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PDA Letter

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March 2008

In This Issue…

April 14–18, 2008
Colorado Springs, Colorado

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China Media Coverage Discounts Quality Efforts by Industry, Regulators

Emily Hough, PDA

Last year the United States was inundated with recalls of products made in China, heightening public and government scrutiny over the supplies of finished goods and raw materials as well as the U.S. companies that purchase them. Questions are now being asked about what more the U.S. FDA can and should be doing in ensuring the safety of the products it regulates—pharmaceuticals, foods and medical devices—which are increasingly reliant on raw materials from China.

While most of the highest-profile recalls in 2007 involved pet foods and toys, an Oct. 9 recall of certain toothpastes manufactured in China because of confirmed diethylene glycol (DEG) contamination showed that the highly regulated pharmaceutical industry was not immune from risk. More problems for the industry hit home in February of this year when Baxter International announced the possibility that variations in batches of the active ingredient for its heparin product might be linked to about 350 allergic reactions and 4 deaths. At this time, the company is unsure if the variable actives originated with Changzhou Techpool Pharmaceutical, a Chinese subcontractor of Baxter's U.S.-based supplier in Wisconsin, The Scientific Protein Laboratories. Yet *The Wall Street Journal* (WSJ) recently picked up this story[1] and emphasized the China connection in the lead article on the front page of its "Marketplace" section. Following the initial WSJ article, reports have surfaced that FDA had inspected "the wrong firm" with respect to the heparin product.[2]

As this issue goes to press, more unsettling news has surfaced from China. The WSJ reported on Feb. 28, 2008 that the Chinese State FDA believes the ultimate responsibility for pharmaceutical ingredient quality is that of the purchasers.[3] An accompanying article highlighted FDA's inability to adequately inspect foreign companies, quoting disparaging remarks about the Agency by one U.S. Representative.[4] The article also states that FDA is in need of a massive infusion of resources to address the issue of foreign supplies.

These situations followed U.S. Health and Human Services Secretary **Mike Leavitt's** July 2007 announcement that "U.S. regulatory agencies are concerned about what they see as an insufficient infrastructure across the board in China to assure the safety, quality and effectiveness of many products exported to the United States."

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China's prominence as the world's number one pharmaceutical ingredient supplier has raised public health questions in the top market for finished drugs.

Coming Next Month:
Media Fills and Risk Management

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Register by 3 April 2008 and SAVE!

Editor's Message

With great prescience, the *PDA Letter* Editorial Committee last May recommended the topic "supply chain management" as the theme for this issue. Recent current events have brought the topic front and center not only in the trade press, but also in the mass media—a development that cannot bode well for industry and regulators alike. In this issue of the Letter, we present two reports on parallel efforts to tighten the control of quality in the supply chain. The cover story examines efforts by the U.S. government to work with Chinese authorities to tighten control over API and excipient suppliers in China. The second feature article explores the possibility of official GMPs for certain drug components, the status of consensus industry standards, quality systems and Drug Master Files on the industry side to control the supply chain (p. 16).

The Sci-Tech Discussion Group returns with a give-and-take on testing raw materials. This issue also is the "show issue" for the 2008 Annual Meeting, so be sure to read the articles throughout covering the big event at the Broadmoor in Colorado Springs!

Finally, at the Letter we would like to correct our own supply chain management breakdown. In last month's issue of the Letter, we neglected to give credit on page 40 to Wendy Haines, PhD, Central Carolina Community College for writing "PDASE Student Awards 2007," and on page 50, the email given for Astrid Günther was incorrect. Her correct email is guenther@pda.org.

Visit www.pda.org/pdaletter

At the Letter's new website, you can read selected articles and link to the members-only archive *before* your hard copy arrives in the mail! Also, you can easily submit your comments and have them published as "Letters to the Editor."

Click on the "Authors Wanted" link to learn about upcoming topics and how to submit articles!

