1.

The objective of the CTD Module 2.7.1 is to summarize all relevant information in the marketing authorization applications dossier with regard to biopharmaceutical studies and associated analytical methods.

The appendix contains a set of forms to assist applicants in their preparation of 2.7.1. It is anticipated that a standardized presentation will facilitate the evaluation process of the guideline.

The consultation for this guideline will end on May 31.

Asia-Pacific

India to Protect Supply Chain by Adding a UID to Products Sold Domestically

India plans to protect its medicine supply chains from counterfeit and spurious products by adding unique identifier (UID) code to all drugs sold in the domestic market.

Unveiled by India's Drug Consultative Committee at its last meeting on February 15, this move follows an earlier requirement for all drugs manufactured in India for export to carry serialized barcodes by July 1.

Every strip of medicine available in India by the above date will need to have a 2D bar code and a UID. A phone number will be mentioned above the bar code, where the consumer can text message the UID. A message will tell the consumer whether the drug is an original or not.

The move is expected to meet opposition, however, from small and medium-sized pharmaceutical manufacturers, who are concerned about the extra cost involved in adding barcodes and UIDs to product labelling.

PDA Provides General Comments on Ch. 5 of the EU GMP Guide continued from page 30

discuss and mutually resolve potential issues.

If you have any questions please contact me, or James Lyda of the PDA staff (lyda@pda.org) who coordinated this project.

With very best regards,
Georg Roessling, Ph.D.
Senior VP, PDA Europe

Single-Use Systems Workshop—A Must Attend Event

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

Christopher Smalley, Merck

Do you believe that single-use systems (SUS) could be a cure-all for your problems? If so, you need to come to the *2011 Single Use System Workshop* planned for June 22-23 at the Hyatt Regency in Bethesda, Md. If you are not sure that SUS are a cure-all, then that is all the more reason for you to attend this workshop. This program will be a balanced, well-vetted presentation of the advantages as well as the disadvantages of implementing single-use systems.

This workshop will present not only the technology, but also the important issues that require your consideration in choosing between a standard reusable stainless steel system or reusable components and a disposable single-use system.

Many of you may have gone to a conference or read an article that made wonderful claims or predicted outstanding benefits from SUS. However, when you tried to apply SUS to your process, your organization struggled with important decisions for months or years, such as:

- Do we invest a great deal of capital in an aging facility to remain compliant?
- How do we insure flexibility in our facility for new products and processes that are on the horizon?
- How can we respond to a request to set up a facility in a developing country and still maintain the corporation's standards?
- How can we reduce the number of batches lost due to sterility failure?
- Can single-use systems be part of the answer?

The right answers will be different for each organization that asks them. The success of SUS is very much dependent on a variety of drivers that are specific to each organization's individual business model and situation. The approaches outlined in the PDA technical report for SUS will offer a flexible approach that can be customized for each organization.

Major topics presented at the workshop will include business drivers, implementation elements, the current state of technology, qualification requirements and regulatory expectations. The business driver session will provide a thoughtful balance of the capital costs of fixed, standard systems versus the costs of single-use systems; construction lead times and flexibility in clinical trial supply and manufacturing; cleaning validation and water usage versus disposable single-use systems; and containment and contamination control, not only for sterile/aseptic applications, but for cytotoxic and high-potency compounds.

The approaches outlined in the PDA technical report for SUS will offer a flexible approach that can be customized for each organization.

The "Implementation Elements" session will provide guidance on assessing process capability and your facility for risks and compatibility related to adopting single-use systems and help you understand the operational requirements which would need to be assessed in moving forward with implementation.

The "Current State of Technology" session will provide examples of current capabilities in connectors, mixing, fluid management, fermenters and bioreactors, storage, freezing, filtration, chromatography, final filling of product, sampling and sensors, and provide real life specific considerations for those examples because the presentation team consists of end users and regulators not just suppliers.

The "Qualification Requirements" session will include risks associated with the use of single-use systems, the greatest risk for most implementations being extractables and leachables. Sanitization and sterilization, process control, integrity testing and other elements that will also be part of your qualification needs will be discussed.

The workshop will wrap up with a series of presentations as well as opportunities for questions and answers with regulators to understand the regulatory assessment and expectations of single-use system implementation.

During this conference, there will be a hands-on technology showcase, so rather than just hearing words and seeing a PowerPoint, you will be able to see demonstrations where the technology, not the products, is highlighted.

It cannot be overstressed how valuable this workshop will be to you. It is based not only on a PDA technical report document, but represents the efforts of a partnership between users who have implemented single-use systems, suppliers, industry enablers such as engineering consultants and regulators. This is a must attend workshop if single-use systems are in your future.

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 by April 28, 2011 and save up to $200!

www.pda.org/Singleuse2011

Photos courtesy of Sartorius Stedim Biotech

PDA/FDA Conference—Too Important To Miss

Washington D.C. • September 19-21 • www.pda.org/pdafda2011

Sue Schniepp, OSO Biopharmaceuticals Manufacturing

The *2011 PDA/FDA Joint Regulatory Conference* is quickly approaching. This year's theme is Quality and Compliance in Today's Regulatory Enforcement Environment. The conference committee has been busy establishing a program focused on educating and exploring some of the complicated global quality and regulatory issues currently facing the pharmaceutical industry stakeholders, manufacturers and regulators.

