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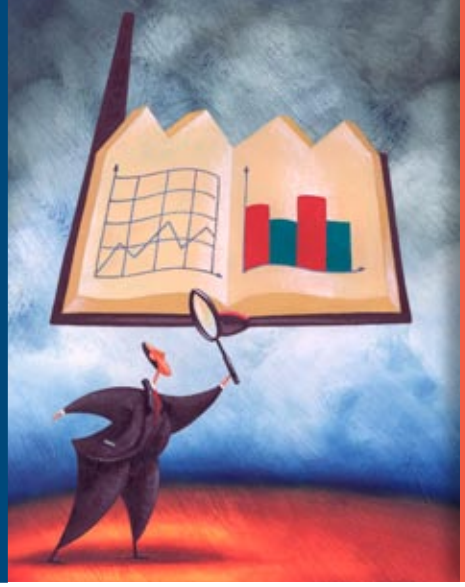
PDA Letter

Volume XLV • Issue #3

www.pda.org/pdaletter

March 2009



In This Issue:

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

PDA Submits over 400 Comments on FDA Draft Revised Validation Guidance

[Editor's Note: The following is the cover letter included with PDA's comments on the U.S. FDA draft guidance on process validation. The comments were approved by the PDA Board of Directors on February 23, 2009 and sent to FDA Dockets. The cover letter and complete comments grid are available at www.pda.org/regulatorycomments.**]**

The Parenteral Drug Association (PDA) is pleased to offer comments on the FDA Draft *Guidance for Industry Process Validation: General Principles and Practices.* PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in process validation and were reviewed and approved by PDA Advisory Boards and Committees. PDA appreciates the opportunity to offer comments on this Draft Guidance and wishes to thank FDA for the opportunity to do so.

PDA Response to the FDA Process Validation Guidance Revision

In order to develop representative comments on this comprehensive guidance, PDA solicited input from a broad range of its members and formed a working committee to review, organize and prepare our comments. We received over 400 comments, indicating strong interest in this long awaited document. We wish to stress that our membership and the committee feel that the guidance is a good document which will advance the new quality paradigm, consistent with the science and risk based approach FDA is advocating. As such, we have organized these comments into a spreadsheet which is available on PDA's web page www.pda.org, as a service to our membership and as an adjunct to this summary document which addresses primarily recurring categories of comments. The categories are presented in order of priority of the subject, as interpreted by the PDA.

We welcome the sprit of the drafted guideline to implement the new paradigm of a science and risk based approach. The following are the six major categories of comments received from PDA respondents for clarification. The category is used as a reference to the expanded list of comments (made available separately on the PDA web page).

continued on page 17

When to identify?
When to investigate?

Automated routine identification to the species level allows in depth knowledge of environmental flora.

Investigation mandates strain typing (i.e: finger-printing) to demonstrate perfect clonal type below species level.

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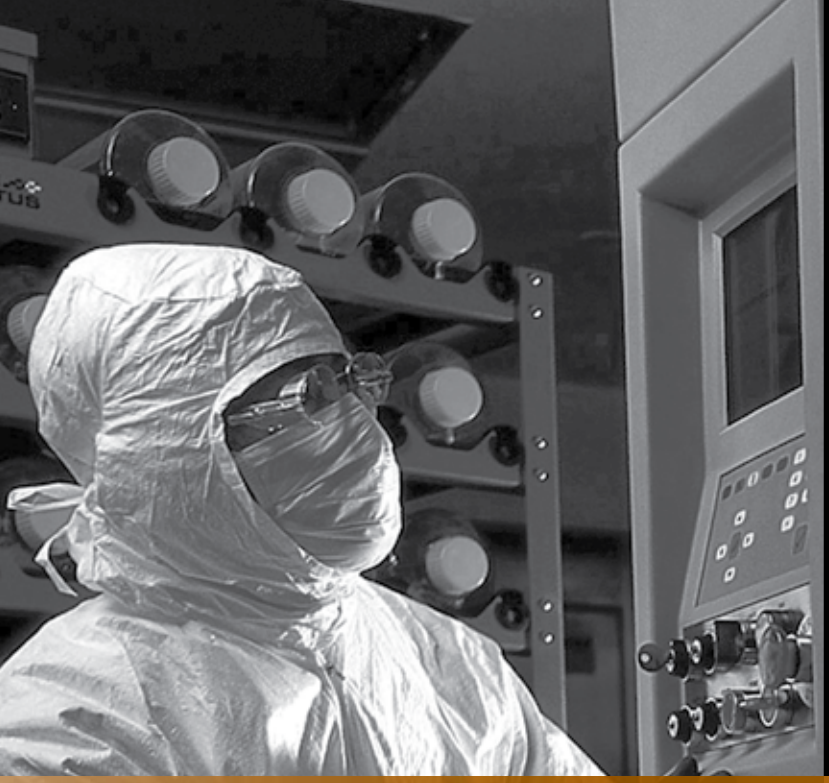

2009 PDA Annual Meeting

The Impact of the Microchip – Application of Modern Technologies in the Development, Manufacture and Testing of Bio/pharmaceutical Products

April 20-24, 2009

Las Vegas, Nevada

Conference	April 20-22, 2009
Exhibition	April 20-21, 2009
Courses	April 23-24, 2009

red rock
CASINO · RESORT · SPA
Las Vegas

Join industry and regulatory colleagues at the *2009 PDA Annual Meeting* to explore some of the most influential factors impacting the current state and future development of the pharmaceutical and biopharmaceutical industry. Built on the theme, *The Impact of the Microchip – Application of Modern Technologies in the Development, Manufacture and Testing of Bio/pharmaceutical Products*, the conference will examine the systems and tools that can help you and your company maximize efficiency and productivity, while consistently delivering safe, pure and reliable drugs to patients.

Complementing the conference are PDA Training and Research Institute (PDA TRI) courses, an exhibition featuring today's leading bio/pharmaceutical companies and service providers, and enhanced networking opportunities that take advantage of all that Las Vegas and the exciting Red Rock Resort and Casino have to offer.

Increase your knowledge, find solutions to every day challenges, make valuable contacts and advance your career at the *2009 PDA Annual Meeting*.

Photos courtesy of Bayer Healthcare and Sartorius Stedim Biotech

New this year!

PDA will host a pre-conference workshop on Cleanroom Technology and Contamination Control on April 19, as well as a post-conference workshop on Process Validation and FDA's new draft guidance on April 23.

www.pda.org/annual2009

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Validation is a critical step in commercializing a drug product and requires careful scrutiny of the manufacturing process.

Coming Next Issue:
Update on Rapid Microbial Methods

Editor's Message

Validating the Value of PDA

The cover letter to the PDA comments on the U.S. FDA's draft revision to the validation guidance warrants the prime position of cover story in this issue, partly because the guidance is extremely important and partly because the comments task force put in an A+ effort to complete their work on time.

Forget for a moment that the FDA ultimately extended the public comment period to March 16, and consider the improbable task the committee faced when the validation guidance first published on November 18 with a comments deadline of January 21. If 60 days seems short to comment on a guidance of this magnitude, in reality, it was even shorter with Thanksgiving occurring at the end of November for our members in the United States and the end of year holidays occupying the time of most of our members worldwide. In addition, PDA does not submit regulatory comments without approval of the governing advisory board—the RAQC in this case—and then the Board of Directors. This approval process takes at least two weeks. Therefore, the task force effectively had about four weeks to compile the comments in this race against the clock.

To do so, the team mobilized quickly. Word was sent to PDA members via our website and the *PDA Connector* that an online tool was available to collect comments on the draft. And the comments came pouring in, more than 400! Despite the ultimate extension of the comments deadline, the task force achieved RAQC and Board approval by Feb. 23.

Our hats go off to the task force. I encourage all PDA members to log on to the PDA website to view the entire comments grid sent to FDA.

Correction: In the feature article "Implementation Strategies for EU GMP Annex 1" by Martyn Becker (Jan. PDA Letter, pp. 16–17 & 22), one line of the article was omitted accidently at "blue line." The sentence impacted by this mistake should have read (missing text in bold): *If "Grade A air supply" means the full Grade A requirements as normally operated within an aseptic core, then there would be no difference in expectation—and such a workstation located outside an aseptic* ***core could not possibly comply with those*** *expectations because of the environment and potential interventions.* The complete and correct version of the article can be downloaded in the member's only PDA Letter archive at www.pda.org/pdaletter. We apologize to our readers and the author for the error.

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First Conference under PDA-SIFDS MOU in June

PRESIDENT'S MESSAGE

Bob Myers

The PDA/FDA Asia/Pacific Pharmaceutical Supply Chain Conference takes place in June and is a milestone event for PDA for many reasons. First, the Shanghai Municipal FDA (SHFDA) has endorsed this meeting, and will be represented by **Tang Minhao.**

The event is also the latest in our series of joint conferences with the U.S. FDA on supply chain, which premiered as a follow-on workshop to the PDA/FDA Joint Regulatory Conference last September in Washington, and continued in San Diego in December and in Munich, Germany, this March. Following the Shanghai meeting, the PDA Training and Research Institute (TRI) is offering three courses.

Most notably, the Supply Chain Conference in Shanghai is the first to be held under the Memorandum of Understanding that PDA and the Shanghai Institute for Food and Drug Safety (SIFDS) signed at the *2008 PDA/FDA Joint Conference.* Under the MOU, we are working with the SIFDS to help enhance quality in China's pharmaceutical manufacturing, to improve pharmaceutical technology and quality control, and to achieve international exchanges on laws and regulations in pharma manufacturing. The conference and follow-on TRI courses meet each of those goals.

The conference is co-chaired by Pfizer's **Janeen Skutnik** and the FDA's **Steven Wolfgang.** While the agenda is not yet finalized, the conference touches on every facet of supply chain management, including the prevailing risks, regulatory concerns, perspectives from drug manufacturers and suppliers, auditing, harmonization and more. I want to thank Janeen for her work on all of the conferences in this series, as well as other members of the committee who took time out of their schedules to appear at all four of our Supply Chain events: **Susan Schniepp, Martin Van Trieste,** and **Eric Berg.**

PDA also intends to promote our technical reports to the industry in China, and two of the three TRI courses are targeted to this specific effort. The one course provides an overview of *PDA Technical Report No. 1 (Revised 2007): Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control.* Another course covers PDA *Technical Report No. 26 (Revised 2008): Sterilizing Filtration of Liquids.* The third TRI course provides an overview of the recently published FDA draft guidance on process validation and PDA's comments on the guidance.

Keep an eye on the *PDA Letter* for more information on the Supply Chain Conference in Shanghai and the follow-on TRI Courses. I look forward to seeing many of you in Shanghai in June!

Broken Pipe, Waterfall Disrupt PDA Workflow, Online Registration

Some PDA members might have discerned a service disruption notice on the PDA website in early February. Here's the story of what happened.

On Wednesday, February 11, just before noon, a plumbing mishap resulted in a serious flood inside the data center at PDA Headquarters, temporarily knocking out systems for online registrations and emails.

The flooding water cascaded from the ceiling directly over PDA's various servers. Not only did this catastrophe impact emails and registrations, it interrupted workflow as all files saved to the servers (100% of work for some, less for others) were unavailable until new servers were in place and loaded with backup information. Fortunately, very little work was lost.

PDA's IT team of **Feng Chen** and **Eugene Zaharescu** literally immersed themselves in the work of salvaging the equipment as a torrent of cold water flowed down from the ceiling, while a maintenance worker scrambled to stem the flow. Assistant Manager **Aaron Carpenter** and Office Specialist **Stephon Jefferson** get an honorable mention for jumping into the fray, or should we say spray, to help pull out drowning computers.

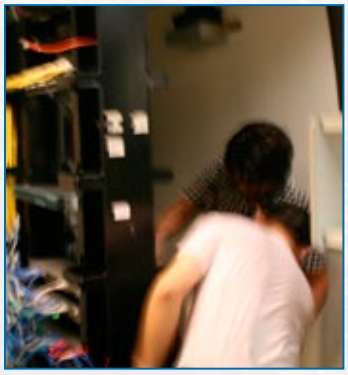
Fortunately for PDA and our members, online registration was operating by Friday morning, less than two days after the flood. The email server was running by Saturday, February 14.

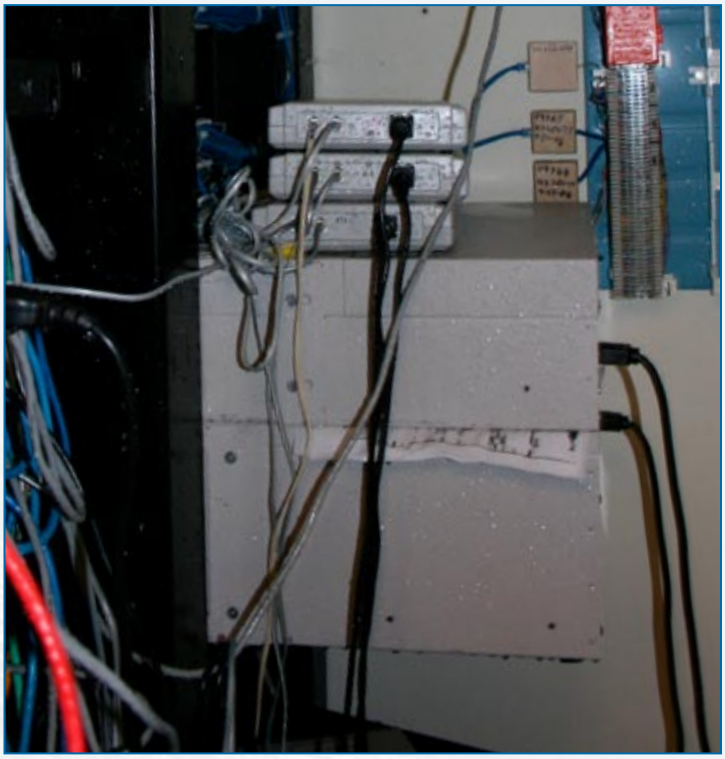
A disaster recovery team, Itek Solutions, was hired to assist PDA's IT team in the recovery effort. The group was contacted immediately after the disaster struck. PDA's Chen worked the entire holiday weekend (President's Day) with an Itek consultant to get the systems up and running.