Images of the Broadmoor are used with permission

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

PDA Europe
Adalbertstr. 9
16548 Glienicke/Berlin
Germany
Tel: +49 33056 43 6879
Fax: +49 33056 43 6884
Email: petzholdt@pda.org

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

2008 PDA Annual Meeting

April 14-18, 2008
Colorado Springs, Colorado

RECOMMENDED READING

Environmental Monitoring: A Comprehensive Handbook, Volume I, Volume II and Protocol CD (Item no. 17239)
Edited by Jeanne Moldenhauer, PhD

Essential Microbiology for QP Candidates (Item no. 17265)
Edited by Nigel Halls, PhD with appendix by Bruce Vernon

Ethylene Oxide Sterilization: Validation and Routine Operation (Item no. 17276)
By Anne F. Booth

Filtration Handbook Series (Item no. 17262)
Pharmaceutical Filtration: The Management of Organism Removal (Item no. 17235)
By Theodore H. Meltzer, PhD and Maik W. Jornitz

Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded
Volume I and Volume II (Item no. 17280) **– New!**
Edited by Richard Prince, PhD

Winner, 2007 PDA/DHI Distinguished Editor/Author Award
Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics (Item no. 17242)
By Scott Sutton, PhD

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple (Item no. 17219)
By James L. Vesper

Systems Based Inspection for Pharmaceutical Manufacturers (Item no. 17243)
Edited by Jeanne Moldenhauer, PhD

Winner, 2007 PDA/DHI Distinguished Editor/Author Award
Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies (Item no. 17264)
By Stephan O. Krause, PhD

PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment (Item no. 01039)

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Please check the PDA 2008 Annual Meeting final program for authors and signing times.

IPQ: Dealing with Issues, Not Sensationalism

PRESIDENT'S MESSAGE

Bob Myers

Many of us see the mass media reports on drug product supplies and China. While the incidences covered in these articles are legitimate public health concerns, the coverage can be sensationalized and does little in the effort to find solutions.

The last two issues of *International Pharmaceutical Quality*™ (IPQ), on the other hand, provide in-depth reports on these complicated supply chain situations. The November/December issue includes coverage of China's efforts to build up its quality regulatory system in view of the Western model, including tightening its GMP certification standards. And the current issue (January/February) reports on the December 2007 signing of an agreement between the U.S. HHS and the Chinese drug regulatory agency SFDA intending to enhance the safety of drugs, excipients and medical devices exported to the United States from China.

It is situations like these for which IPQ was launched. The goal of IPQ is to advance the global dialogue on regulating drug and biotech product quality in a constructive, balanced and objective way, not the biased, one-sided and sensational way you will find in the mass media. Each bi-monthly report will contain an in-depth analysis of an evolving area of concern.

Initial feedback from PDA members, both in industry and the regulatory authorities, indicates IPQ already is recognized as a leading source of the type of news and information that helps facilitate greater understanding and solutions. We hope all members will benefit from this periodical. In the coming months, look for coverage of dialogue involving extractable and leachables and global regulatory trends.

If you are enjoying IPQ and find it a valuable resource, please tell your colleagues who might not belong to PDA they too can subscribe to IPQ. Anyone who subscribes to *International Pharmaceutical Quality* by March 31, will receive the first three issues free of charge. For more information, go to www.ipqpubs.com.

Lastly, keep sending us your feedback on IPQ and all of your member benefits. Hearing from you helps us tailor our offerings to maximize your member experience.

Cold Chain Management On Wheels

PDA is pleased to announce the formation of a new partnership with the World Health Organization (WHO) to present *Pharmaceutical Cold Chain Management On Wheels* (PCCM on wheels). This training course is aimed at developing critical evaluation and supervisory skills. The course encourages participants to make direct observations at the storage and health facilities which participants will visit while physically travelling down the length of the cold chain. This competency-based training approach offers real life, hands-on observations at a variety of storage and health facilities. **Umit Kartoglu,** PhD, coordinator of WHO Global Training Network on Vaccine Quality (GTN/VQ), designed the course and has teamed with **Rafik Bishara,** PhD, chair of Pharmaceutical Cold Chain Interest Group (PCCIG), to champion this effort. The very first course will be offered in association with **Tip Kurumu** (Medical Society - Turkey) and the Turkish Pharmacists' Association.