One of the more complex issues facing the industry today is the environment in which we conduct business. The first day of the conference will introduce this topic in a plenary session, titled, "Accountability in a Global Environment." This session will address the topic from three unique perspectives: regulatory, contract manufacturer and global pharmaceutical manufacturer. The focus of this session will be to explore how these industry sectors have adapted their operations and compliance initiatives to effectively conduct business in the emerging global regulatory environment.

Day two of the conference will kick off with a plenary session that will take an in-depth look at recalls. Titled "Recall Lessons," the session will highlight the need for companies to establish and maintain a robust process for handling recalls on an international level and in compliance with worldwide regulatory expectations. The session will emphasize what can be learned from the recent recall experiences and how to improve processes to handle recalls in a timely and efficient manner while keeping consumer-needs and expectations in focus.

The committee has developed individual track sessions that build upon the concepts presented in the plenary sessions. The three track sessions for this year's program are **Foundations, Innovation and Regulatory Science,** and **Quality and Compliance.** The Foundations track is structured to help participants understand the expectations of the U.S. FDA in today's current environment. Some of the individual topics in the track include

continued on bottom of page 49

Advisory Board Update continued from page 28

- Engage in activities, for example, training and education, in BRIC countries when we can benefit the general membership
- Engage regulatory agencies in the development and adoption of PDA TRs

Stephan explained that while all the objectives were important, providing science- and technology-based regulatory commentary drawn from the expertise of the membership is the most important activity for RAQAB, as that activity is the epitome of "Connecting People, Science and Regulation."

When asked which objectives would be the immediate focus of the group, Sue said that the RAQAB has decided to first lay a foundation with the help of its three specialty teams—Regulatory Comments; Regional & Quality Regulatory Snapshots; and Links to Health Authorities and Organizations—so it can more easily meet its targets.

The co-chairs made it a point during the interview to say that it is important for RAQAB to continue to represent big and small companies in its comments, so that the whole industry is given a chance to voice their concerns.

PDA thanks all of the volunteer members of RAQAB for lending us their time and energy; without them, there would be no advisory board. Membership on RAQAB is limited to a three-year term (renewable one-time). RAQAB is always looking for new volunteers, if interested please send your CV to **Iris Rice** (rice@pda.org).

Regulatory Affairs and Quality Advisory Board: Current Members and Functions

Co-chair Dr. –Ing. **Stephan Rönninger,** F. Hoffmann-La Roche; European Regional Leader

Co-chair **Susan J. Schniepp,** OSO Biopharmaceuticals Manufacturing; PDA Training and Research Institute Liaison and *PDA Letter* Editorial Committee Liaison

Ruhi Ahmed, PhD, BioMarin Pharmaceuticals

Jeffrey R. Broadfoot, Cangene Corporation; Canada Regional Leader

Alan C. Burns, Sartorius-Stedim Biotech; North American Regional Leader

Robert B. Caunce, Hospira; Australia Regional Leader

Robert L. Dana, PDA Staff Liaison

Don E. Elinski, Lachman Consultant Services; Science Advisory Board Liaison

John D. Finkbohner, PhD, MedImmune

Amy Giertych, Baxter Healthcare Corporation

Karen Ginsbury, PCI Pharmaceutical Consulting Israel

Louise Johnson, Takeda Pharmaceuticals International

James C. Lyda, PDA Staff Liaison

Brian R. Matthews, PhD

Steven Mendivil, Amgen; Immediate past chair and Board of Director Liaison

Shin-ichiro Mohri, Sakai Plant; Japan Regional Liaison

Iris D. Rice, PDA; PDA Staff Liaison

Junko Sasaki, Sumitomo Pharmaceuticals; Asia Pacific Regional Leader

Siegfried Schmitt, PAREXEL Consulting

Janeen Skutnik, Pfizer; Emerging Regions Liaison (BRIC)

Michael VanDerWerf, GlaxoSmithKline Biologicals; Biotechnology Advisory Board Liaison

Jacqueline Veivia-Panter, Abbott Laboratories

Hongyan Xie, Qilu Pharmaceuticals; China Regional Leader

Barbara B. Zinck, Zinck Consulting

The Parenteral Drug Association presents the...

2011 PDA/FDA Joint Regulatory Conference

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

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

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

www.pda.org/pdafda2011

Supply Chain Regs to be Discussed at Conference

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

Co-chair Eric Berg, Amgen

The *2011 PDA/FDA Pharmaceutical Supply Chain Conference* is going to be excellent! Building upon the momentum of successful conferences in 2009 and 2010, this event will further advance the supply chain security movement within the industry. As a demonstration of the collaboration that is happening across the industry, PDA is co-sponsoring this conference with IPEC-Americas and Rx-360.

Regulatory and industry representatives from today's leading organizations will share their perspectives and solutions regarding the implementation of innovative approaches aiming to prevent illicit acts that threaten the safety of the drug supply such as counterfeiting, diversion and economic adulteration. New laws, regulations, and guidance continue to evolve and help stimulate innovation toward enhancing good manufacturing, distribution and importation practices.

Come to this meeting and hear regulators speak about their expectations and emerging regulations. Hear from industry leaders on solutions that are being developed and implemented to work hand-in-hand with new regulations to secure the supply chain end-to-end. Industry leaders will share their own practical experiences with implementation providing you with ideas that you can apply in your company to secure your supply chain.

The conference will use an interactive audience response system to engage all participants during each plenary session, providing dynamic speaker and audience interaction as well as real-time benchmarking that you can use to advance solutions within your company.

For more information regarding this exciting conference, please visit www.pda.org/supplychain2011. We look forward to seeing you and your colleagues on June 6 in Bethesda, Md.