Part of the recovery effort involved replacing damaged parts in several servers and replacing one of the servers completely. All the servers will be replaced within a few months. By the time the rest of PDA staff returned to work on Tuesday, February 17, the network drives were fully operational.

The incident shows how important it is for companies to have strong data backup and recovery plans. Considering that the whole data network was washed out, Chen was happy with the recovery effort, commenting, "It was an incredible disaster recovery effort. We got a system up and running in a few days which would normally take *at least* a week-and-a-half."

PDA President **Bob Myers** informed the staff that Feng and his team "did a great job under tough circumstances." While the work of replacing all the servers continues, Myers expressed is gratitude to the team for getting the systems up so quickly.





Gallons of water flooded directly on top of the servers, leaving workers and equipment soaked and inches of water covering over the surrounding area.

Science & Technology Snapshot

Advisory Board Powwow to Plot PDA's Strategic Course

Emily Hough, PDA

To help advance the Association's mission, PDA is holding a joint Advisory Board meeting at its *2009 Annual Meeting*. Participating will be PDA's all-volunteer advisory boards for science, regulatory affairs and biologics. The Program Advisory Board also might participate.

PDA's Mission **To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of its global membership.**

This meeting will begin the process of coordinating PDA scientific and regulatory activities, according to PDA's **Rich Levy,** PhD. "At this meeting, we will review our current 'project portfolio,' redefine our strategic plans based on members needs, and, through this process, ensure that there are no duplicate project activities or redundant deliverables in the works."

Chairs and co-chairs of the Science Advisory Board (SAB), the Biotechnology Advisory Board (BioAB) and the Audit Guidance Advisory Board(AGAB) previewed what was going to happen at this historic meeting of PDA's top strategic panels in Las Vegas and how it will impact PDA moving forward.

SAB co-chairs, **Hal Baseman,** ValSource, and **Jens Henrik Eilertsen**, PhD, Novo Nordisk, said this joint meeting would be an excellent way to exchange ideas and develop plans for implementing initiatives and projects. This meeting demonstrates that "PDA has identified the needs of its members which can best be accomplished by initiatives supported by more than one of the advisory boards," said the SAB leaders. According to Baseman and Eilertsen, "The joint advisory board leadership meeting is an excellent way to develop the mutual understanding of the priories of the different advisory boards."

They hope to encourage the exchange of ideas between advisory board members and leaders; to discuss common goals, practices and needs; to identify projects to meet the needs of the advisory boards, membership and industry; to develop plans to accomplish projects; and to indentify best practices for advisory board functions.

BioAB co-chairs, **Norbert Hentschel,** Boehringer Ingelheim, and **Jeff Baker**, PhD, MedImmune, also think that the joint advisory meeting in Las Vegas will help improve the interaction between the different PDA advisory boards and make better use of Association resources. They said that they hope to have a clear and commonly understood communication process between the advisory boards after the meeting. Hentschel and Baker reiterated that, in order to achieve alignment between PDA's different advisory boards, it is important to have close contact between the groups.

AGAB co-chairs **Janis Olson**, EduQuest, and **Steven Walter,** MBO Partners, hope to learn how other boards are operating and will also gain support from the other groups on projects that are underway. They believe that the meeting is important so that all of the advisory boards can exchange information.

Annual Meeting *Book Signings*

2009 PDA Annual Meeting

Monday April 20, 2009		
9:45 a.m. – 10:45 a.m.	Morning Refreshment Break	**Jeanne Moldenhauer** "Biological Indicators for Sterilization Processes"
12:30 p.m. – 2:00 p.m.	Networking Luncheon	**Anne F. Booth** "Radiation Sterilization: Validation and Routine Operations Handbook"
3:45 p.m. – 4:30 p.m.	Afternoon Refreshment Break	**Jack Lysfjord** "Practical Aseptic Processing: Fill and Finish"
Tuesday, April 21, 2009		
10:00 a.m. – 11:00 a.m.	Morning Refreshment Break	**Siegfried Schmitt, PhD** "Risk Based Compliance Handbook"
3:30 p.m. – 4:30 p.m.	Afternoon Refreshment Break	**Theodore H. Meltzer, PhD and Maik W. Jornitz** "Anatomy of a Pharmaceutical Filtration: Differential Pressures, Flow Rate, Filter Areas, Throughputs and Filter Sizing"

Technology *Trend*

Pfizer's Green Chemistry Cuts Waste, Saves Money

Emily Hough, PDA

Many industries and governments around the world are "going green," as as the world focuses more and more on the environment and the potentially negative effects of human activity. All one has to do is browse the internet, read newspapers, watch T.V., or live in California to learn about the latest green initiatives. The pharmaceutical industry cannot help but to be impacted in everything that it does in terms of practices, policies, procedures and materials.

Peter Dunn, PhD, a Global Green Chemistry Leader who works for Pfizer took some time to talk to PDA about how the "going green" movement is impacting his company and what it take to implement green initiatives. According to Dunn, initiatives like "Green Chemistry" are occurring more and more in the pharmaceutical industry. He believes there will be a global solution, especially "in the [innovator] part of the business." Dunn said that he has seen new companies join the pharmaceutical roundtable, of which he is a co-chair, each year. "I really see this [green] initiative growing throughout [the world], especially through the innovator pharmaceutical companies like Merck, Lilly, Pfizer, GSK and AstraZeneca."

The Green Chemistry Institute's Pharmaceutical Roundtable

In 2005, several firms, along with the American Chemical Society's Green Chemistry Institute (GCI), established the American Chemical Society Green Chemistry Institute's Pharmaceutical Roundtable, to promote the integration of green chemistry and green engineering in the industry. The following ten companies are now members: Boehringer Ingelheim, DSM, Schering-Plough, Codexis, Merck, Eli Lilly, Pfizer, GlaxoSmithKline, and AstraZeneca.

He said that he didn't feel Pfizer was the only pharmaceutical company in recent years to promote and apply Green Chemistry. Dunn said "I think [Pfizer] is *one* of the companies that has raised the bar, but I don't think we are the only one. I think each individual company sets their own targets; I know GSK does, Lilly does and we do. The targets that each company sets are more ambitious than the ones from 10 years ago."

Dunn said that there is a mixture of environmental and financial rewards that make Green Chemistry attractive. "I think people see the financial rewards, and they see the

continued on next page

Annual Meeting *Preview*

15 IGs, 5 Task Forces, SAB, BioAB to meet

PDA members and volunteers will dedicate some of their time at the 2009 Annual Meeting conducting the business of the Association.

All participants at the *2009 PDA Annual Meeting* are welcomed to participate in interest group discussions. Nearly all of PDA's interest groups (IG) are holding discussion sessions during the conference.

The first IG session is on Monday, April 20 from 4:30 p.m.–5:30 p.m., when the following five groups are meeting concurrently: Microbiology and Environmental Monitoring; Combination Products; Facilities and Engineering; Vaccines; and Lyophilization. The Microbiology and Environmental Monitoring IG is holding a panel discussion with featured speakers **Ken Muhvich,** PhD**,** Reliance LLC, and **James Akers,** PhD**,** Akers, Kennedy & Associates.

The second IG session cap off Tuesday, April 21, with the following groups meeting: Sterile Processing; Process Validation; Visual Inspection of Parenterals; Filtration; and Packaging Science. The Filtration IG feature talks by **Paul Genest,** Millipore, and **Rachel Specht,** Genentech, on alternative strategies for virus filter validation. The Packaging Science IG is exploring thermal package design advances with a talk by **Kevin O'Donnell,** Tegrant Corporation, and container closure integrity with a presentation by **Mihaela Simianu,** Eli Lilly.

The final IG session opens the final day of the Annual Meeting on Wednesday, April 21, with the following groups: Clinical Trial Materials; Inspection Trends/Regulatory Affairs; Pre-Filled Syringes; Pharmaceutical Water; and Quality Systems. Check the Annual Meeting website for more details on these IG sessions at www.pda.org/annual2009.

The Biotechnology Advisory Board (BioAB) is using its lunch period on Monday, April 20 to meet, and the Science Advisory Board (SAB) will do the same on Tuesday, April 21. The two groups establish PDA's scientific and biotech-related initiatives, sanction the creation of task forces, and serve as the first official line of review for PDA technical reports. Participation in these meetings is limited to members of the advisory boards only.

Finally, five task forces are gathering at the 2009 Annual Meeting to advance their respective projects. The Mycoplasma Task Force meets on Monday at 3:45 p.m.–5:45 p.m. On Wednesday, 8:00 a.m.–9:00 a.m., both the Early Phase Clinical Trial Materials Task Force and the Single Use Systems Task Force hold their respective meetings. Later on Wednesday, the Ampoules, Cartridges and Syringes Task Force will meet at 12:30 p.m.–5:00 p.m., and the Phase Appropriate Application of GMPs Task Force will meet 12:30 p.m.–2:45 p.m. Like the advisory board sessions, participation in these sessions is limited to task force members only.

Technology Trend, continued from previous page

benefits for their company reputation. There are probably a few companies that have almost been shamed into it—you know being left out—'everybody else is doing it, so we have to do it'; there is a portion of that."

Dunn said the real problem in implementing a green program within a company wasn't as much financial as it was changing people's perceptions and mindsets. "I think the problem in the early stages is getting concepts across and winning the hearts and minds of the scientific community that can be hard going at the start. The financial aspects are the rewards that come with the program."

Dunn said that advanced scientific innovation lies at the heart of Green Chemistry and is a great way to develop sustainable, environmentally sound and cost-effective processes. Since implementing the Green Chemistry initiative, Pfizer has reduced the use of some hazardous solvents, and eliminated their use in other cases. According to Dunn, the company has made "big progress" in getting the undesirable solvents out of its research labs.

Dunn shared how the Green Chemistry initiative has increased the yield and reduced the "E-factor"* for Pfizer's production of sildenafil. The average chemical yield over the last four steps is 97.5% on a 1000 Kg scale. The firm minimizes the amount of solvents used in the process by performing two of seven chemical steps in water, which has lowered the E-factor to 8. Dunn noted that the average E-factor for a pharmaceutical product is 25–100.

The "E-factor"

Dutch Professor Roger Sheldon, Delft University of Technology, put the "E" in E-factor in the late 1980s. The E-factor, or Environmental Factor, is the ratio of the mass of waste per unit of product. The factor is widely used for determining the efficiency and environmental impact of chemical processes.

Another area where Pfizer has made a "big impact," Dunn said, is in the development and the manufacturing part of the organization. "You can see in our sildenafil program that in 2000, we were down to 6.3 liters per kilo, and you see a dramatic reduction ➤

The Twelve Principles of Green Chemistry

According to the Environmental Protection Agency (EPA), the term, "Green Chemistry" consists of "environmentally friendly, sustainable chemicals and processes whose use results in reduced waste, safer outputs, and reduced or eliminated pollution and environmental damage. Green Chemistry encourages innovation and promotes the creation of products that are both environmentally and economically sustainable."

The EPA on their website, www.epa.gov, lists the twelve principles of Green Chemistry. The twelve principals are as follows:

Prevent waste
Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.

Design safer chemicals and products
Design chemical products to be fully effective, yet have little or no toxicity.

Design less hazardous chemical syntheses
Design syntheses to use and generate substances with little or no toxicity to humans and the environment.

Use renewable feedstocks
Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are mined.

Use catalysts, not stoichiometric reagents
Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.

Avoid chemical derivatives
Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.

Maximize atom economy
Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.

Use safer solvents and reaction conditions
Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use innocuous chemicals.

Increase energy efficiency
Run chemical reactions at ambient temperature and pressure whenever possible.

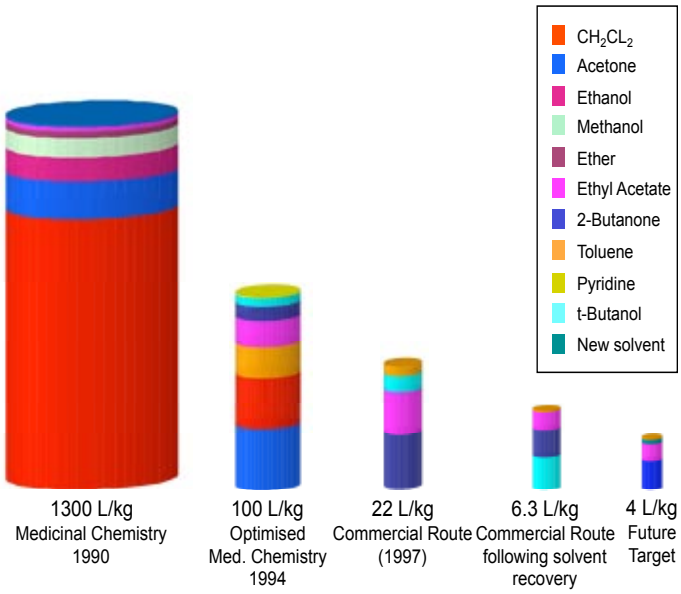
Design chemicals and products to degrade after use
Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.

Analyze in real time to prevent pollution
Include in-process real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts.

Minimize the potential for accidents
Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

in the amount of waste used in that process. It is not common for a new pharmaceutical product to produce such low levels of waste. We've been setting very aggressive targets."

Next, Dunn spoke about Pfizer's pregabalin, for which the firm has implemented an enzymatic process and all the chemical reactions are preformed in water. This "extremely unusual" process reduces the amount of waste that would be derived from a conventional process.



Green Chemistry is reducing waste at Pfizer.

Dunn said that the initiative had no major affect on cGMP compliance or QA procedures. He said that sometimes a new process is slowed down by a few months by "going green," because the U.S. FDA and EMEA have to approve the new process, but that both Agencies are much quicker today in approving second generation processes than they were in the 1990's. "Basically we have to work within the constraints of regulatory environment, but within the restraints of cGMP and quality you could still make significant environmental improvements."