This represents a closer cooperation between the two organizations which started in 2006 at the PDA Berlin Cold Chain conference. For details of the course, registration and participation please contact the course director Dr. Kartoglu at kartogluu@who.int

WHO's Umit Kartoglu to speak at PDA's Biennial Training Conference

Dr. Kartoglu will provide an overview of the PCCM On Wheels program at PDA's Biennial Training Conference, May 19–21, in New Orleans. Visit www.pda.org/training2008 for more information.

Umit Kartoglu and Rafik Bishara

Science & Technology *Snapshot*

Annual Meeting Features 14 IG Sessions

Ian Elvins, Vice Chair, PDA 2008 Annual Meeting Committee

I am excited to tell you that the PDA 2008 Annual Meeting will feature fourteen Interest Group sessions. This is the largest number of Interest Groups to ever meet at a PDA Annual Meeting! The following PDA Interest Groups will meet:

- Clinical Trial Materials
- Combination Products
- Facilities and Engineering
- Filtration
- Inspection Trends/Regulatory Affairs
- Lyophilization
- Microbiology/Environmental Monitoring
- Packaging Science
- Pharmaceutical Water Systems
- Pre-filled Syringes—***New Interest Group!***
- Process Validation
- Quality Systems
- Vaccines
- Visual Inspection of Parenterals

These sessions will bring together industry professionals with common interests to network and exchange information that directly impacts pharmaceutical and biopharmaceutical manufacturing. In addition, PDA Interest Group leaders and members will be on hand to provide specialized information on these areas of interest and facilitate group discussions.

PDA Interest Group sessions at the PDA 2008 Annual Meeting are just one highlight of this strong conference program entitled *Science Driven Manufacturing: The Application of New Technologies.* Conference sessions will focus on new grounds of science and technology within a highly regulated manufacturing environment, covering topics such as new aseptic and downstream processing approaches, filling technology advances and implications of upcoming regulations.

Technical Report *Watch*

In Production: *TR scheduled to be included with next available PDA Journal.*

- **TR-44 *Quality Risk Management for Aseptic Processes (BoD)***

The goal of this Technical Report is to address the basic concepts of quality risk management and to introduce a model that may be used as a tool for conducting risk assessment. The Risk Management Task Force established its charter in October of 2005 to establish guidance for the development and implementation of risk management programs intended for aseptic processing facilities and manufacturing operations. The Technical Report will be applicable to biotechnology, pharmaceutical and medical device industries and will educate users on the concepts of Risk Management related to aseptic processing. It provides specific examples using risk management approaches to decision making related to elements of aseptic processing of regulated drug, medical device and biotechnology products.

The Technical Report was posted to an electronic "Online Review Tool" so that expert peers could provide their comments and was submitted to and approved by the PDA Science Advisory Board in November of 2007. After the SBA comments were addressed and the final editing was completed, the Technical Report was submitted to the PDA Board of Directors last month, and is pending approval. The Task Force is chaired by Hal Baseman of Valsource.

Journal *Programs*

Rally Round the Students

Lee Kirsch, Editor, PDA Journal

We were all students once upon a time. Remember how it felt the first time you woke-up in a cold sweat, sure that you had just slept through a really important test, only to realize that you've been out of school for some years? What a relief! Student life: well, it may be out of our minds, but it should not be out of our sight.

For the past few years PDA has taken considerable steps to support students through fellowships grants, travel awards and by offering opportunities to participate in PDA events such as the Annual Graduate Research Symposium hosted at the PDA Annual Meeting. These outreach efforts benefit the student, their mentors and the Association. Ideally, PDA can play a key role as a conduit between the student's current and future life in the pharmaceutical sciences; students can contribute their knowledge, ideas and energy to the PDA community.

The Association's involvement extends beyond its leadership and financial investment and now a critical need exists for the involvement of its members. The participation of the membership in student activities such as the upcoming symposium truly demonstrates the commitment of the organization to its future. And the member's participation is simple: grab a cup of coffee and attend the symposium.