Workshop Evaluates Usability of Combination Product Design

Washington, D.C. • September 21-22 • www.pda.org/2011comboproducts

Co-chairs Michael Gross, PhD, Biologics Consulting Group and Lisa Hornback, Hornback Consulting

As co-chairs of PDA's second combination products workshop, we invite you to attend this year's workshop on combination products which is tentatively titled, *Life-Cycle Design Validation for Combination Products.* The workshop begins at 1 p.m. on Wednesday, September 21 immediately following the close of the *2011 PDA/FDA Joint Regulatory Conference* and ends on Thursday, September 22.

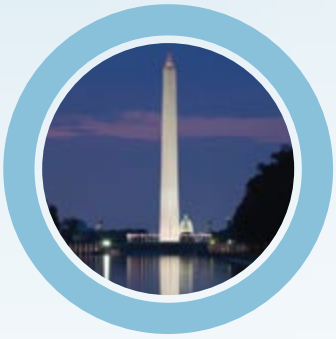
With the recent changes in health authority expectations for human factors, usability and design validation, this year's workshop will focus on the design validation requirements of FDA's Quality System Regulation (21 CFR 820) and the international harmonized quality standard ISO 13485:2003 which may be applied during the lifecycle of a combination product. The workshop will provide a forum for discussion, review and interpretation of regulations, guidance and standards applicable in the United States and in Europe regarding the evaluation of *usability* as it relates to combination product design. It will include case studies and presentations by companies currently developing and managing the lifecycles of combination products and will offer networking opportunities which will create an environment that stimulates discussion to provide a wealth of information.

The workshop will provide a forum for discussion, review and interpretation of regulations, guidance and standards applicable in the United States and in Europe regarding the evaluation of usability as it relates to combination product design

We look forward to seeing you in September at this unique event on matters important to development, manufacturing, quality assurance and regulatory activities for combination products.

Parenteral Drug Association Training and Research Institute (PDA TRI)

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals



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

Hosted in conjunction with the *2011 PDA/FDA Glass Quality Conference*:
2011 PDA Glass Quality Conference Course Series
May 25-26, 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/FDA Pharmaceutical Supply Chain Conference:*
Developing a Robust Supplier Management Process
June 8, 2011 | Bethesda, Maryland | www.pdatraining.org/suppliermanagement

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

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

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

July 2011

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

A Risk Based Approach to Technology Transfer
July 25, 2011 | Bethesda, Maryland | www.pdatraining.org/riskbasedapproach

Practical Applications of Risk Management – *New Course*
July 26, 2011 | Bethesda, Maryland | www.pdatraining.org/practicalapplications

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**

Best Practices to be Discussed at Glass Quality Conference

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

Richard M. Johnson, PDA; and co-chairs Joyce Bloomfield, Merck Sharp & Dohme and Martin Van Trieste, Amgen

In the recent past there have been many recalls and increasing concerns about pharmaceutical glass packaging with regard to defects and/or incompatibilities with finished products over their shelf life. Pharmaceutical manufacturers, regulators and glass suppliers all share a common goal of assuring the highest quality products (including packaging) for patients. As such, the U.S. FDA is co-sponsoring a conference with PDA to bring all interested parties together in an attempt to address these important patient safety issues.

Therefore, we would like to extend to you a personal invitation to meet with other key decision and opinion leaders within the pharmaceutical glass container industry at the *2011 PDA/FDA Glass Quality Conference.* Your attendance will give you the opportunity to hear directly from and to work collaboratively with the FDA and other glass manufacturers/pharmaceutical firms to take the industry at the next level.

Best practices will discussed to aid prevention and/or detection to at-risk glass packaging and to review current expectations to ensure that recalls are avoided and container closure integrity is assured. Topics to be covered include:

- Current issues with glass packaging
- Best practices on glass handling
- Current expectations for incoming glass and pharmaceutical product packaging
- Effective glass supplier relationship for product improvement
- Possible improvements in glass manufacturing, characterization, handling or packaging to be pursued

The program has been designed to bring together all parties in order to develop a common understanding and best practices

The program has been designed to bring together all parties in order to develop a common understanding and best practices. Glass suppliers are key partners in this dialogue.

2011 PDA Visual Inspection Forum

October 3-6, 2011 | Hyatt Regency | Bethesda, Maryland

The 2011 PDA Visual Inspection Forum Program Planning Committee invites you to submit a scientific abstract for presentation at the *2011 PDA Visual Inspection Forum*. Abstracts are being sought on all aspects of visual inspection processes as applied to injectable pharmaceutical products and production. Suggested topics for papers include, but are not limited to:

- Fundamental investigations into inspection processes
- Development and control of manual inspection processes
- Selection and training of human inspectors
- Statistical considerations for sampling
- New developments in automated inspection technology
- Validation of automated inspection systems
- Particulate/Foreign Material identification
- Foreign material sources in the manufacturing environment and their control
- Preparation and use of standards in assessing visual inspection processes
- Definition and classification of defects and the preparation of defect libraries
- Procedures and action levels developed specifically for glass particulates
- Case studies in the area of particulate or defect control and inspection
- Regulatory requirements affecting the visual inspection process
- Component quality and supplier qualification
- Special considerations for the inspection of biopharmaceuticals
- Detection and characterization of protein aggregation

Abstracts must be received by April 20, 2011 for consideration.
Please visit www.pda.org/visual2011 to submit an abstract

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

When submitting you abstract, please include the following information; submissions received without full information will not be considered.