At the end of the interview, Dunn reiterated, "I think [setting up a green initiative] can be hard work in the initial stages, but the financial rewards are there and also the environmental rewards are there. It can be hard work in the initial stages—you need to win the hearts and minds of colleagues and especially scientific colleagues at the bench, they are often the people that make decisions as to what materials go into the process, but I think the rewards are there; both financial and social."

[Editor's Note: Be on the lookout for more articles on this subject, and if you have your own stories on this topic email them to morris@pda.org, subject line "Green Chemistry Within Industry."**]**

Recent Sci-Tech Discussions: Lyophilization with Thermocouples

The following unedited remarks are taken from PDA's Pharmaceutical Sci-Tech Discussion Group, an online forum for exchanging practical, and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. The responses in the Sci-Tech Discussions do not represent the official views of PDA, PDA's Board of Directors or PDA members. Join at www.pharmweb.net/pwmirror/pwq/pharmwebq2.html.

Does anyone have "hands-on" practical advice for feeding thermocouples into a lyo chamber in a manner that is truly airtight. My system has a standard tri-clover port. When fitted with a blank, the system passes the built-in leak test.

When I connect a K* [sic] feed-through kit with thermocouples connected, the system will draw vacuum, but not maintain it for very long. I've removed the outer sheathing at the point of the feed through kit, to prevent air escape between the wires and sheathing.**

I've started doing "creative" things such as using silicone sealant. Well, the less said, the better, but the results are the same.

Thanks to all.

Respondent 1: We had to go to the remote memory type chip monitors and then download afterward. Hope this helps in your situation.

Respondent 2: We have had success with using a stainless steel fitting that is triclovered on one end, but just open on the other end. Our instrumentation staff puts the thermocouples through and then fills the interior with an epoxy that, once it dries, holds up pretty well. If you want, I can ask them what type of epoxy it is.

Respondent 3: [Respondent 2], Could you let us know the type of epoxy which has given good results please?

Respondent 4: Try a Connax flange (Connax Technologies). With a Connax flange you can achieve deep vacuum (around 20 um Hg) leak test with no problem. The setup is however long (several days) since each TC have to strip and inserted in the compression flange. This company can however do it for you.

Respondent 5: I am impressed with the ingenuity of the people in this group. Looking through the Conax catalogue, I happened upon something that might be perfect for a lyophilizer feed through. This is something called a HAST fitting, used in the semiconductor industry.

Respondent 6: If you insist on using thermocouples, I recommend that you use a type with stainless shield on the part inserted into the lyophilizer, instead of conventional cable type.

The stainless steel shield type of thermocouples can be vacuum tight, when using a feed through (compression fitting type) available from sensor supplier (Pentronics or Thermocoax among other).

Alternatively try to contact Ellab. They have a temperature data logger designed for validation of lyophilizers.

sartorius stedim biotech

BACTair™ – Big Impact

for Microbiological Air Monitoring

- Integrated disposable sieve, eliminates handling, cleaning and sterilizing of reusable sieves
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PDA's Proactive, Comprehensive Response to

Timothy Ramjit, Schering Plough and Scott Bozzone, Pfizer

On November 18, 2008, the U.S. FDA released its highly anticipated draft revision of the Guidance on the *General Principles and Practices of Process Validation.*

Published jointly by the Centers for Drugs (CDER), Biologics (CBER) and Veterinary Medicine (CVM), this draft guidance outlines the general principles and approaches that the U.S. FDA considers to be appropriate elements of process validation for the manufacture of medicinal products, including active pharmaceutical ingredients (APIs). Once approved, this document will supersede the twenty-one year old original guidance that was issued in 1987.

This revision comes as no surprise. In the Agency's 2004 report, titled *Pharmaceutical GMP's for the 21st Century – A Risk Based Approach*, the provision of new process validation guidance was described as one component of a holistic life cycle approach embraced by other complimentary documents, particularly those by the International Conference on Harmonisation (ICH). The tripartite guidelines produced by ICH that are linked to the 21st Century GMPs outline ideas on development (ICH Q8), risk management (ICH Q9), and pharmaceutical quality systems (ICH Q10).

As promised, FDA's revised validation guideline nicely integrates the concepts of Quality by Design and continuous improvement, and presents process validation as a continuous activity rather than a one-time snapshot of product performance.

So what's new?

It's fair to say that FDA's original thoughts on process validation, expressed over two decades ago, remain largely intact in the new guidance. What has changed is the significant emphasis on process validation as a 21st century activity with state-of-the-art process validation principles and practices, ongoing assessments and the use of statistics through the various life cycle phases. It reflects the use of current technology and design space concepts. It is a good step forward to use science and risk based approaches to process validation. There is some alignment with ICH and acknowledgement of more progressive approaches such as PAT and continuous verification.

The Guidance

The guidance describes the three stages and activities of process validation in a product's life cycle: **Process Design, Process Qualification,** and **Continued Process Verification.**

Having anticipated the publication of this draft guidance for some time, PDA assembled a task force which was prepared to develop the Association's comments on the draft guidance.

Process design, or stage 1, involves building and development of process knowledge and establishing a strategy for process control. **Process qualification,** or stage 2, has two elements: a) design and qualification of facilities, utilities and equipment and b) performance qualification where protocol and reports are described. **Continued Process Verification,** or the final stage 3, applies to post-process qualification commercial manufacture and assures continual control through activities such as data trending, monitoring and improvements.

The PDA Task Force

Having anticipated the publication of this draft guidance for some time, PDA assembled a task force which was prepared to develop the Association's comments on the draft guidance. The task force, co-chaired by **Hal Baseman,** COO, ValSource, and **Scott Bozzone,** Pfizer, held their first meeting to organize the commenting process the same day the draft guidance was published. Advance preparation was key, since the *Federal Register* notice only allowed a 60 day comment period due Jan 20, 2009, and much of this time was consumed by several major US and international holidays. This original comment period has subsequently been extended to March 16.

The task force's strategy to solicit comments involved utilization of the web-based *PDA Connector* to reach our membership so that all would have an opportunity to submit comments for consideration in a joint PDA response to FDA.

Secondly, the task force developed a list of targeted reviewers who had expressed a keen interest in commenting or participating with the guidance review. Their expertise and knowledge in process validation and related areas made their participation particularly important to this effort. Comments were also welcome for submission separately by individuals or companies.

The PDA Task Force met a few times to organize, review and discuss the comments. **[Editor's Note:** The cover letter to the comments is published in this issue (cover story) and includes a complete listing of task force members.**]**

Comments

Over 400 comments were received in this short time from 27 respondents, repre-

FDA's Revised Process Validation Guidance

senting pharmaceutical, biotechnical and consulting firms. A big thanks and appreciation to all those who commented!

Comments were reviewed, categorized and summarized in a report by the task force. Many comments were complimentary; many sought clarification and harmonization with existing guidance; some call for modification and or removal of certain recommendations. As one reviewer noted, *(it) presents a well articulated and broad based approach for validation. It is certainly a major leap toward a science and risk-based approach and is consistent with what FDA has been presenting in the industry over the past year or two.*

A report was prepared by the task force which highlighted several key areas of PDA membership concerns. PDA recommends that these comments should be considered, including:

Scope and Legacy Products: Committee comments regarding the scope of the guidance are divided into two general categories: (1) applicability to other product forms such as vaccines and blood products, and (2) applicability to other areas such as validation of cleaning processes.

The committee questions the applicability of stage 1 and stage 2 practices to currently validated legacy products.

Approach and Assurance for Commercial Distribution: The committee comments on the continued use of enhanced performance qualification sampling in Continuous Process Verification Phase 3 and the appropriate use of statistics during the various phases to achieve appropriate assurance.

Viral and Impurity Clearance Studies: Regarding this section of the guidance, the committee inquires about the expectation to perform certain early-phase studies under full cGMP conditions compared to other GxP conditions.

Concurrent Release: One of the concerns here is the expectation to perform stability testing for all concurrently released PQ batches.

Qualification, Documentation, Organization and Regulatory Impact: This section requires some clarification, according to the committee, particularly with respect to:

- Qualification expectations such as capability of equipment to maintain operating ranges over anticipated production times, especially with extended processing times.
- Documentation and regulatory impact such as inspectional expectations for stages of process validation and documentation of qualification plan versus protocols.

Wording and Terminology: The committee is concerned with the level of consistency or inconsistency in definitions and terminology with approved guidance documents including those issued by the FDA and ICH. A glossary of terms has been suggested.

Within each key area, the task force summarized recommendations for the Agency's consideration.

Workshops

To ensure all our members are aware of the new draft guidance and its impact, we are currently developing a series of one-day public workshops at various locations. Plans, which are tentative at the time of this writing, are for these workshops to take place throughout 2009 in the following locations:

- **San Francisco, California (March 4)**
- **Munich, Germany (March 9)**
- **Las Vegas, Nevada (April 23) - in conjunction with the PDA 2009 Annual Meeting**
- **Chicago, Illinois (June 8–9)**
- **Bethesda, Maryland (October 26–28)**

The workshops will focus on changes to the content of the draft guidance, PDA's comments and implementation-related case studies. An FDA representative from CDER's Office of Compliance will appear at each workshop to discuss the new guidance. Tentatively, **Edwin Rivera Martinez,** Chief, Manufacturing Assessment and Preapproval Compliance Branch, **Grace McNally,** Consumer Safety Office, and **Brian Hasselbalch,** Consumer Safety Officer, will represent FDA.

To further support our member needs, our Training and Research Institute plans on offering training courses focused on validation strategies and applications associated with some of these workshops. Once again, stay tuned and watch your mail. Don't miss the opportunity to be part of this new PDA initiative in 2009. If you would like to participate as a presenter in any of the workshops, or have ideas for a new training course, don't hesitate to contact the authors or **Bob Dana** at dana@pda.org.

About the Authors

Scott Bozzone is a Senior Manager in the Global Quality Operations-Validation for Pfizer, Inc. based in Peapack, New Jersey. At Pfizer, Scott has served in a number of capacities in both in Pharmaceutical R&D, manufacturing sites (Cork, Ireland) and Pfizer Global Manufacturing (PGM) Center. In his current position he is responsible for validation site support concentrating on process and cleaning validations, and part of the Quality Risk Management training team.

Timothy Ramjit is a Senior Director in Schering-Plough Corporation's Global Technical Services organization based in Summit, New Jersey, where his primary responsibilities deal with validation, technical support, and process management. Prior to joining Schering Plough Corp. in 2001, Tim worked in various pharmaceutical development, quality management, and validation roles with Merck & Co. Inc, in West Point, PA. Tim is an active member of PDA and most recently co-chaired PDA's Risk Management Task Force and the development of Technical Report 44 – Quality Risk Management for Aseptic Processes.

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PDA Submits over 400 Comments on FDA Draft Revised Validation Guidance, continued from cover

Wording and Terminology

This category on the use and definition of specific terms and language had the most questions and comments. Collectively, these comments promote the value of including a document glossary, as well as the desire to use terminology which is consistent with ICH and other FDA regulatory guidance definitions in order to reduce potential misinterpretation. It is felt such updates could be achieved without altering the intent of the guidance.

Some examples include:

- the difference between 'design stage' vs. 'product development stage'
- 'continued process verification' vs. 'continuous quality verification'
- process qualification vs. performance qualification use of ICH Q9 terms (e.g. risk analysis, risk control)

PDA believes many of these comments are valid, because this document will be used as a guide by a diverse section of the industry with varied levels of experience with a varied range of terminology; including many international firms and sites. Clarity and consistency of language will help those companies interpret and meet with the expectations presented in the guidance.

Approach and Assurance for Commercial Distribution

There were several questions and comments on expectations for determining the level of assurance required to initiate commercial product manufacture and release batches for commercial distribution. Related to this issue was the concern that a limited number of developmental batches would not be sufficient to develop a statistically sound rationale for commercial product distribution. The guidance indicates extensive testing on early commercial batches to achieve statistically sound process controls might be required, yet offers no indication of expectation for what constitutes the acceptable level of assurance in order to reduce this level of testing. The guidance was interpreted not to allow risk assessment as a means to reduce the number of samples and level of monitoring on relatively low risk processes and steps.

PDA recommends FDA allows for and encourage the use of risk assessment to determine the level of testing and data required to achieve the acceptable level of assurance needed to release batches for commercial distribution, and ongoing evaluation. To satisfy the concerns of these respondents, the PDA suggests the concept of risk assessment described in Stages 1 and 2 should be applied in Stage 3 and throughout the process and product lifecycle.

The guidance indicates extensive testing on early commercial batches to achieve statistically sound process controls might be required, yet offers no indication of expectation for what constitutes the acceptable level of assurance in order to reduce this level of testing

Viral and Impurity Clearance

Our members expressed objections relative to the expectation of viral and impurity clearance studies performed at small scale under full CGMP conditions. Many of these comments cited inconsistencies with other guidance including ICH Q5A, ICH Q10, and European guideline CPMP/BWP/268/95. There were also requests for clarification on the implication that impurity studies included both biological and small molecule API impurities. Comments contended that these studies are typically performed at small scale laboratory levels under GLP conditions and should not require full CGMP conditions. Performing these studies under full CGMP procedures would be burdensome and fail to add benefit or value.

PDA suggests the recommendation or requirement for execution of small scale level viral and impurity clearance studies under CGMPs should be removed, because it is overly prescriptive, inconsistent with current regulatory guidance, and of limited value when discussed in the context of process validation.

Concurrent Release

Several concerns were raised on the recommendation for stability testing of all concurrently-released batches. PDA feels that a recommendation to conduct additional post-market surveillance of concurrently-released (CR) batches implies an apparently lower confidence threshold for the release of those batches. It should be clear to industry, and consumers that batches released under a CR program have the same level of product quality as batches released after a prospective validation program. Therefore, PDA suggests that the recommendations for enhanced *post*-market analysis be removed.

Scope and Legacy Systems

Scope There were several questions and comments requesting clarification of and changes to the scope of the guidance. These included clarifying whether the guidance covered clinical product supplies, investigational medical products, blood products, in-vitro diagnostic products, and vaccine products. These also included questions related to whether processes such as cleaning, sterilization, sanitization, holding and distribution of commercial products were included in the scope of the guidance. While the committee felt that some of these questions were addressed in the guidance, it was notable that respondents experienced in the field of validation expressed concerns

and required additional clarification. This reflects the potential for confusion regarding the scope of the guideline. PDA recommends that FDA reinforce that the Guidance is intended to be applied to direct commercial product manufacturing processes; for example synthesis and formulation.