This year's version of The Annual Graduate Research Symposium at the PDA 2008 Annual Meeting will feature five presentations from students aspiring to join the profession. They are:

- **Anshul Gupte, University of Kentucky**
- **Sajal M. Patel, University of Connecticut**
- **Archana Rawat, University of Tennessee**
- **Hari R. Desu, University of Tennessee**
- **Vinayagam Kannan, University of Tennessee**

Your attendance at this year's Annual Graduate Research Symposium is very important. I encourage you to find the opportunity to meet these students afterwards and express an interest in their work and their future plans. This type of interaction is among the most energizing and rewarding for these students, who, unlike lucky you and me, may still wake up in a cold sweat because they really did sleep through that critically-important early-morning examination.

[**Editor's Message:** In the February S&T Snapshot, PDA chapter liaison Henry Kwan highlighted the topics to be presented at the Symposium. See the Feb. *PDA Letter,* page 10.]

In *Print*

To Rotate or What to Rotate—Now that is a Question!

From "Disinfectant Programs" *by Paul Priscott and Yung Dai, a chapter in Volume II of the forthcoming two-volume* Microbiology in Pharmaceutical Manufacturing, Second Edition, *edited by Richard Prince, PhD.*

We have seen few topics that polarize microbiologists quite as much as this one! It has become a regulatory expectation that disinfectant programs in manufacturing facilities will include a rotation of different types of disinfectants. The logic behind this is that use of a single type of disinfectant could lead to a build up of resistant organisms and thereby render the microbial control program ineffective. Unfortunately there appears to be little, if any, empirical evidence that this occurs in actual pharmaceutical practice.

It is true that there have been examples of disinfectants and antiseptics that have been contaminated during manufacture, usually with pseudomonad or coliform organisms, and usually in quaternary ammonium compound formulations. This is now almost non-existent in developed marketplaces with specialized manufacturers. For those less developed markets it is suggested that such products are included in microbiological assessments of incoming raw materials. Notwithstanding this we are not aware of any practical evidence of resistance build-up from using a single disinfectant, except in laboratory-based experiments. It is our belief that it is far more important for disinfectants to be stored properly, used at the manufacturers recommended dilutions and within a validated in-use period once dispensed. We have certainly seen examples of quaternary ammonium products diluted and stored for too long having bacterial contamination and of 70% alcohols (in clean rooms) similarly contaminated with *Bacillus* spp. Further, if a manufacturing environment remains in a state of microbial control (whether in terms of total counts or types of microbes identified), this strongly suggests that the existing disinfection regimen is working and should not be changed.

However, if we accept the reality of a regulatory expectation for disinfectant rotation, how should we put into practice a scientifically-based scheme? First, we believe that there is no imperative that says that one disinfectant must be rotated with another. In other words, if you have a demonstrated effective formulation for your particular manufacturing situation and follow the proper use instructions for the product, this can, and probably should, remain the principal disinfectant for the plant. An alternative product that is equally suitable for the purpose could

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Recent Sci Tech Discussions: Identity Testing

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.

Identity Testing

Some raw materials are stored in silos or other large containers, making precise sampling of lots difficult (in a manner to prevent contamination and cross-contamination). In such a circumstance, assay certification from the vendor should be on file. There should always be some evidence of manufacturer to establish identity, even if it is only a visual examination of containers, examination of labels, and recording of lot numbers from the labels. A supplier's certificate of analysis might be used in lieu of performing other testing, provided that the manufacturer has a system in place to evaluate vendors and establish the reliability of the supplier's test results at appropriate intervals.

From a regulatory point of view, is this approach acceptable?

Respondent 1: Unacceptable. Look at what happened in Panama with the deaths resulting from ethylene glycol instead of glycerin. CoAs accompanied this material through several countries, and none tested—all relying on the paperwork.

Respondent 2: Are you aware of the substitution of diethylene glycol for glycine by Chinese excipient manufacturers? These counterfeit materials entered the distribution system and have been used in Central American countries to manufacture oral suspensions, resulting in multiple deaths. I believe the manufacturer should always be identifiable, full testing conduced on the first batches purchased and acceptance of the material on review of the certificate of analysis and identity testing only after the reliability of the supplier is established.

As for sampling incoming shipments, it would be more representative to sample from the tanker truck or box car than from your tank farm/silo. See www.nytimes.com/2007/05/06/world/americas/06poison.html

Respondent 3: You could get your vendor to supply samples for analysis.