- Abstract/presentation title
- Full contact information of primary and co-presenter (professional title, company, address, phone and email address)
- Presenters' biography
- Identify delivery method: podium or poster
- A 2-3 paragraph abstract summarizing your topic and identifying the appropriate category
- Presentation objectives
- Take home benefits - tools to use immediately on the job
- Target audience - by job title

ALL ABSTRACTS WILL BE REVIEWED All abstracts will be reviewed by the Program Planning Committee for inclusion in the meeting or for poster presentation.

ATTENTION EXIBITORS PDA is seeking vendors who provide excellent products/services in support of this conference. Space is limited and is on a first-come, first-served basis. To reserve your space, please contact David Hall at hall@pda.org or +1 (301) 760-7373.

QUESTIONS? Contact Jason E. Brown at brown@pda.org or +1 (301) 656-5900 ext. 131.

www.pda.org/visual2011

PDA/EMA Conference to Cover Partnerships with Authorities

London Heathrow • May 3-6 • europe.pda.org/pdaema2011

Jim Lyda, PDA

PDA and the European Medicine Agency will soon present the 2011 PDA-EMA Conference in London. The theme, "Regulation/Cooperation/Innovation: An Effective Partnership among Authorities and Industry in Europe" is most appropriate, and the scientific planning committee has worked diligently to bring you a very special program.

For 2011, the agenda has been expanded beyond Good Manufacturing Practices to include a range of quality issues relating to pharmaceutical development, production and quality management. Input from EMA's Quality Working Party (QWP), Biologics Working Party (BWP) and GMP/GDP Inspectors Working Group has resulted in substantial CMC-related content in the agenda, in addition to the always comprehensive GMP coverage. The agenda has been extended from two days to two-and-a-half days, and the number of concurrent tracks has increased from three to five to make room for the expanded content. The number of EMA speakers and speakers from the national health authorities is impressive due to the convenient conference venue at London's Heathrow Airport.

The plenary sessions on each morning of the conference will address universal themes of interest to all segments of our business. The five parallel tracks on the afternoons of May 3 and 4 will provide half-day coverage of more detailed technical or regulatory topics. It is important to note that some tracks will be repeated.

The parallel tracks include the following topics:

- Process Optimization
- Quality
- Regulatory Affairs
- Advanced Therapies
- Supply Chain
- Trends in Manufacturing
- Biologics and Orphan Drugs

There will be interactive panel discussions capping each of the parallel tracks. The planning committee has also focused on issues of interest to start-up, small and medium enterprises.

PDA is honored to feature some of the most authoritative and influential leaders from the EMA and the EU national Authorities at the conference.

Highlight Presentations:

- "How will the European Regulatory Network Develop in the next 20 years," by recently retired **Thomas Lönngren.** He was the Executive Director of the EMA since its founding, shepherding the Agency thru its growth and development into the effective organization that it is today.
- "EMA Roadplan 2015," by **Noel Wathion.** He is the head of Patient Health Protection at the EMA, managing groups responsible for Compliance and Inspection, Medical Information, Pharmacovigilance and Risk Management and Regulatory support.
- "Implementation of ICH Q8, Q9 and Q10 – Are We Going In the Right Direction?" by **Jean-Louis Robert,** head of EMA's Quality Working Party (QWP).
- "What will be the Quality Issues for the Next 25 Years for Biological Medicinal Products?" by **Jean-Hugues Trouvin,** head of the EMA's Biologics Working Party (BWP).

Inspections, Quality & GMP Authoritative Presentations:

- "Update on Regulatory, Quality & GMP Guidelines" by **Riccardo Luigetti** and **Peter Richardson.** Luigetti is responsible for Compliance and Inspections, Patient Health Protection, EMA. Richardson is responsible for Biologicals in the Quality of Medicines group, Human Medicines Development and Evaluation, EMA.
- "The Borderline Between GMP and Submissions – Collaboration Between Assessors and Inspectors" by **Jacques Morénas** and **Jean-Louis Robert.** Morénas is the head of inspections for AFSSAPS, France and past chair of PIC/S. Robert is with the health authority in Luxembourg, current chair of the QWP and chair of the ICH Q-IWG for implementation of ICH Q8, Q9 & Q10.
- "Current Status of API Audits," by **David Cockburn** and **Tony Storey.** Cockburn is the head of Manufacturing & Quality Compliance, in Patient Health Protection, EMA. Storey is the COQA Manager of Pfizer.
- "Annex 16, The Qualified Person – Is It Time to Revise?" by **Anne Junttonen,** head of inspections at the Finnish Medicines Agency.
- "The Lifecycle Approach to Process Validation," by **Lina Ertle,** pharmaceutical inspector, AFSSAPS, France, and **Birgitte Holst,** Manager, Manufacturing Science and Quality, NovoNordisk.

Regulatory Affairs and CMC Presentations:

- "Regulatory Harmonization Processes within the EU," by **Anabela Luis De Lima Marçal** of the Regulatory, Procedural and Committee Support group, Patient Health Protection, EMA.
- "Trends in European Submissions" by **Zaide Frias** of the Regulatory, Procedural and Committee Support group, Patient Health Protection, EMA.
- "How the EMA Supports Submissions" by **Spiros Vamvakas,** expert on Scientific Advice in the Human Medicines Special group, Human Medicines Development and Evaluation, EMA.
- "Experiences with the New EU Variations Regulations," by **Keith Pugh,** an Expert Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA), UK, and **Gavin Fitzgerald,** Regulatory Affairs Manager, Amgen.➤

PDA
Parenteral Drug Association

Register by 2 May 2011 and SAVE!