Some comments registered concern over the mention of "single source" products and "production output and (product) supply problems" and asked if this indicated the agency expected qualification and validation of systems which do not affect product quality, but otherwise do affect product availability. If this is the case, then it represents a significant departure from current industry practice. PDA believes that the references to assuring product supply should be removed or the guidance should clarify that it does not cover processes which do not affect product quality, but may affect product supply.

Legacy Processes and Systems Clarification was sought regarding the application of this guidance to existing products and processes. The guidance did not appear to address the agency's expectation for these systems and processes; specifically to what extent these systems and processes should be validated with the new approach and to what extent systems previously validated would be "grandfathered". While PDA agrees that companies should utilize the approach presented in this version of the guidance to confirm that systems and processes continue to operate in a validated state, we recommend the guidance clearly indicate that full "revalidation" of existing systems and processes is neither expected nor required in the manner described in the draft revision.

Qualification, Documentation, Organization and Regulatory Impact

Qualification There were several comments on clarification of equipment, utility, and facility qualification expectations and interaction; including expansion of facility and process design qualification/review and commissioning. Significant concerns were expressed regarding the expectation to demonstrate the capability of equipment to maintain operating ranges over anticipated production times, especially where extended processing times are encountered. Such qualification approaches should be risk and engineering based. In addition, there were comments expressing concern over inconsistencies in terminology for segments of facility qualification.

PDA believes the guidance should not make recommendations related to how validation efforts should be named or how the execution team should be organized

PDA believes current industry practices and developing techniques surrounding execution, documentation, and approval activities for commissioning and qualification are appropriate and further regulatory input is not needed.

Documentation and Organization There were several comments requesting clarification of documentation expectations for all stages of process validation, in particular the clarification of qualification plans versus protocols. We also recommend removal of language which prescribes organizational dynamics and personnel activities such as having a variety of disciplines and "project plans" (lines 215–216) and trending production line operator's errors (lines 541–545).

PDA believes the guidance should not make recommendations related to how validation efforts should be named or how the execution team should be organized.

Regulatory Impact There were several comments requesting clarification of regulatory submission, reporting impact, and inspection expectations related to process validation. While PDA understands these issues to be clearly excluded in the document scope, FDA may wish to update related submission guidelines where such discussions are provided.

Summary

The PDA and the committee are pleased to have had the opportunity to develop comments on this document and hope it assists FDA to finalize the guidance. As our large number of comments suggests intense interest in our membership and more than likely the general industry, we feel it will be invaluable for further public discussion in the form of a workshop or other means of shared learning.

PDA would also like to thank the PDA Task Force members that helped with the commenting process. Members include **Tim Ramjit,** Senior Director, Schering Plough; **Kris Evans,** Director, Amgen; **Marc Roache,** Director, Bayer; **Bob Dana,** Senior Vice President, PDA and **Iris Rice,** Executive Coordinator, PDA.

PDA offers its further assistance to explain or provide additional information on the comments or to otherwise assist the FDA in this endeavor. When these have been conducted in the past, there is greater understanding and faster acceptance both by industry and the regulators of new guidance. If FDA wishes to pursue that opportunity, or if there are any other questions, please do not hesitate to contact PDA.

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Quality & Regulatory Snapshot

Health Authority *Special Report*
EMEA Creates International Liaison Officer

Jim Lyda, PDA

In recognition of the increasingly global nature of the pharmaceutical industry and its regulation, the EMEA has appointed an International Liaison Officer whose chief responsibility will be to create a clear strategy for developing the Agency's relationship with international stakeholders. Effective January 1, 2009, the new position was filled by **Emer Cooke,** previously Head of the EMEA Inspections Sector. Emer brings to the position a wealth of international experience from her career in a wide range of scientific and regulatory roles in the pharmaceuticals sector.

Emer Cooke

Head of PDA Europe, **Georg Roessling**, PhD, said, "Emer has been a model of what a regulator can be in today's complex pharmaceutical regulatory environment: a good listener, open to dialog and, in the end, a firm and effective regulator. She understands the need of the industry to understand not only what the regulators are saying, but why they are saying it. PDA has valued her steady hand and open attitude for many years. We look forward to working with Emer in her new and important position."

Cooke shared the following comments with PDA members in late December: "I have immensely enjoyed serving as EMEA's Head of Sector, Inspections. I have especially appreciated the opportunity to Chair the GMP/GDP Inspectors Working Group which includes joint meetings of the member state inspectorates several times per year. The goal of the working group is to harmonize GMP interpretation by the Inspectorates, to 'make Europe work' in the GMP inspection area. This includes hosting the annual 'interested parties' meeting with the Working Group to keep groups such as PDA informed of developments in the GMP area."

In 2003 Cooke instituted joint meetings of GMP inspectors and quality assessors in a move to maximize the synergy between the assessment and inspection activities. She also directed creation of EMEA's process analytical technology (PAT) team and organization of training sessions on PAT and QbD for European inspectors and quality assessors. On the international front, Cooke was one of the EU topic leaders for the harmonized ICH Q9 guidance on Quality Risk Management. Most recently she launched a pilot project for international coordination of API inspections among several European authorities, the U.S. FDA and Australia's Therapeutics Goods Administration (TGA), a project which will remain important in her new position.

"During my time in Inspections, PDA and EMEA worked together to establish the series of PDA/EMEA Joint Conferences, London in 2006 and Budapest in 2008," said Cooke. "Both of these conferences have been a great success allowing both inspectors and industry to discuss the most important GMP issues of the day. I am confident that the third conference, October 13–14 in Berlin will show this activity going from strength-to-strength.

"My new position in EMEA represents a significant challenge to me, particularly in a changing and increasingly global environment. I strongly believe that the future of pharmaceutical regulation must be built on regulators working together internationally. Cooperation, not competition, is the key to more effective international collaboration. We have seen how effective this can be on the European level. I want to see how much we can extend this concept within a wider international framework, in order to better protect public health, save resources, avoid duplication and create more efficient synergies. Organizations with a strong international presence, such as PDA, can be facilitators in moving such cooperation forward."

EMEA International Functions

The EMEA has had a role in international activities since its creation in 1995. Early activities centered on the International Conference on Harmonisation for drugs and vet products (ICH and VICH) processes, certificates of medicinal products and mutual recognition agreements—all conducted in cooperation with the European Commission. From the beginning

there was significant interest from external regulatory authorities in the European medicines system and the EMEA. The entry of new Member States to the EU brought demands on the Agency to prepare them for accession, as has its work with the European Commission on pharmaceutical-related activities in countries including Canada, China, India, Japan, Russia, Switzerland and the United States.

Revision of the EMEA founding regulation in 2004 introduced a more comprehensive recognition of the Agency's international role. This includes the unique relationship with the World Health Organization (WHO) to address public health needs in developing, non-EU countries. Similarly there was increasing need for the Agency to have a role in the conduct of clinical trials in non-EU countries, GMP coordination for starting materials and other topics. The EMEA now receives more requests for visits to and from international regulators than at any time in its history, and is involved in the implementation of confidentiality arrangements with Canada, Japan and the United States.

These developments result in a clear business need for overall coordination of the EMEA's international activities. The international liaison officer is part of the Executive Support Sector of the EMEA which provides secretariat, organizational and policy support to the Executive Director and the Agency's management team. The position will work with Agency colleagues to:

- Establish and implement the EMEA's international strategy
- Establish and implement an annual program of international activities, including the Agency's international visitor program.
- Coordinate planning for European Union candidate and accession countries as they prepare to work with the EMEA
- Work with colleagues on activities relating to third country confidentiality arrangements and implementation plans already in place
- Work with colleagues on new third country (i.e., non-EU) agreements and relationships where there is currently no arrangement in place
- Coordinate the Agency's participation and contribution to international forums such as WHO, International Conference of Drug Regulatory Authorities (ICDRA), etc.

Replacement Head of the Inspections Sector

A recruitment process has been launched for a new Head for EMEA's Inspections Sector. Until a new Head is appointed, interim responsibilities will be shared between **David Cockburn**, acting Head of Sector, GMP and related matters, and **Fergus Sweeney**, acting Head of Sector, GCP and related matters.

2009 PDA Annual Meeting

Annual Meeting *Preview*

Regulatory-Focused AB, IGs and Task Force Gathering at Annual Meeting

While the PDA Annual Meeting is focused on the scientific and technological side of PDA, the Association's regulatory groups will be busy during the meeting.

The Regulatory Affairs and Quality Committee (RAQC), PDA's advisory board in all things regulatory, will hold a strategic planning meeting on Sunday, April 19, 10:00 a.m.–3:00 p.m. The full RAQC will meet on Monday, April 20, at lunchtime for its regular meeting. The leaders of RAQC will also participate in a new Advisory Board Chairs Meeting on Wednesday, April 22 at 8:00 a.m.–9:00 a.m. (see related article, page 8). Advisory board meetings are closed to board members only.

Two regulatory focused interest groups (IG) will meet from 7:30 a.m.–9:00 a.m. on Wednesday. The Inspection Trends/ Regulatory Affairs Interest Group, led by PDA's **Bob Dana**, has invited a speaker from the U.S. FDA to participate and discuss the latest inspection trends

The Quality Systems IG, led by Genentech's **Anders Vinther**, is meeting to discuss two specific topics: 1) Implementation of ICH Q10, with a focus on how Knowledge Management may be defined and used; and 2) Different approaches to controlled printing and where the added value is to this requirement. An FDA speaker is also invited to this IG meeting.

All attendees of the Annual Meeting are welcomed to attend these IG discussions.

Finally, the PDA Phase Appropriate Application of GMPs Task Force is meeting after the final plenary session on Wednesday, April 22 at 12:30 p.m.–2:45 p.m. This meeting is open to Task Force members only, and is intended to further their Technical Report project on the topic.

European GMP – What is Happening? What is on the Horizon?

Annual EMEA Interested Parties Meeting held on November 26, 2008 in London gave insight to upcoming plans

Tesh K. Patel, Astellas Pharma Europe; Stephan Roenninger, F. Hoffmann-La Roche; Jim Lyda, PDA

The Interested Parties Meeting is hosted by the EMEA Inspections Sector once per year in conjunction the GMP/GDP Inspectors Working Group (formerly the 'Ad hoc Inspection Services Working Group').

Attending the meeting were representatives of the inspectorates from each of the 27 EU Member States, 2 accession countries, the 3 European Economic Area countries and a representative of the European Commission. The meeting was chaired by **Emer Cooke**, then, Head of the EMEA Inspections Sector, and attended by **Sabine Atzor**, Pharmaceuticals Unit, Enterprise and Industry DG, European Commission.

A number of industry organizations attended the briefing. PDA was represented by the authors.

[Note: The following is an informal summary of the discussions prepared by the PDA attendees at the conference. While every effort has been made to be accurate, readers should not regard this report as an official record.]

GMP Guidelines Update – presentation by EMEA: An all-encompassing update plan is due for publication in early 2009. Highlights are given below.

Chapters 3 & 5 – In relation to Dedicated Facilities: EMEA is aware of an industry proposal to integrate a "risk-based" approach in the guidelines. There was a request to incorporate the principles in the Veterinary Directives, but EMEA needs to be cognizant of the differences that may apply to animal products, e.g., penicillin sensitivity is only human related and not animal. *Chapter 5*: Improve the guidance on qualifying suppliers and testing of starting materials – EMEA work held pending assessment of the impact of Commission legislation on combating counterfeits.

GMP Annexes: A mistake made on the Commission's website regarding Annex 1 – Sterile Products has been clarified. The revised Annex is effective March 1, 2009, *except* for provisions affecting capping of vials, which have been extended by a year to March 1, 2010. The original text suggested that the extension for capping applied only to "freeze dried" vials. This error has been corrected on current versions of the annex, noting that the extension applies to *capping of all vials.*

Regarding Annex 2 – Biological Products, numerous comments have been incorporated during the revision process following public consultation. EMEA proposes a face-to-face meeting with industry in due course.

COMSTAT (FDA's manufacturer compliance tracking system) is now accessible by EMEA and FDA has access to the EudraGMP database.

Release of Annex 6 – Medicinal Gases is expected in early 2009.

EMEA welcomed the huge response from industry on Annex 11 (and Chapter 4) – Computer systems, but made a plea to avoid duplication of comments numerous times from different organizations. Final release is expected later in 2009. Industry requested a face-to-face meeting before the guidance is finalized, and the EMEA rapporteur (the Irish Medicines Board) will consider the request.

Revisions of Annex 13 – Investigational Medicinal Products (IMP) will take into account the definition of "reconstitution" and the final consultation deadline was extended. A clarified Annex 13 may be released by early 2009.

The consultation phase for Annex 14 – Blood Products: expected to begin in early 2009.

Part II – APIs: QRM principles will be incorporated into Part II per the approach taken for Part I. Release expected by mid-2009.

GMP Related Guidance and Information: Regarding the Reflection Paper on QP Discretion: There will be limited changes for clarification only, and no increased discretions than previously proposed. Release date not confirmed.

The format for Batch Certificate for IMPs has been agreed upon; Eudralex volume 10 will be updated.

Guidance in the form of Q&A was issued October 2008 on QP Declarations for "Atypical Actives," and addresses atypical actives where the QP cannot completely confirm manufacture in line with GMP.

Site Master Files (SMFs) have been used for many years and are useful to inspectors when conducting audits and preparing reports. How SMF's can be officially incorporated into European system will be considered once a PIC/S revision is complete.

About the Authors

Stephan Roenninger is the Global Quality Manager for Global Quality at F. Hoffmann-La Roche and the co-chair of PDA's Regulatory Affairs & Quality Committee.

Tesh K. Patel is Senior Director for Quality Assurance (Europe) at Astellas Pharma Europe Ltd. and a member of the planning committee for the 2009 PDA/EMEA conference, which is scheduled for October 13–14, in Berlin.