I disagree with, "There should always be some evidence of a manufacturer to establish identity, even if it is only a visual examination of containers, examination of labels, and recording of lot numbers from the labels." This does not establish identity, merely label details. Imagine a tanker of ethylene glycol labeled as propylene glycol. Your approach would "confirm" it is propylene glycol, but an ID test would confirm it is not.

Questioner: Measures should be taken to open, sample and reseal containers in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers or closures [21 CFR 211.84(c)(2)]. In this case, a sampling area for large containers of raw material should be designed.

Respondent 4: I would suggest that more information from you is required to comment (or answer). It's obvious what a silo is (and, in my experience, that would relate to a tank in a "tank farm," which uses time and date of replenishment), but what exactly do you mean by "Large Container"? A 55 gallon drum of liquid, a 55 gallon lever pack, a dozen 100 lb. bags, etc?

Respondent 4: [Respondent 1], but the key here is, [do] the companies shipping and selling have a history with the manufacturer? If not, testing is a must.

Questioner: [Respondent 3], I was thinking this possibility is more economic than to design a sampling area for large containers of raw material, but I don't really know if it is a normal practice? What do you suggest from the inspectors' eyes?

Questioner: [Respondent 4], Large containers for me are, for example, a 55 gallon drum of liquid and bags of 50 kg.

Respondent 5: I believe the test is a must, especially for ID and assay testing. The point of your issue is how to conduct the appropriate sampling.

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then be used on a rotating, occasional additive or substitution basis, say monthly. Of course some microbiologists decide that it is simpler to rotate on an equal basis, often because this is seen as the path of least resistance during a regulatory audit. When choosing the alternate product for the rotation program, it is advisable to select one from a different class of disinfectant, e.g., a quaternary ammonium formulation and a phenolic formulation. However, it has been suggested that two phenolic disinfectants with differing pH made an effective combination that would deter any resistant organism build-up (Connor and Eckman, 1992). For sterile manufacturers at least one of the selected products should be a sporicidal formulation. A good discussion of the subject was made by Sutton (2005).

Recent Sci Tech Discussions: Identity Testing, continued from page 12

If you stored you incoming raw material in a silo, you should provide some sampling points in the silo, e.g., on the bottom, top and middle of the silo. To prevent the incoming material from mixing with the previous lot, you should have at least two silos. So, every time you receive new incoming material, you can place it in one empty and clean silo.

For the large container (I assume the large container came from your vendor together with the material), you may use some sampling device to help, e.g., sampling stick.

Respondent 3: If you are using a reputable supplier (preferably)—a manufacturer with a suitable vendor approval program—I see no issues with the supplier taking the samples and supplying them with the bulk goods.

The sampling plan is set by your company, and the vendor approval process should give you confidence it is being adhered to. I see no difficulty from an inspection viewpoint; although, I would be interested in the opinions of those "stateside," regarding FDA's viewpoint.

I have used this with suppliers of packaging components (labels and leaflets), suppliers of sugar in 1 ton bags/tankers, etc., with no EU issues.

PDA Interest Groups & Leaders

PDA Interest Groups are divided into five sections by subject matter. This aligns them for improved effectiveness, supports increased synergies and provides the opportunity for Interest Group members to play a more active role in Task Forces. The five sections are Quality Systems and Regulatory Affairs, Laboratory and Microbiological Sciences, Pharmaceutical Development, Biotechnological Sciences and Manufacturing Sciences. PDA's goal is for each group to have co-leaders from the three major regions in which the Association is active: Asia, Europe and North America. Any PDA member can join one or more Interest Group by updating their member profile (www.pda.org/volunteer). Please go to www.pda.org/interestgroups for more information.