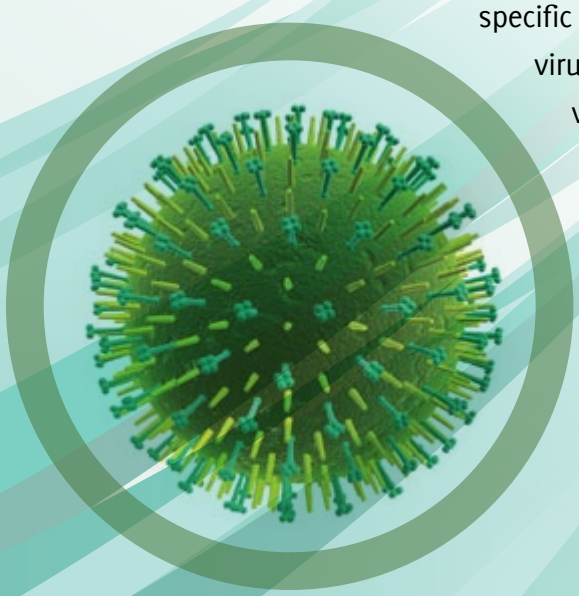
2011 PDA European

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

- "Filing a Dossier Using QbD and Real Time Testing – A Case Study," by **Evdokia Korakianiti,** Scientific Administrator in Quality of Medicines (Chemicals), Human Medicines Development and Evaluation, EMA.

Biologics and Biotechnology Products Presentations:

- "Comparability Versus Filiation," by **Kowid Ho,** lead assessor at AFSSAPS, France, and a lead expert in Monoclonal Antibody developments in the EU.
- "EMA Guideline on the Requirements for Quality Documentation Concerning Biological IMPs," by **Brigitte Brake,** Assessor with BfArM in Germany.
- "The New GMP Annex 2 – Consequences for European Manufacturers," by **Ian Rees,** Senior Inspector at the MHRA in the UK, and the Rapporteur for GMP Annex 2, Manufacture of Biological Medicinal Substances and Products for Human Use.
- "The European Legislative Framework for ATMPs," by **Patrick Celis,** Quality of Medicines, Human Medicines Development and Evaluation, EMA.

Orphan Drugs, SME, Innovation and Presentations:

- "The Regulatory Environment of Orphan Medicinal Products in the EU; Incentives and Orphan Drug Designation," by **Jordi Llinares Garcia,** EMA's Human Medicines Development and Evaluation unit.
- "The Innovative Medicines Initiative," by **Marisa Papaluca Amati,** EMA's Human Medicines Development and Evaluation unit, Scientific Support & Projects.
- "The Practical Impact of the Anti-falsification Legislation," by **Katrin Nodop,** Compliance and Inspections unit, Patient Health Protection.
- "How the EMA Supports Small and Medium Size Enterprises" by **Melanie Carr,** SME Office of the Human Medicines Development and Evaluation unit, EMA.

Training Courses

Following the conference, PDA is offering two one-day training course on May 5-6, covering:

- "Development and Manufacture of a Pharmaceutical Product with Benefit of QRM/ICH Q9 Methodology," by **Stephan Rönninger,** Head External Relations Europe/Japan, F. Hoffmann-La Roche, (Workshop Leader); **Véronique Davoust,** PGM Global Quality Operations, Quality Strategy, Pfizer; **Malcolm Holmes,** Independent Consultant; **Robert Puskeiler,** Manager Development Fermentation, Roche Pharma Biotech; and, **Emma Ramnarine,** Head of Global Quality Risk Management, Genentech (Roche).
- "The Expanding Role of the Quality Professional in Europe and USA, GMPs and Responsibilities of QPs in the Supply Chain," by **Sue Mann,** a certified QP, and **Karen Ginsbury,** a pharmaceutical consultant.

Recognizing the need for convenient and economical travel, the conference is being held at the recently opened Sofitel Heathrow Hotel, located at Heathrow's modern Terminal 5. This venue offers easy accessibility to EMA regulators and participation from UK members, while saving time for travelers from other countries. Backup hotels are located at Terminal 4 and the airport perimeter.

To find out all details of this event, download the updated agenda and conference brochure at europe.pda.org/pdaema2011.

Join us in London for this very unique opportunity to learn about the future of pharmaceutical development, manufacturing, GMP and quality management in our business.

Industry, Regulatory Dialogue to Take Place at ATMPs Workshop

Helsinki, Finland • June 7-8 June • europe.pda.org/atmp2011

Co-chairs Stephen Brown, PhD, Vivalis and Paula Salmikangas, PhD, Finnish Medicines Agency

Increasing scientific knowledge in the fields of genetics and cell biology has led to the rapid development of new innovative therapies, especially for diseases and tissue/organ defects for which traditional therapies and medicinal products are not satisfactory or available. Gene and cell-therapies (known as Advanced Therapy Medicinal Products or ATMPs in Europe) are not only intended to treat diseases through metabolic/immunological/pharmacological action, but they may be also designed for repair/regeneration/replacement of missing or damaged tissues.

Skin replacement products and articular chondrocytes for cartilage repair have already been in use for a decade, while the development of many new cell–based therapies (e.g., stem cell-based products) is hampered by particular risks, limitations and challenges related to the characteristics of these cells. The first, and thus far, only licensed ATMP product in the EU has been ChondroCelect. It is used for cartilage repair and was approved in 2009.