Jim Lyda is the Director of Regulatory Affairs Europe for PDA.

Integration of Q9 principles into GMP is almost completed. A strategy to incorporate Q10 into the GMP Guide is under consideration. A Q&A guidance addressing the interpretation of Q8/Q9/Q10 is being developed be a working group set up within ICH (ICH-Q IWG).

All existing EU MRAs will be expanded to cover GMP for APIs.

EMEA reported that the EudraGMP database provides for the first time a Europe-wide overview on authorized manufacturing sites and inspected sites subject to common European legislation. References to EudraGMP can be provided in new applications instead of paper documents. The issuing of GMP certificates to a manufacturer is a new requirement from October 2005. The QP declaration is still required for API compliance to GMPs, even if EudraGMP certification of the manufacturer from an authority is available. Access to EudraGMP by the general public may be available in early 2009, facilitating transparency.

Representatives from the European Fine Chemicals Group (EFCG)/CEFIC noted that the European Pharmaceutical Excipients Certification Project has launched globally and includes excipients audits conducted by ISO-oriented auditors and based on quality systems, not based on compliance with GMP. Some discussion on this program: Quality Systems apply to Excipient manufacture already, be it through Part II GMP, ISO standards, PQG/IPEC Guidelines, etc. Certification could assist in recognizing "robustness" at the supplier since it difficult to gain access to excipient suppliers; and when there is access, it is unclear which standard to audit against. There is concerns about proportionality of GMP standards during audits (e.g., are validation studies same as API?) and that audits at each supplier will be resource intensive.

Supply chain security was discussed by representatives from PDA and ISPE. A summary of the Pharmaceutical Ingredient Supply Chain conference recently held in the United States was presented by a PDA representative. No single solution to guarantee security of supply chain exists.

- "Quick Hits" can be implemented – e.g., photo library for imports; drums, labels, seals, CoAs
- Heparin issue – Was there a "signal" when the price increased just before the incident, could we have been proactive in spotting the potential threat?
- E-Pedigree – Can we learn from other industries that have practiced traceability for number of years e.g., Vehicle Identification Number (VIN) for automobiles, tracking parcels via FedEx, etc.
- "Sunset" terms for not referenced, possibly bogus DMFs. If DMF is not accessed for a period of time, than that DMF could be deleted!

The EMEA is taking the subject very seriously and welcomes opportunity to work together with industry. EMEA commented:

- Not to "reinvent the wheel" as existing documents (e.g., WHO) should be evaluated for managing the supply chain before writing any new guidance.
- Security of supply chain vs. economy—EMEA would be interested to know how industry is balancing the two.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) presented a discussion of variability in GMP implementation and interpretation. The purpose of the presentation was to share examples of inconsistencies of interpretation and action between authorities, showing the need to ensure appropriate and consistent interpretation. Interested parties were asked to provide more details in time for discussion at a meeting of GMP/GDP IWG before the next interested parties meeting. In discussion it was noted that the Rapid Alert System is under review by EMEA for improvement. A workshop is being planned for users of the Rapid Alert System. A transparent system for Centrally Authorised Products (CAP) and their recalls is also under consideration, though the decision to recall is a "national" one, even for CAPs.

EMEA also talked about the Pilot Project to Rationalize International GMP Inspection Activities. The initiative involves the sharing of information between the U.S. FDA and EMEA regarding compliance and inspections. COMSTAT (FDA's manufacturer compliance tracking system) is now accessible by EMEA and FDA has access to the EudraGMP database. Other activities include rapid alert exchanges between FDA and EMEA; mutual invitations to meetings e.g., heparin issue coordination and an inspectors working group; staff exchanges (many successful ones); pilot joint inspections on APIs and finished products between the United States and the European Union, and more. The objective is more efficient use of resources for greater supervision of third country manufacturers, resulting in higher safety levels for patients. Publication of an "outline paper" and the rules of engagement for shared inspections explain this further. Volunteers from industry who would like to host a joint FDA/EU inspection are welcome!

PDA highlighted recently published Technical Reports. These reports provide technical guidance on topics of importance to the membership. The technical reports are not standards, but guidance is written from an "industrial" perspective that is not necessarily same as "industry" perspective. The reports are consensus based; authors are scientific experts supported by a task force. Regulator input is frequently requested during review, and there is institutional review and approval within PDA. Examples include reports on Cold Chain Shipping, Quality Risk Management for Aseptic Processing and Viral Filtration.

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 http://www.pda.org/regulatorynews.

North America

U.S. FDA Extends Comment Period on Process Validation Draft Guidance

The U.S. FDA has re-opened the comment period for the draft guidance entitled *Process Validation: General Principles and Practices,* which was published in November. The comment period originally closed on January 20, but because of the end-of-year holidays, the Agency has extended it until March 16. This will allow interested persons to review the draft guidance and submit comments.

Independent Food Agency Gains Momentum Over Peanuts

A recent spate of illnesses and deaths caused by contaminated peanut products might force "Foods" out of the U.S. FDA.

Similar to a bill originally introduced in 2007, the Food Safety Modernization Act was recently introduced by Congresswoman Rosa L. DeLauro (D-Conn.). Under the proposal, FDA would be split into an agency responsible for food safety (the Food Safety Administration) and another responsible for regulation of drugs and devices.

This move would create an agency solely focused on protecting the public through better regulation of the food supply. The Act would establish a farm-to-fork system for protecting foods that are currently regulated by FDA, which has jurisdiction over 80 percent of the food supply. It would also serve to fix systemic problems in the food safety system by modernizing food safety laws and establishing a separate Food Safety Administration headed by an expert in food safety within the Department of Health and Human Services, according to DeLauro.

In addition to the structural change, the bill would update food laws and would change the focus to preventing disease-causing contamination. It would utilize a modern approach to food safety by requiring food producers to: control health hazards in their operations; meet federal standards for preventing or removing contaminants and pathogens from food; and be subject to regular inspections by federal officials based on the risk profile of the products they produce. When prevention fails, the Food Safety Administrator would have sufficient enforcement authority, including authority to order recalls, seize unsafe food before it enters the market, and impose fines on companies that refuse to abide by the law.

The peanut butter incident follows a series of 2008 salmonella-related recalls in 2008, the most well-known involving spinach.

U.S. FDA Issues Q&A Document on USP <467>

The U.S. FDA's Office of Generic Drugs issued a question and answer document on residual solvents in ANDAs in late 2008 in response to the Coalition for Rational Implementation of USP General Chapter <467> queries for clarification on USP chapter <467>.

The document is comprised of twelve questions that relate to the recently revised chapter and further amplify the interpretation of FDA on <467>.

Europe

Comments Sought on Revisions to Annex 14

The EMEA has published a notice about public consultation revisions of GMP Annex 14. The *Manufacture of Medicinal Products Derived from Human Blood or Plasma* has been revised in the light of Directive 2002/98/EC, and relevant implementing directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

These directives apply to the collection and testing of blood for all uses, including the manufacture of medicinal products.

Comments should be sent to entr-gmp@ec.europa.eu and GMP@emea.europa.eu by July 31, 2009.

ANMV and Israel's Pharmaceutical Inspectorate Joins PIC/S

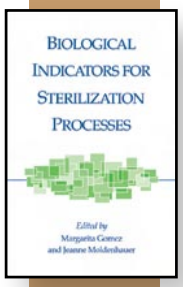
France's Agency for Veterinary Medicinal Products (ANMV) and Israel's Pharaceutical Inspectorate became the 35th and 36th Pharmaceutical Inspection Co-operation Scheme (PIC/S) Participating Authorities respectively.

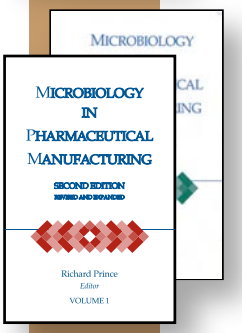
ANMV is the second Veterinary Agency to join PIC/S, and ISCP is the first competent Authority from the Middle East to join.

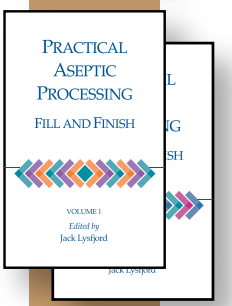
France and Israel joined PIC/S January 1, 2009.

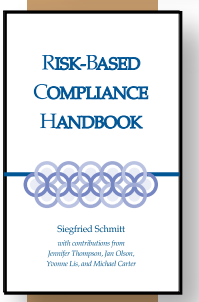
RECOMMENDED READING

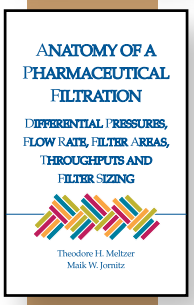
From the PDA Bookstore











Biological Indicators for Sterilization Processes (Item No. 17268)
Edited by Margarita Gomez, PhD and Jeanne Moldenhauer

Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded, Volume I and II (Item No. 17280)
Edited by Richard Prince, PhD

Practical Aseptic Processing: Fill and Finish (Item No. 17283)
Edited by Jack Lysfjord

Risk-Based Compliance Handbook (Item No. 17281)
By Siegfried Schmitt, PhD

Anatomy of a Pharmaceutical Filtration: Differential Pressures, Flow Rate, Filter Areas, Throughputs and Filter Sizing (Item No. 17261)
By Theodore H. Meltzer, PhD and Maik W. Jornitz

Save 10% when you purchase any PDA-DHI Book(s) of $200 or more at the PDA Bookstore booth during the PDA 2009 Annual Meeting. Enter to win a copy of the PDA CD Archive (a $590 value). The PDA Technical Archive will give you easy access to more than 60 years of papers written by highly qualified research scientist in the pharmaceutical/biopharmaceutical industry.

For the latest publications and multimedia training tools please visit the PDA Bookstore Booth and pick up a copy of PDA 2008/2009 Publications Catalog.

www.pda.org/bookstore

Firms Should Select Tools to Implement Annex 13 – PDA Comments

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

29 January 2009

David Cockburn, Inspections Sector, European Medicines Agency
Sabine Atzor, Pharmaceuticals Unit, Enterprise and Industry DG, European Commission

Ref: EU Guidelines to GMP, Medicinal Products for Human and Veterinary Use, Draft Annex 13, Manufacture of Investigational Medicinal Products (11 April 2008)

Dear David and Sabine:

PDA is pleased to have the opportunity to provide comments on the revisions to Annex 13, GMP for Manufacture of Investigational Medicinal Products. Our comments were prepared by a group of member experts in this field after considerable discussion. Our comments are attached in detail in the requested EMEA format.

In general the proposed revisions are acceptable and helpful. We have proposed some changes in order to allow companies to select their own tools for implementation based on their specific pharmaceutical quality systems. There are two areas where revision of the proposed text is important:

1. Storing reference samples of intermediate product can be problematic and goes beyond generally accepted GMPs for commercial products. This could place a significant new burden on companies. We propose to delete the relevant sentence.
2. The revised annex appears to require the storage of reference samples in the EU except under exceptional circumstances. PDA suggests that the actual location of storage need not be prescribed provided that the sponsor and manufacturer ensure the ability to retrieve and deliver these samples expeditiously if needed. Courier services allow for this to be done from any location in the world within a day or two.

If I can be of further assistance, please feel free to contact me, or our Director of Regulatory Affairs, Jim Lyda at: lyda@pda.org.

Yours sincerely,

Georg Roessling, PhD, Senior Vice President, PDA Europe

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NEPDA Starts Innovative Student Chapter Meetings,

Louis T. Zaczkiewicz, GXP Quality Consultants

A new year begins with a new administration and new programs, however mindful to tradition and the legacy already in place. The New England Chapter of the PDA (NEPDA) began its 20th year with an outstanding educational meeting on current trends in visual inspection on January 14 at the Hilton Garden Inn in Burlington, Mass. Over 100 people representing small and large companies throughout New England and beyond came to augment their knowledge of visual inspections through the world-class presentations by **John Shabushnig**, PhD, and **Mike de la Montaigne.** Attendees were treated to complimentary hors d'oeuvres and drinks due to meeting sponsorship by Masy Systems, Eisai Machinery, Genesis Packaging Technology, David Begg Associates and the Seidenader Group. Additionally the New England Student Chapter of the PDA presented a poster on microbial identification.

After an outstanding networking period and dinner, the meeting began with NEPDA President **Jerry Boudreault,** introducing the 2009–2010 NEPDA Board of Directors. **[Editor's Note:** The complete list of 2009-2010 NEPDA Board of Directors appears in the January 2009 *PDA Letter,* page 34.**]** Louis, NEPDA's immediate past president, was also presented with a recognition award on behalf of the NEPDA BoD from Jerry.

Jerry then presented NEPDA's 2009 goals:

1. **Provide Outstanding Development Opportunities**
   - Produce five profitable dinner meetings
   - Hold five efficient business meetings
   - Publish four newsletters
   - Promote member participation at the global level
   - Global/National events
   - Articles/papers/technical reports
   - Task Forces/Advisory Committees
2. **Increase Membership by 10% (approximately 80 people)**
3. **Support New England Student Chapter**
   - Strengthen succession process
   - Initiate monthly meetings
   - Sponsor one student chapter field trip
   - Establish scholarship program

John began the educational portion of the dinner meeting with his presentation "Hot Topics in the Visual Inspection of Injectable Products." Besides his extensive involvement at PDA, John is well-known for his establishment of the PDA's Visual Inspection of the Parenterals Interest Group. He discussed why we inspect, followed by a review of recent regulatory observations in the area of visual inspection with an historical analysis of common themes in these observations. Next, he presented the results of a recent industry benchmarking study with the purpose to better define the current state of visual inspection. This study compares the most recent responses from the 2008 survey with those from past surveys in 1996 and 2003.

Mike followed with his presentation on "Technology Update – Automated Inspection," which entailed looking at new technologies that improve the efficacy of visual inspection of liquids, powders, lyophilized products, glass defects and empty vials. He pointed out that the use of an automated inspection machine is not only important for assurance of final product quality but also for evaluating a process in real time. Many recent advances in automated inspection have come along with the application of light-emitting diode technology (LED).

The program then proceeded into a forum where John and Mike answered application and technical questions for over a half-an-hour. **[Note:** John and Mike's presentations are available at the NEPDA website. Visit www.pdachapters.org/newengland/ and select the link for presentations.**]**

Prior to the educational meeting, NEPDA met with the New England Student Chapter to plan out events and programs. This meeting included **Jerry Boudreault, Jessie Klein**, **Richard Paiva**, **Paul Patev**, **Maurice Perez, Matt Piasecki** and **Louis Zaczkiewicz**. An exciting program was started for students with PDA members at the Middlesex Community College. The meetings will provide students an industry perspective to supplement what the students learn in their courses. For example, a student may learn sterile technique in class to ensure that their actions do not contaminate a

PDA's *Who's Who*

Jerry Boudreault, President, Drug Development Resources and NEPDA Chapter President

Jessie Klein, PhD, Associate Dean, Math and Science, Middlesex Community College and PDA New England Student Chapter Faculty Advisor

Mike de la Montaigne, President, Eisai Machinery

Richard Paiva, Technical Writer, Hyaluron and NEPDA Student Chapter Committee Member

Paul Patev, PhD, Professor, Biotechnology, Middlesex Community College and PDA New England Student Chapter Faculty Advisor

Maurice Perez, Student, Middlesex Community College and PDA New England Student Chapter President-Elect

Matt Piasecki, Student, Middlesex Community College and PDA New England Student Chapter President

John Shabushnig, PhD, Sr. Manager/ Team Leader, Global Quality Operations, Pfizer

Louis Zaczkiewicz, CQE-ASQ, Consultant, GxP Quality and NEPDA Chapter Immediate Past President

Holds Visual Inspections Dinner Meeting

bioreactor or their cultured organism. In industry, however, they learn that sterile technique is one part of a robust sterility assurance program of clean room design, sanitation programs, aseptic gowning practices, environmental monitoring, clean room test and certification, instrument calibrations, training, Standard Operating Procedures, airflow studies, aseptic process simulations, building monitoring systems, component sterilization, qualification and requalifications, trending, etc., and *documentation.*

The sessions will be held at Middlesex Community College in Massachusetts, typically on a weekday from 5 p.m.–6 p.m. We will rely on our experienced PDA membership to volunteer to speak about any topic. The format will follow an open forum in order to minimize the presenter's preparation time and to encourage multiple representatives. The schedule and information will be posted on the NEPDA website. PDA members are encouraged to review the schedule and volunteer in advance to attend by contacting Jerry Boudreault, the NEPDA President, at boudreault@ddres.com.

He pointed out that the use of an automated inspection machine is not only important for assurance of final product quality but also for evaluating a process in real time.

NEPDA encourages you to go to its website, http://pdachapters.org/newengland, where you can learn of upcoming educational meetings, such as the immediate Container-Closure Integrity event in March and the meeting on FDA Inspections in May; business meetings; advertising opportunities for sponsorship and newsletters; policies; contact information and six years of presentations.

Workshop 2008 on Pre-filled Syringes in Japan to be Continued in 2009

Brigitte Reutter-Haerle, Vetter Pharma-Fertigung, PDA Pre-Filled Syringes Interest Group Leader (Europe) and program committee member

At the beginning of November, representatives from the Japanese and European pharmaceutical and biotech industries met in Tokyo for the *Workshop on Pre-Filled Syringes*. The event was held under the theme of *Primary Packaging and Drug Delivery Trends for Injectables,* a day before the Annual Conference of the PDA Japan Chapter. Over 90 experts from Japan and Europe used the opportunity to share information on the requirements and advantages of pre-filled injection systems.

We are delighted at the lively participation in the conference. The program revolved around such questions as approval, safety and quality in pre-filled injection systems.

One highlight was the lecture of **Daikichiro Murakami**, Advisor, Industrial Facilities, Taikisha, and Director of PDA Japan and Co-chair of the event. He discussed the regulatory guidelines for pre-filled syringes in Japan and how they differ from those in Europe and the USA.

Other topics on the agenda were various aspects of aseptic filling under cGMP conditions, the growing demand for patient-friendly solutions, closure systems and the criteria for selecting a suitable system for self-injecting.

It was the third time that the workshop was held in the Japanese capital. The event was organized by the PDA Japan chapter and sponsored by Nuova Ompi, Ypsomed and Vetter Pharma-Fertigung. The preparations were made in close collaboration with PDA Europe.

The great support of our Japanese colleagues made a significant contribution to the success of the meeting. Because of active interest, the PDA Japan and the PDA Europe are already planning to continue the event in 2009.

Annual Meeting Events for New Members, Volunteers

New Member Breakfast–*Space is limited*

Monday, April 20
7:00 a.m. – 8:00 a.m.

Welcome new PDA members! If you joined PDA on or after Sept. 1, 2008, you are invited to kick-start your PDA membership by attending the New Member Breakfast hosted on site at the 2009 PDA Annual Meeting. This is a wonderful opportunity to learn more about PDA and to meet other new members, board members and staff.

Please RSVP by March 19. For more information and to RSVP, please contact **Hassana Howe** at +1 (301) 656-5900 ext. 119 or *howe@pda.org.*

You must be a full conference attendee to attend this event. RSVP is required.

Volunteer Luncheon–*Space is Limited*

Tuesday, April 21
12:45 p.m. – 1:45 p.m.

Take part in a complimentary networking lunch and learn how PDA volunteer opportunities can support your career while contributing to the PDA community and industry. Areas that will be covered include PDA Task Forces, Committees, Advisory Boards, Interest Groups, chapter leadership and publishing opportunities. There are many different levels of involvement.

Please RSVP by March 19. For more information and to RSVP, please contact **Hassana Howe** at +1 (301) 656-5900 ext. 119 or *howe@pda.org.*

You must be a full conference attendee to attend this event. RSVP is required.

Volunteer Spotlight

Melissa J. Smith

Founder and Principal Consultant, MJQuality Solutions, LLC

Education: Masters of Biochemistry, MIT; Bachelor of Science in Chemistry and Bachelor of Science in Nutrition, Syracuse University; MBA with concentration in computer systems, Bentley College; Certificate in Project Management, Boston University; International Regulatory Affairs Program enrollment, Northeastern University.

PDA Join Date: 1989

Areas of PDA Volunteerism: New England PDA (NEPDA) (Newsletter founder, past Secretary, Member-at-Large); Analytical Method Validation Task Force (member); Analytical Method Development Task Force (member)

Interesting Fact about Yourself: One thing that might surprise people is that my first job was as a self-employed caterer at the age of 13, which was pretty successful for a few summers. I enjoyed studying the science of nutrition and food science, and then got into chemistry. Biochemistry after that just made sense. My alter ego would have liked being a chef.

The work on the newsletter and on the Task Forces bring my experiences to a new level and really adds a sense of fulfillment to my day.

Why did you join PDA and start to volunteer? I joined PDA in the early days at Biogen (late 1980's) when the New England chapter was just forming. As the years went on, my involvement with PDA continued. I got involved in volunteering during a conversation with Myron Dittmer, who was then President of NEPDA and has been a friend of mine from the early Biogen days (as is Jerry Boudreault, 2009 President of NEPDA!). I had decided to form my own consulting firm after having done consulting work on and off for a few years-so we happened to be talking and Myron mentioned he always wanted to try to have a newsletter, so I said 'Hey, I'll do it!'. I thought it would be fun, and for those people who know me, I don't like being idle, so designing the newsletter, arranging discussions with potential authors…just blended into my daily activity. From there, it expanded to participating on the NEPDA board for a time as Secretary and also now on the Analytical Method Validation Task Force and the Analytical Method Development Task Force, both activities I really enjoy.

Of your PDA volunteer experiences, which stand out the most? The work on the newsletter and on the Task Forces bring my experiences to a new level and really adds a sense of fulfillment to my day. There is also a defined output so that brings with it satisfaction.

How has volunteering through PDA benefited you professionally? I really enjoy my work on the two Task Forces because I like to participate more as a guide to the discussion and a source of information that may be of help. I enjoy being able to help a process go more smoothly, to help people find solutions and to see if I can help a group be more successful. It has been great talking with other people on the Task Force with their particular experiences and knowledge. I always enjoy the meetings and listening to the group's ideas. PDA has provided me a way to expand my knowledge and skills through the interactions with authors on the newsletter to NEPDA meetings and through the discussions with members of the Task Forces. They provide wonderful forums for discussion.

Which member benefit do you most look forward to? I enjoy having access to the Conference Presentation Archives, being able to participate in the Task Force, and being involved with the local NEPDA chapter as well as global PDA.

Which PDA event/training course is your favorite? The PDA/FDA joint conference is a great venue for finding out current issues, meeting up with other members and having a great time as well.

What would you say to somebody considering PDA membership? Valuable resource. It provides great opportunities for networking at both the global scale and also through your local chapter, and you can use the resources available to advance your knowledge of current topics and cutting-edge technology.

PDA Volunteer Spotlights are available online:
www.pda.org/spotlight

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Scott Anderson, J&J

Murielle Andre, afssaps

Jonathan Anstett, AAIPharma

Jennifer Asleson, Becton Dickinson

Dave Atkinson, Amgen

Karin Austurian, Argenta

Matthew Azuh, Global PharmaDevice Solutions

Jennifer Ball, Ben Venue

Elena Barmanova, Roszdravnadzor

Doug Bauer, Cangene

Joerg Bausback, Roche Diagnostics

Dean Bird, BSI Product Services

Brian Blasquez, Amylin

Holly Bloomfield, GSK

Patricia Bonner, Ben Venue Laboratories

Joseph Boyce, Teva Pharmaceuticals

Douglas Brewster, Genentech

Dawn Brinkman, ThermoFisher

Geri Brousseau, Genentech

M.Taylor Burtis, Tokai Phrmaceuticals

Charles Calderaro, Genentech

Tom Calderwood, Affymax

Kwong-yu Chan, Bayer Healthcare Pharmaceuticals

Jenni Chi, Polypeptide

Jun Chihara, Otsuka Pharmaceutical Factory

Chin-Sung Cho, Chong Kun Dang Pharmaceutical

Miller Cho, Wyeth Pharma

Kelvin Chuu, Abbott

Lawrence Cinque, Merck

Alan Cochran, OneLegacy

Theresa Coker, Gilead Sciences

Marnix Collier, GSK

Kristina Conroy, Teva Pharmaceuticals

Una Cusack, Elan Pharma Int'l

Mohammad Damavandi, Boehringer Ingelheim

William Dawson, Novartis

Janine de Bruyn, AKF University

Manorack de Kok-Somviengxay, Millennium

Adeana Dorsey, BioTechLogic

Dan Dorsey, R&D Partners

Kieran Doyle, Wyeth Biotech

Joerg Dressler, PMT Partikel-Messtechnik

Tracey du Laney, BioAbility

Phil Duncanson, Enzon Pharmaceuticals

Scott Engelhardt, Laureate Pharma

Daniel Eshete, APP Pharmaceutical

Robert Finamore, Q Pharma

Paul Fiorio, Bausch & Lomb

George Firmstone, Sanofi Pasteur

Tom Fitzpatrick, UCB

Alison Floyd, Regado Biosciences

Kenneth Fogle, DSM Pharmaceuticals

Deborah Forrest, Acusphere

Shawn Garcia, Thomas Engineering

Regis Gervier , Sanofi Pasteur

Ameena Gill, Merck

Anita Gondi, Frontage Laboratories

Robert Goodwin, Genzyme Corp.

Antonio Grandon, Universitetssjukhuset

Scott Hackman, Pakoil

Andrinanda Halim, Millennium Pharmaceuticals

Dennis Hall, Banner Pharmacaps

Donald Handley, Bausch & Lomb

James Hanisak, Mallinckrodt Baker

Reed Harris, Genentech

Cate Hass, Sartorius Stedim

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Karrin Hogan, Kelly Scientific Resources

Natasha Howard, Ben Venue Laboratories

Timothy Howard, Commissioning Agents

Janice Ingram, Covidien

Manzoor Iqbal, Emergent BioSolutions

Chiquita Jackson, Eisai

Renee Jansen, UCB

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Clayton Jokerst, Genentech

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Erich Kilchherr, Novartis Pharma

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Marcus Klinkicht, Roche

Martha Kliss, UCB Manufacturing

Leaders to the PDA Community

Thomas Koning, Safety Syringes

Ajoy Koppolu, Merial

Guiyang Li, Amgen

Mary Liebowitz, Vivaldi Biosciences

Barbara Lowe, Genentech

Bin Lu, Vivaldi Bioscience

Michael Lucido, Covidien

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Alexander Macdonald, Pharma Science

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Carlos Porras, Bristol-Myers Squibb

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Vaishali Shukla, Millennium Pharmaceuticals

Susan Sloan, MassBiologics

Justin Smith, Mentor Biologics

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Alexis Stroud, QPharma

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Iris Tavor, Pluristem

Alexey Terekhov, Roszdravnadzor

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Radhakrishna Tirumalai, United States Pharmacopeia

Eric Tofteroo, Immunogen

Ruth Toledo, Amgen

Ergin Uzun, Biogen Idec

Borke Van Belle, Cilag AG

William Veazie, AMAG Pharmaceuticals

Jeramy Viet, University of Iowa

Christopher Vinson, Life Technologies

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Christie Vollmar, Alkermes

Paul Weber, SAVIS

John Weber, Boehringer Ingelheim

Jo Ann Wells, Aastrom Biosciences

Diane Wells, Boston Scientific

Douglas Westlund, SQA Services

Johanna Whelehan, Takeda

Sylvia Wilson, UCB

Andreas Witzel, Eli Lilly

Cherilyn Woodland, Baxter BioScience

Bhushan Yeola, Dr Reddys Laboratories

Lisa Yoest, Helvoet Pharma

Alexander Zaydenberg, Baxter Healthcare

Looking to 2020 at the 2009 PDA/FDA

Washington, D.C. • September 14–16 • www.pda.org/pdafda2009

PDA/FDA Joint Regulatory Conference Co-chairs Martin Van Trieste, Amgen and Rick Friedman, FDA

The 2009 PDA/FDA Regulatory Conference, tilted, *Securing the Future Quality of Medical Products: 2020 Vision*, is designed to look at the future to understand what challenges must be overcome for industry to continue providing safe medications and embrace continuous improvements that will enhance the quality of the products.