Gene therapy has more recently seen many interesting successes and has overcome many of the concerns regards safety and efficiency of gene transfer. Today, to name just a few, there have been successful trials for Parkinsons Disease and heart failure, and treatments for Retinitis Pigmentosa and Dry Age-related Macular Degeneration.

Upcoming challenges will be to further optimize delivery systems to find the best solution on a case-by-case basis. For example, what is the best approach for gene therapy for muscular dystrophy? Vector choice; injection of the vector by IM; or diffusion? Technical solutions to these issues are now being discussed and implemented.

Developers of ATMP products are currently struggling with similar problems just as biotech product developers did twenty years ago. Though the new European regulatory framework (Reg. 1394/2007/EC, Dir.2009/120/EC and EMA guidelines) has been established and the U.S. FDA has published a new guidance *(Potency Tests for Cellular and Gene-Therapy Products),* both developers and regulators are still lacking experience of drug development in this particular field. But, it should be noted that quality development and non-clinical and clinical studies for ATMPs may not be as straight forward as they might be for other pharmaceuticals. It is clear, however, that expertise and information sharing is needed between all stakeholders in order to ensure a positive outcome for new ATMP products under clinical development.

It is clear, however, that expertise and information sharing is needed between all stakeholders in order to ensure a positive outcome for new ATMP products under clinical development.

The goal for the PDA/FIMEA workshop on ATMPs is to bring together experts from academia, industry and regulatory bodies around the world. The program covers the entire development of gene and cell-based therapies, including CMC issues, non-clinical and clinical development as well as the most recent regulatory advances. The agenda is designed to encourage dialogue between stakeholders on the specific challenges in the development of these products. The latest achievements relating to approved EU and US products and the risk-based approach, according to Annex I, part IV of dir. 2001/83/EC applied to Advanced Therapy Medicinal Products, which was introduced into European ATMP legislation in 2009, will be presented and discussed.

Planning Committee Members

Stephen Brown, co-chair of Workshop, Vivalis, France/Great Britian

Paula Salmikangas, co-chair of Workshop, Finnish Medicines Agency (Fimea), Finland

Manuel Carrondo, IBET, Portugal

Egbert Flory, Paul-Ehrlich-Institut, Germany

Dirk Groenewegen, Glycostem Therapeutics, Netherlands

Niels Guldager, NNE Pharmaplan, Denmark

Ailyn Kandora, PDA Europe, Germany

Rich Levy, PDA, USA

Georg Roessling, PDA Europe, Germany

Robert Shaw, Ark Therapeutics, Finland/Great Britain

Hannelore Willkommen, RBS Consulting, Germany

TRI Unveils New Approach to Courses that will Save Firms Money

Themed Weeks and eLearning to provide extra savings for companies

Bob Dana, James Wamsley and Stephanie Ko, PDA

As we write this, yes, this is an article written by a committee; we are two months into the new year and some of our new approaches to our educational offerings are already underway and paying off. In addition, we are getting involved in some new activities at the Training and Research Institute that will benefit our students and the PDA community.

One of the things we are doing new this year is presenting courses on PDA-owned material. The first of these, *PDA Technical Report No. 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing,* is scheduled to be presented at the upcoming PDA 2011 Glass Quality Conference in Arlington, Va. on May 25. This course will provide manufacturers and users of glass containers with valuable knowledge related to the quality of glass containers, including the types of defects associated with glass manufacture, the development of standardized quality criteria and sampling plans for use in the quality decision-making process. The course will be especially valuable for individuals involved with glass manufacture, quality control and quality assurance, package engineering, manufacturing and regulatory affairs.

The beauty of enrolling in one of these courses based on PDA owned material such as TR-43 is that participants will learn first-hand from one of the report's authors; there will be no secondhand interpretation by someone not associated with the actual preparation of the technical report. Participants in these courses will come away not only with a knowledge of the science and technology that the report is based on, but an understanding of what is and isn't in the report and why. That's sure to be helpful to those students putting the knowledge into practice when they return to their day jobs by avoiding missteps and blind alleys. The report's authors will convey the wisdom of their experience to the course participants. In addition to TR-43, there will be more coming later this year. We would really encourage you to enroll in one of these courses.

Another new approach to education is an increased emphasis on research. After all, TRI stands for the Training and Research Institute. We've been known for our training since 1997, but not so much for research. While we have always worked to include it into our goals (and producing some very interesting data), it hasn't been one of our main priorities in the past. That will change this year with one research project planned, and preliminary discussions with other companies may lead to a few more on the way.

By blending eLearning with our traditional training methods, we can reduce your out-of-office time and expenses related to traveling for courses

The first project we will be working on in 2011 will hopefully provide data that will eventually help the industry be more "green" in their HVAC design and operation while maintaining the controlled state required for aseptic manufacturing.

On the training side of things at PDA TRI, we are working to incorporate new technologies into our training. We are going to pilot an eLearning program in 2011, and the first step will be offering eLearning trials at the TRI exhibit booth at the *2011 Annual Meeting* in San Antonio, Texas. We are partnering with a company to develop four prototype training courses that people can try out in the exhibit hall. Our next steps will be to develop a few more comprehensive training courses for testing with our instructors and members, and then incorporate the eLearning with one or more of our courses in 2011. Our hope is to provide training to a larger audience during these changing times. We understand that travel and training budgets have been cut, and it can be difficult for our members to attend training, so we want to bring it to you. By blending eLearning with our traditional training methods, we can reduce your out-of-office time and expenses related to traveling for courses. In the future, we hope to offer select full courses electronically, completely eliminating the need for travel.

In the meantime, we're reducing the travel time needed to receive in-depth training by offering, for the first time, three PDA TRI themed weeks this year: Pre-filled Syringe Week, Lyophilization Week and Filtration Week. Each themed week consists of two or three courses, giving students the opportunity to take more than one course on a particular topic in a single trip.

Pre-filled Syringe Week recently took place in late March. Three courses were held during the week. The first was a two-day lecture course, "Solving Strategic Quality, Regulatory, and Technical Issues During the Development of Pre-filled Syringes, Autoinjectors and Injection Pens," on March 21-22. Next, we ran a two-day, hands-on laboratory course, "Development of Pre-Filled Syringes," March 23-24. The third course on March 25 was called, "Syringes and Elastomers: Understanding the Effects on Quality and Demonstrating the Production Process, Influences and Needs."

Lyophilization Week takes place June 20–24 and also consists of three courses, two of which are new. "Fundamentals of Lyophilization," June 20-21 is a recurring lecture course that has been extremely popular the past several years. This course is recommended, but not a requirement, for the next course, "Economical Design of Lyophilization Experiments Workshop." This is a new course

that will take place on June 22. "Validation of Lyophilization," is a new two-day course that will take place from June 23-24.

Finally, PDA TRI will host Filtration Week from October 24–28 with two new courses: "Filters and Filtration in the Biopharmaceutical Industry–Basics Course" and "Filters and Filtration in the Biopharmaceutical Industry–Advanced Course." The basic course is in lecture format and lasts two days from October 24–25. The advanced course, with a hands-on laboratory component, will be held from October 26–28. Both courses are taught by the same expert instructors and are designed to allow students to take one course right after the other. Or, you can take just one course, depending on the level of knowledge and application you want to achieve.

Special pricing applies to all of the themed weeks and you will receive greater discounts if you take more than one course throughout the week. We encourage you to visit the website at www.pdatraining.org for more details.

PDA/FDA Conference—Too Important To Miss continued from page 38

foreign inspections, first cycle review and standards. The Innovation and Regulatory Science track will feature topics such as GMP by lifecycle phase and drug safety. The Quality and Compliance track will explore the subjects of good inspection practices from the FDA and PIC/S as well as an international compliance update, which will feature speakers from CBER, CDER, CDRH and CVM. These are just a few of the individual topics that will be discussed in detail at the conference.

In addition to the plenary and track sessions, attendees will also have an opportunity to further their knowledge by attending breakfast sessions. Some of the featured topics include a case study of an effective, implementable quality risk map approach to manufacturing; a discussion on the new FDA process validation guideline; and a presentation on the roles and responsibilities of the Qualified Person (QP); and practical experiences of a practicing QP.

The conference will close with two sessions featuring speakers from CBER, CDER, CDRH, CVM and ORA. In the first of the two final sessions, each Center will provide their perspective on current compliance issues affecting the manufacture, testing and distribution of pharmaceutical products. In the second session, titled, "Center Initiatives," conference attendees will hear directly from some of the Agency leaders with regard to their Center's current and future initiatives.

As always, one of the most important takeaways from the meeting are the people interactions and connections. It is a perfect venue for networking and sharing best practices with others who have similar backgrounds, issues and experiences.

You won't want to miss such an important, educational and timely opportunity to engage with global industrial colleagues or regulators. So, mark your calendar now to attend the *2011 PDA/FDA Joint Regulatory Conference* from September 19-21 at the Renaissance Washington Hotel in Washington D.C.

Editor's Message

Keeping Busy in Uncertain Times

Like everyone else, the people who make up the PDA community must deal with the continued barrage of bad news. Bad economic news has given way recently to political upheaval in North Africa and the Middle East and the devastation following the Japanese earthquake. It is unsettling, for sure, and leaves you asking, "What's next?"

For our members in these regions, the daily routine of going to work and making pharmaceuticals has probably been interrupted. For the rest of the PDA community, as hard as it might be, we must not let these events derail us from the collective goal our industry shares, which is to produce safe and effective medicines.

At least when it comes to Japan, if you haven't done so already, you can help simply by making a contribution to the Red Cross. PDA has set up a link on our website to make it easy to do so, and our members, I'm proud to say, have responded. **Katja Yount,** our publications designer, helped set up the website and kindly volunteered to write the update for this issue (see, "PDA Contributes to the Red Cross Japanese Relief Effort," p. 6).

At times of crisis, pharmaceuticals are more important than ever; thus, ensuring an uninterrupted supply is vital. Part of that is ensuring a well-validated and robust process for manufacturing pharmaceuticals. The U.S. FDA's new process validation guidance is intended to help firms incorporate the latest quality methods into their validation efforts. Risk management, quality systems, and pharmaceutical development—the ICH Q8-11—heavily influence the new guidance. PDA's Process Validation Task Force commented on the draft guidance when it was released and in this issue, our first feature, takes a close look at how the comments influenced the final guidance and identifies potential implementation challenges.

Our second feature also addresses the process validation from FDA's perspective. It is based off of a Q&A session at a February PDA Europe discussion forum on the topic. I want to thank **Karen Ginsbury,** member of many PDA committees (including the PLEC) for providing the notes that I used to develop the article. I also thank some of our good FDA members for taking a look to make sure the major points were articulated accurately.