Before we can look at the future, however, we must be willing to learn from the past. 2008 was a year full of significant events that will change our industry forever; some of these events were good, some were bad and others were just scary.

On the good side ICH Q10 was finalized, prescribing and promoting a holistic quality system approach to developing, manufacturing and distributing medical products. This change will go a long way to move the industry to embrace a quality system based on continual improvement principles and designing in quality versus the current test and inspect quality system. Many firms are well on their way to a successful implementation of Q10 and are prepared to share their experiences implementing a modern quality system. The quality systems approach, will enable firms to use their change control systems to promptly adapt processes over the life cycle in response to new information.

ICH Q8R also was completed. This document helps industry understand how good process design can be facilitated through well-conceived development studies.

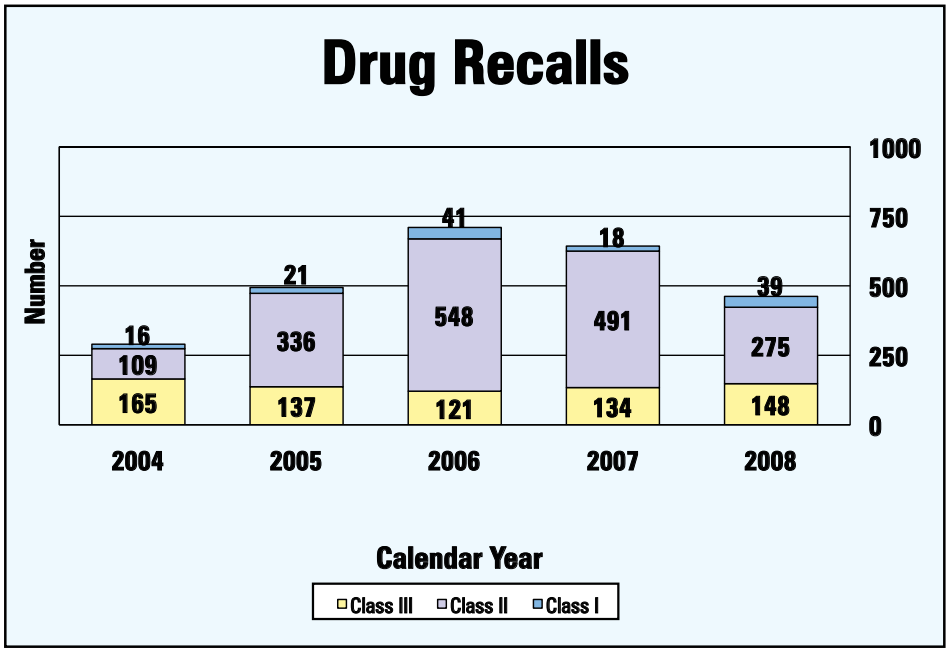
The FDA issued the long awaited draft guidance for process validation and we are eagerly awaiting comments. This guidance addresses the linkage between process development, qualification of the commercial manufacturing process, and maintaining a state of control throughout the life cycle.

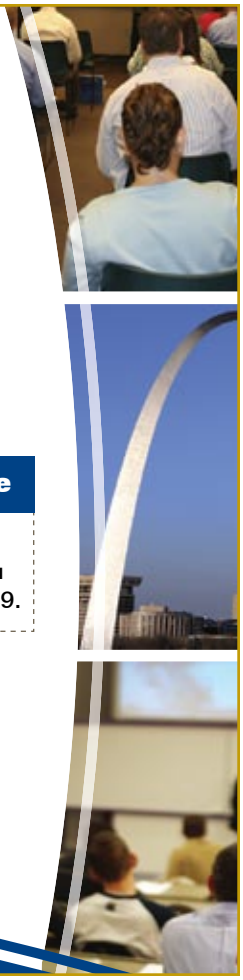
Joint Regulatory Conference

Regarding the latter, the draft guidance seeks to stress the ICH Q10 principle that post-market information gathering promotes maintenance of a stable process by identifying areas in need for continual improvement.

FDA also published the first phase of its revisions to the 21 CFR 211 cGMP Regulations which became effective on Dec. 8, 2008, and finalized its guidance entitled *Current Good Manufacturing Practice for Phase 1 Investigational Drugs* as part of the Agency's Critical Path Initiative.

On the bad side, there were far too many product recalls that were a result of GMP failures. There were Class 1 and Class 2 recalls in 2008. The following table provides the 5-year trend. ➤





Many of these recalls were due to poor raw material quality as well as a lack of supply chain security. The particularly worrisome trend of counterfeiting and illegal substitution has never been more worrisome than this year when the potential for adverse impact on the consumer was illustrated in multiple international incidents.

The real scary issues concern illicit trade cumulating in the criminal adulteration of several raw materials around the world leading to a series injuries and deaths, and a rampant increase in global counterfeiting of pharmaceuticals. Recent highly publicized events have highlighted a weakness in the pharmaceutical supply chain. Significant harm to patients, including death, has been associated with these events. Examples include:

1. Adulterated glycerin with diethylene glycol (antifreeze) used to manufacture cough syrup has led to 67 deaths in Panama and 103 deaths in Haiti (mostly children).
2. Adulterated heparin with hypersulfated chondroitin sulfate was associated with a significant number of deaths in the United States.
3. Adulterated milk with melamine has led to contaminated infant formula causing kidney stones and deaths of infants in China.
4. Adulterated glycerin with diethylene glycol used to manufacture teething gel has led to over 40 infant deaths in Nigeria.
5. The World Health Organization (WHO) estimates that 10% of all medicines around the world are counterfeit. In addition it estimates that up to 30% of medicines sold in developing countries may be counterfeit, and some studies conclude that the percentage may be even higher.

Management of the pharmaceutical supply change has become one of the top public health concerns with respect to consumer safety. The globalization of distribution for both drug components and finished products has introduced many complications that to date have yet to be resolved. Tragic consequences can result from just one unethical player or noncompliant company along the supply chain which introduces counterfeited, adulterated and contaminated materials. Naturally, such incidents lead to a loud and swift reaction from the public, the health authorities and legislators.

Millions of people around the world are treated everyday with the vital medicines that we collectively provide. As pharmaceutical executives, supplier executives, regulators, and members of professional organizations, our ultimate mission is to serve patients. That is what we do. However, the threats to the supply

chain have not only prevented us from supplying drugs to patients, but many individuals have been tragically impacted. In order to achieve this mission, we require secure and reliable supply chains that deliver the right materials at the right quality so that these vital medicines can be trusted by health care practitioners and patients.

This conference will celebrate accomplishments and provide attendees with data, information and tools to fully leverage many of the ideas resulting from the good events. Speakers from the FDA, industry and other diverse sources will provide detailed information and share best practices related to FDA expectations, detailed implementations and case studies.

The conference will also analyze how the 2008 incidents occurred, develop lessons learned, discuss solutions implemented and provide future actions required to assist the industry to be more successful.

This year's 1½ day conference will include three educational tracks that will cover:

- Modern Quality System
- Securing the Supply Chain
- Hot Topics

Many of these recalls were due to poor raw material quality as well as a lack of supply chain security.

There will be four plenary sessions throughout the conference. The Opening Plenary Session, which kicks off the conference, will look at the future to understand how global social-economic factors will influence our industry. Plenary Session Two will demonstrate how management responsibility and effective management review can drive significant quality improvements that also result in productivity gains and lower costs. Plenary Session Three will highlight ICH Q10 and Supply Chain Security. Finally the Closing Plenary will include two FDA Panels; one discussing and answering questions related to center initiatives, and the other panel focusing on compliance objectives.

As you can see, the conference is packed with important topics and information that will be not only useful to conference attendees conducting their duties on a daily basis but to assist them in preparing for the future. So please join us at the 2009 PDA/FDA regulatory meeting and reserve September 14–16 for a unique and exciting learning experience.

2009 PDA Annual Meeting Networking Events: Come Join the Fun!

Las Vegas, Nev • April 19–21 • www.pda.org/annual2009

Make your conference experience a well-rounded one by taking advantage of networking activities that bring you face-to-face with your peers, as well as industry and regulatory leaders. Share ideas, exchange information, make valuable contacts to take home with you—and have fun while doing it!

Sunday, April 19

3rd Annual PDA Golf Tournament at Siena Golf Club

7:30 a.m.–12:30 p.m.

Challenge your colleagues and fellow conference attendees to a round of golf during the *3rd Annual PDA Golf Tournament* at the Siena Golf Club. Renowned throughout Las Vegas for its natural beauty and unprecedented serenity, the course features a wide variety in the routing and pacing of holes to keep all levels of golfers entertained from the opening tee shot to the final tap-in.

Appropriate golf attire is required. Collared shirts and soft spike golf or athletic shoes are required. Denim clothing is prohibited.

$190 per person. Price includes green and cart fees, practice balls, a boxed lunch, transportation and professional tournament coordination.

Fun Run/Walk Event (3K walk and 5K run)

8:00 a.m.–10:30 a.m.

Departure from Red Rock Casino, Resort and Spa at 7:30 a.m.

Join your friends, family and colleagues for a 3K walk and 5K run.

One ticket is included with full conference registration. Additional tickets can be purchased for $40 per person. Transportation will be provided.

Monday, April 20

New Member Breakfast–*Space is limited and RSVP is required*

7:00 a.m.–8:00 a.m.

See article on page 31 for more information. Please RSVP by April 1, 2009. For more information and to RSVP, please contact **Hassana Howe** at +1 (301) 656-5900 ext. 119 or howe@pda.org.

NOTE: You must be a full conference attendee to attend this event. RSVP is required.

Vegas Extravaganza Networking Reception

5:15 p.m.–7:30 p.m.

Your odds are always good at this popular networking event! Enjoy food and drinks as you mingle with colleagues, make valuable business contacts and browse the Exhibit Hall for technologies, trends and products that could be valuable to your company.

One ticket is included with full conference registration. Additional tickets may be purchased for $50.

LE RÊVE at the Wynn Las Vegas Hotel–*Las Vegas Signature Show*

7:00 p.m.–8:30 p.m.

Departure from Red Rock Casino, Resort and Spa at 6:00 p.m.

LE RÊVE offers breathtaking performances in an intimate aqua theater in-the-round.

The show features aerial acrobatics, provocative choreography and artistic athleticism.

The performance will capture your imagination with its outrageous antics and daring feats of strength and agility. Live music and elaborate special effects will immerse you into a world of fantasy, adventure and intrigue. The farthest seat is just 40 feet from the action creating a uniquely intimate and personal experience.

$157 per person. Price includes one admission ticket and transportation to/from the Red Rock Casino, Resort and Spa and the Wynn Las Vegas Hotel.

Monday, April 20 and Tuesday, April 21

Cirque du Soleil Mystère at the Treasure Island Hotel–*Las Vegas Signature Show*

7:00 p.m.–8:30 p.m.

Departure from Red Rock Casino, Resort and Spa at 6:00 p.m.

Mystère is classic Cirque du Soleil, combining the powerful athleticism, high-energy acrobatics and inspiring imagery that has become the company's hallmark. Deemed a theatrical "flower in the desert," Mystère thrills generations of audiences with its exhilarating blend of whimsy, drama and the unimaginable brought to life on stage.

$140 per person. Price includes one admission ticket and transportation to/from Red Rock Casino, Resort and Spa and the Treasure Island Hotel.

Phantom–The Las Vegas Spectacular–Las Vegas Signature Show

7:00 p.m.–8:30 p.m.

Departure from Red Rock Casino, Resort and Spa at 6:00 p.m.

Experience the world's most recognized musical theatre masterpiece, *The Phantom of the Opera,* as you've never seen it before. *Phantom–The Las Vegas Spectacular* is an all-new production of the most influential musical of all time.

By incorporating special effects and enhancements made possible today by modern technology into the timeless music and story of Phantom, new audiences and loyal fans alike will be awed by the all-new Phantom. The unique theatre was designed to create an ongoing sense of anticipation with a layout that literally surrounds the audience in action.

$175 per person. Price includes one admission ticket and transportation to/from Red Rock Casino, Resort and Spa and Venetian Hotel and Casino.

Tuesday, April 21

Volunteer Luncheon–*Space is limited and RSVP is required*

12:45 p.m.–1:45 p.m.

See page 31 for more information.

Please RSVP by April 1, 2009. For more information and to RSVP, please contact **Hassana Howe** at +1 (301) 656-5900 ext. 119 or howe@pda.org.

NOTE: You must be a full conference attendee to attend this event. RSVP is required.

Exhibition and Passport Raffle at the *2009 PDA Annual Meeting*

On Tuesday, April 21, hundreds of today's leading pharmaceutical and biopharmaceutical companies will gather to showcase the emerging technologies, trends, services and products driving the industry. Take advantage of this opportunity to compare the latest innovations, network with company representatives and learn about the future of the industry.

And don't forget to join us in the Exhibit Hall for refreshment breaks, networking receptions and prize drawings.

Exhibitors include industry-leading organizations such as Sartorius Stedim North America, Vetter Pharma-Fertigung, BioScience International, bioMerieux Industry, and many more!

Visit www.pda.org/annual2009 for a complete listing of the *2009 PDA Annual Meeting* exhibitors and sponsors.