The issue is full of articles showing how busy our members are in supporting PDA. From comments on regulatory documents to updates on technical reports, our members contribute a lot to the industry through their PDA activities. These combined with their day jobs make for many a late night. Who knows, maybe that's the best way to cope with all the bad news these days?

As we move headlong into spring, let's hope some good news will be coming round the corner soon!

PDA Letter

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

Subscriptions are not available.

PDA Global Headquarters — Bethesda Towers

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

PDA Europe — Adalbertstr. 9

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

PDA Training & Research Institute

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

PDA
Parenteral Drug Association

Save the date for the

2012 PDA ANNUAL MEETING

JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

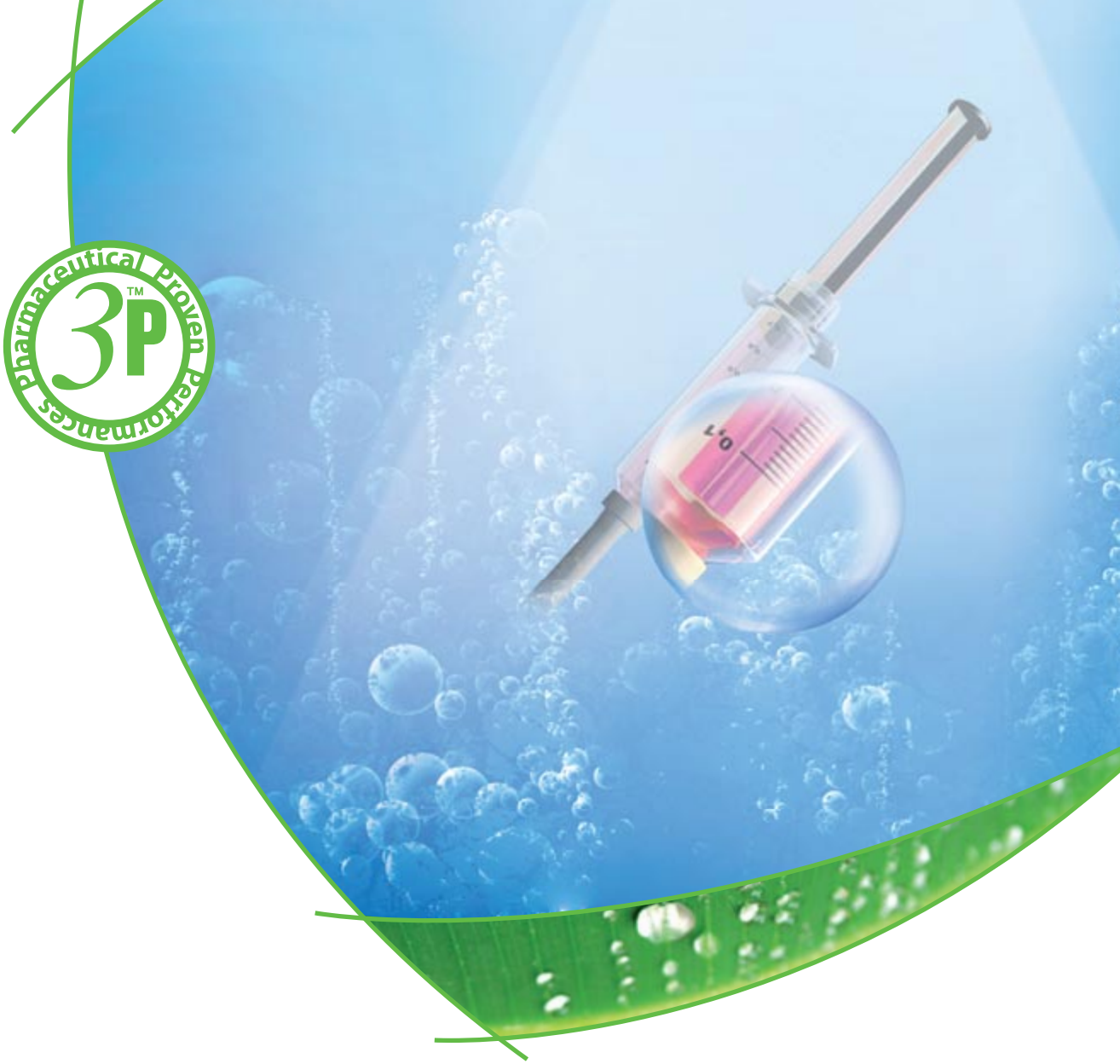
April 16-20, 2012

Be the first to know!

Sign up for the *2012 PDA Annual Meeting* Advanced Notice Alert. Be the first to know when information has been published on the *2012 PDA Annual Meeting* by registering for our Advanced Notice Alert. Simply fill out the form at **www.pda.org/annualnotice** and you'll automatically receive an e-mail once the website is available.

We look forward to seeing you in 2012!

CONFERENCE APRIL 16-18 | **EXHIBITION** APRIL 16-17 | **COURSES** APRIL 19-20



A New Vision,
on the Media Fill Test

GROUNDBREAKING CULTURE MEDIA FOR EASIER READING OF MEDIA FILL TESTS

Bringing a new dimension to the MFT with a unique colour indicator to easily detect contamination

TSE-free,
Cold-filterable,
Gamma irradiated with a minimum dose of 25kgy

both Vegetable and Animal peptone formulations comply to the requirements of the pharmacopoeias for the growth of non-fastidious micro-organisms with the highest performances

www.biomerieux-industry.com/mft

BIOMÉRIEUX
INDUSTRY