Exhibitors at the 2009 PDA Annual Meeting include:

AAIPharma
Acceleration, LLC
Accugenix, Inc.
AdvantaPure, Div. of NewAge Industries, Inc.
AES-Chemunex, Inc
Alcan Packaging
Althea Technologies, Inc.
American Stelmi Corporation
Applied Biosystems
Asahi Kasei Medical America, Inc.,
Aseptic Technologies
Battelle
Bausch+Stroebel Machine Company, Inc.
BD Diagnostics
BD Medical - Pharmaceutical Systems
Berkshire Corporation
Biocorp, Inc.
bioMerieux Industry, Inc.
Bioscience International, Inc.
Biotest Diagnostics Corporation
BioVigilant Systems Inc.
Bosch Packaging Technology
Brightwell Technologies, Inc.
Catalent Pharma Solutions
Celsis Rapid Detection
Charles River
Commissioning Agents, Inc.
Computype, Inc.
Cook Pharmica
David Begg Associates
Drumbeat Dimensions, Inc.
Duoject Medical Systems, Inc.
DuPont Qualicon
Eisai Machinery U.S.A., Inc.
Elan Software Systems
EMD Chemicals (Silver Sponsor)
Environmental Monitoring Technologies
Fluid Imaging Technologies
FP Developments, Inc.
Gavin Pharmaceutical Services
GE Sensing & Inspection Technologies
GEA Pharma Systems
General Physics Corporation
Genesis Packaging Technologies
Gerresheimer AG
Greiner Bio-One
Groninger USA L.L.C.
Helvoet Pharma, Inc.
HRA Research
Hyaluron Contract Manufacturing, Inc.
IMA Edwards
IMA North America, Inc.
International Pharmaceutical Incorporated
IPS (Invensys Process Systems)
Isogen, LLC
JM Hyde Engineering & Consulting
Lancaster Laboratories, Inc.
Laureat Pharma, Inc.
Lighthouse Instruments
Lonza
Mass & Peither AG Gmp-Publishing (Passport Raffle)
Masy Systems, Inc.
Metall + Plastic
Microbiolology International
MICROBIOTEST, Inc.
MIDI, Inc.
Millipore Corporation
MOCON, Inc.
MODA Technology Partners
Molecular Epidemiology, Inc.
Nicos Group, Inc.
Novatek International
Omni International, Inc.
Ompi of America
Optima Group Pharma
Overlook Industries, Inc.
Pace Analytical Life Sciences
Pall Life Sciences
Pharma-Bio Serv, Inc.-US
PharmaSys, Inc.
ProPharma Group
PTI Inspections Systems
Raland Technologies, LLC
Rapid Micro Biosystems
Rap-ID. US
Raven Labs
Regulatory Compliance Associates, Inc.
Remel, Part of Thermo Fisher Scientific
RJ Lee Group, Inc.
Roche Applied Science
Sartorius Stedim North America, Inc. (Bronze Sponsor)
SCHOTT forma vitrum
Seidenader Equipments, Inc.
SGD North America
Sharp Corporation
Skan US, Inc.
Sparta Systems, Inc. (Passport Sponsor)
SQA Services, Inc.
Sterigenics International, Inc.
STERIS Corporation
TRI
Uhlmann VisioTec
Veltek Associates, Inc.
Vetter Pharma-Fertigung GmbH & Co. KG (Gold Sponsor)
West Pharmaceutical Services, Inc.
WILCO AG

PDA Parenteral Drug Association

2010 PDA Annual Meeting

March 15-19, 2010
Gaylord Palms Resort & Convention Center
Orlando, Florida

CALL FOR PAPERS

Dear Colleagues:

Manufacturers and distributors of sterile drug and related products face the challenge of optimal performance and improvement in an unprecedented economic environment. PDA recognizes that this challenge reflects a global need and that is why the Program Planning Committee for the *2010 PDA Annual Meeting* has chosen to emphasize this as the theme of next year's meeting.

The *2010 PDA Annual Meeting* will explore an area of immense importance to our industry – **Manufacturing Excellence**. The manufacturing of quality products is a keystone of our industry. Properly planned and performed process design, development, validation, sourcing, process control, contamination control, testing, handling, product and supply chain security, distribution and manufacturing all have an impact on **Manufacturing Excellence** and the cost of production.

We are seeking presentations on subjects related to **Manufacturing Excellence**. Almost all we do has a link to supporting the manufacturing process and creating an environment of quality and excellence. It is important to note and explore ways to improve yields and efficiency, to do more with fewer resources. Have you or a colleague in the pharmaceutical, biological, medical device or related industry who has been involved in or solved an issue related to **Manufacturing Excellence**? This is your opportunity to promote understanding and learning from collective experiences.

PDA encourages you to submit an abstract for presentation at the *2010 PDA Annual Meeting*, which will be held on March 15-19, 2010, in Orlando, Florida. Abstracts must be noncommercial, describe developments or work and significantly contribute to the body of knowledge relating to pharmaceutical manufacturing, quality management and technology. Industry case studies demonstrating advanced technologies, manufacturing efficiencies or solutions to regulatory compliance issues will receive the highest consideration. Abstracts related to sterile or related product manufacture are preferable, but those addressing other technologies are welcome. All abstracts will be reviewed by the Program Planning Committee for consideration.

Upon the creation of your user profile, you will receive an email confirmation from Oxford Abstract Management System containing submission instructions. Submissions received without full information will not be considered.

Please include the following information with your abstracts:

> Name
> Professional Title
> Full mailing address
> Email address
> Phone number
> 2-3 paragraph abstract, summarizing your topic and the appropriate forum (case study, discussion, traditional, panel, etc.)
> Take-home benefits
> Session objectives
> Rationale

Visit www.pda.org/annual2010 to submit your abstract today!

PDA is seeking presentations of 30 minutes in length, which present novel solutions and practical approaches. The following list is a guide of the suitable topics for papers. It is not exhaustive and any paper which fits the overall topic of the conference is welcome.

DEVELOPMENT SCIENCE

- Advances in Dosage Form Delivery Systems
- Automated Sterilization Technologies
- Contamination Control/Facility Manufacturing Control
- Cell Culture/Line Development
- Application of ICH Q8 and the Q8 Annex to process design and development
- Knowledge and Information Management
- Process Analytical Technologies (PAT)
- Process Modeling and Creation of a Design Space During Product Development

MANUFACTURING/PROCESS SCIENCE

- Aseptic Processing
- Automated Manufacturing Systems
- Barrier/Isolators/RABs
- Blow-Fill-Seal
- Building Management and Control
- CIP/SIP
- Multi-product Manufacturing
- Design/Management of Multi-product Facilities
- Innovative Manufacturing Approaches
- Knowledge and Information Management
- Online In-process Testing (e.g. Container Closure/Filter Integrity, etc.)
- Production Strategies for a Global Market
- Robotics
- Visual Inspections
- Warehouse Control Systems
- Supply chain security

QUALITY SCIENCE

- Application of ICH, Q9, Risk Management to Quality Systems and GMP Compliance
- Compliance Monitoring and Trending
- Data Spreadsheet
- Qualification Case Studies
- Designing Pharmaceutical Quality Systems Across the Product Lifecycle, ICH Q10
- Environmental Monitoring
- Knowledge and Information Management
- LIMS and Lab Management Systems
- Microbiological Methods and Trends
- Quality Management Systems
- Supplier Quality Management
- Systems including Contract Manufacturing
- Tracking and Tracing Systems
- Training and Education Systems
- Validation of Pharmaceutical and Biopharmaceutical Processes

ABSTRACTS MUST BE RECEIVED BY JUNE 30, 2009, FOR CONSIDERATION.

For more information, please contact Wanda Neal, Vice President, Programs and Registration Services at (301) 656-5900, ext. 111 or Jason Brown, Programs Manager at ext 131

Microchips at Meeting, Poker Chips at Casino!

Las Vegas, Nev • April 20–24 • www.pda.org/annual2009

2009 PDA Annual Meeting Planning Committee Member Maurice Phelan, Millipore Corporation

In April 2009, the PDA Annual Meeting will be held at the Redrock Resort, Casino and Spa in Las Vegas. The program planning committee is very busy putting the finishing touches the conference and events which we have planned for you. This years PDA Annual Meeting will take place April 20-24. We believe this meeting has the perfect blend of education, excellence in science and yes, *fun*! This is PDA's "flagship" event and continues to be considered as the year's most valuable networking opportunity. We look forward to seeing you there.

The Program Planning Committee has selected, *The Impact of the Microchip – Application of Modern Technologies in the Development, Manufacture and Testing of Bio/pharmaceuticals* as the theme for our 2009 event. The meeting will be conducted in the traditional format with three parallel conference tracks:

1. Manufacturing Process Science
2. Data Management
3. Quality Science

The microchip has changed our businesses, our careers and most importantly the lives of millions of patients forever. This meeting explores the impact, challenges and opportunities presented by these new technologies. With 21 individual conference sessions and 16 interest group meetings, this event will appeal to the broadest possible audience.

At the opening plenary session on Monday, April 20th The committee is excited to present two keynote addresses. First up will be **Ian Morrison,** Consultant, the internationally known author and futurist. We look forward to Ian's and description and vision of what's to come. In our second keynote presentation we will be "brought back to earth" by **J. David Doleski** and **Nicole Trudel** from the U.S. Food and Drug Administration, CBER, Division of Manufacturing and Product Quality. It has been several years since FDA have delivered the keynote address and the title of their presentation is "Computer Systems Application within a cGMP Environment."

In addition to the formal conference proceedings we have put together an impressive choice of optional and fun events beginning with the PDA Annual Golf Tournament and "Fun Run" on Sunday, April 19th. On Monday April 20th you have a choice of three Las Vegas shows, *Le Rêve*, *Cirque De Soleil – Mystère* or *Phantom – The Las Vegas Spectacular.*

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

We look forward to seeing you in Las Vegas in April.

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

emea

2009 PDA/EMEA Joint Conference

Ensuring Patient Safety through Supply Chain Control and GMP

The 3rd PDA/EMEA Conference covers legislation, guidance and initiatives from the European Commission and EMEA. Three parallel tracks will address: (1) Supply chain quality, (2) Implementation of ICH Q8-9-10, and (3) Manufacturing and GMP. Key topics include:

- The QP: role in outsourcing; responsibilities in light of ICH guidance
- Inspection of importers, pedigree, and management of supply chain
- Risk based inspections - planning and practice by inspectorates
- QbD and Inspections
- Translating design space into CMC section of dossier
- Investigational Medicinal products and GMP Annex 13
- Advanced Medicinal therapies and GMP Annex 2
- Dedicated facilities

And much, much more.....

Based on your requests, we will be allowing extra time for discussions of key issues and to focus on 'real life' and practical experiences. As in previous years, more than 50 inspectors and 400 total delegates will join us for this unique European opportunity. This is the only GMP and Inspections event in Europe with direct support from the EMEA to reach affected stakeholders. As an attendee last year commented, "....more than a conference, more than training, a one-of-a-kind opportunity that can't be missed."

Scientific Planning Committee

Conference co-Chairs: Katrin Nodop, EMEA Inspections Sector; Regine Leo, Inspectorate, Germany; Veronique Davoust, Pfizer

Authorities/Inspectorates: David Cockburn, EMEA Inspections Sector; Vjaceslavs Krauklis, Lativa; Karl-Heinz Menges, Germany; Annie Rietveld, The Netherlands; Ian Thrussell, UK

Industry: Thomas Barthel, Boehringer Ingelheim; Martyn Becker, MB Associates; Anita Derks, F. Hoffmann La-Roche; Liam Murphy, Amgen Ireland; Tesh Patel, Astellas Pharma Europe

13-14 October 2009
Berlin, Germany

Conference, Exhibition: 13-14 October
Training Courses: 15-16 October

See the complete program at:
www.pda.org/europe

Register by 11 Sept 2009 and SAVE!

Preview a TRI Course at PDA's Annual Meeting

Las Vegas, Nev. • April 20–21 • www.pda.org/annual2009

James Wamsley, PDA

I'm sure many of you head to the movie theaters at least a few minutes before showtime to purchase your snacks and grab a good seat. But if you're like me, that's not the only reason you get there early—you're there to see the previews! You actually get to see whether a movie is worth two hours of your time by watching, rather than by guessing how you might like it from just reading a description in the paper, on the internet or through an e-mail. Well, now you have an opportunity to take the same sneak peak into the training courses offered by PDA's Training and Research Institute (TRI).

Last year at PDA's Annual Meeting in Colorado Springs, TRI had a large exhibit booth consisting of a working clean room, a filling line and a seating area for attendees to take a break, rest their feet and watch demonstrations (previews, if you will) of the training we offer at TRI. In total, four training courses were demonstrated in two days.

Each demonstration was focused on a different subject area: gowning, transfer of materials into a controlled environment, aseptic fluid transfer and an airflow visualization (smoke) study in the filling room. Each demonstration drew progressively more viewers that left only standing room available during the final demonstration. As an added benefit for attending these demonstrations, each viewer received a $100 discount coupon for a TRI course, with one lucky raffle winner receiving a free course!

Due to the success in 2008, TRI will once again have a booth at the *2009 PDA Annual Meeting* in Las Vegas. One demonstration will take place during each exhibit hall break. The demonstrations will be short, 10–15 minutes, and informative with a question and answer session with the instructor following the demonstration. Each will preview a course that TRI is offering from May to December 2009. The four courses being previewed are "Contamination Control"; "Rapid Microbiological Methods"; "Developing and Validating a Cleaning and Disinfection Program for Controlled Environments" and "Sterile Filtration in the Biopharmaceutical Industry—Course II." Each of these demonstrations will be presented by the instructor teaching the course.

So, if you've never been to a TRI course (why not?!), or even if you have, stop by and see what our training is all about! Just sit back, enjoy the show and you might even learn something new. And, once again, we will be raffling off a free TRI course to one (or more) lucky attendee(s)!

Bio/Pharma Issues Examined by European Speakers at PDA's Annual Meeting

Emily Hough, PDA

At the *2009 PDA Annual Meeting* industry members from the United States and Europe are coming together to explore some of the most influential factors impacting the current state and future development of the pharmaceutical and biopharmaceutical industry.

Speakers from Europe include PDA's Board member, **Stefan Köhler**, AstraZeneca; **Thomas Virot**, BD; **Martyn Becker**, Martyn Becker and Associates; **Stephan Roenninger**, F. Hoffmann-La Roche and **Norbert Hentschel**, Boehringer Ingelheim Pharma, to name a few.

The speakers mentioned, and others who are not, will present on topics that will examine the systems and tools that can help you and your company maximize efficiency and productivity, while consistently delivering safe, pure and reliable drugs to patients.

Themed casinos provide a flavor of Europe in Vegas!

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Microbiology – It's what we do

- Consistency in quality
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- Assurance in meeting regulatory requirements

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