SECTION TITLE

Biopharmaceutical Sciences	Laboratory and Microbiological Sciences	Manufacturing Sciences	Pharmaceutical Development	Quality Systems and Regulatory Affairs

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RELATED IGS AND GROUP LEADERS

Biotechnology
Group Leader (USA):
Jill A. Myers, PhD
BioPro Consulting
Email: jmyers@bioproconsulting.com
Group Leader (EUR):
Hannelore Willkommen, PhD
Reg. Affairs & Biological Safety Consulting
Email: Hannelore.Willkommen@gmx.de

Lyophilization
Group Leader (USA):
Edward H. Trappler
Lyophilization Technology
Email: etrappler@lyo-t.com
Group Leader (EUR):
Harald Stahl, PhD
Niro Pharma Systems
Email: hstahl@niro-pharma-systems.com

Vaccines
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Frank S. Kohn, PhD
FSK Associates Inc.
Email: fsk@iowatelecom.net

Microbiology/ Environmental Monitoring
Group Leader (USA):
Jeanne E. Moldenhauer, PhD
Excellent Pharma Consulting
Email: jeannemoldenhauer@yahoo.com

Pharmaceutical Cold Chain
Group Leader (USA):
Rafik H. Bishara, PhD
Email: rafikbishara2@yahoo.com

Visual Inspection of Parenterals
Group Leader (USA):
John G. Shabushnig, PhD
Pfizer Inc.
Email: john.g.shabushnig@pfizer.com
Group Leader (EUR):
Markus Lankers, PhD
Rap.ID GmbH
Email: markus.lankers@rap-id.com

Facilities and Engineering
Group Leader (USA):
Christopher J. Smalley, PhD
Wyeth Pharma
Email: smallec2@lwyeth.com
Group Leader (EUR):
Philippe Gomez
Sartorius SA
Email: Philippe.gomez@sartorius.com

Filtration
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Pharmaceutical Water Systems
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Theodore H. Meltzer, PhD
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Prefilled Syringes
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Brigitte Reutter-Haerle
Vetter Pharma-Fertigung GmbH & Co KG
Email: brigitte.reutter-haerle@vetter-pharma.com

Sterile Processing
Group Leader (USA):
Richard M. Johnson
Email: rmj_quality@yahoo.com

Clinical Trial Materials
Group Leader (USA):
Vince L. Mathews
Eli Lilly & Co.
Email: vlm@lilly.com

Combination Products
Group Leader (USA):
Michael A. Gross, PhD
Chimera Consulting
Email: michaelgross.chimera@gmail.com

Nanotechnology
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D F Chowdhury
Aphton BioPharma
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Wyeth Pharmaceuticals
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Are GMPs on the Horizon for Pharmaceutical Suppliers?

Walter Morris, PDA

The challenges facing industry and regulators with respect to controlling the complicated, global supply chain was summarized neatly during an exchange between **Martin Van Trieste,** VP, Quality, Amgen, and **Kim Trautman,** Consumer Safety Officer, CDRH, U.S. FDA, at the PDA/FDA co-sponsored conference on Quality Systems last November. During an extensive discussion over quality audits, Van Trieste drew Trautman's attention to the difficulties companies endure when monitoring the quality of their suppliers. He pointed to glass vendors as an example: "They will tell you they are not a regulated industry, and there is no regulatory hammer to make them move forward. And glass is made the same way today that it was made 100 years ago. We have not been successful as an industry in driving those suppliers to the next level [of quality]. What is the Agency thinking right now? Because I do see this as a major problem."

When it comes to active pharmaceutical ingredients, regulators in Japan, the United States and Europe, as well as a host of other nations, began tightening GMP controls in the 1990's to better ensure the quality of supplies. Their various efforts culminated in the International Conference on Harmonisation (ICH) quality guideline Q7A, GMPs for APIs. As a result, GMP oversight of APIs is not the sole responsibility of finished product companies; the weight of regulatory inspection and enforcement action is helping to raise quality worldwide, although problems—mostly related to criminal activity—still exist.

But what about other product components critical to quality, such as excipients, glass for sterile products or delivery systems for inhalation products? Can industry police its suppliers to the extent necessary to ensure product safety and quality? Will continued problems like diethlyne glycol (DEG) contamination in glycerin supplies force regulators worldwide to issue new GMP regulations for excipients? If GMPs are issued for excipients only a decade after they were issued for APIs, does it follow that other critical components will be subject to official GMPs in the future?

Already, two independent initiatives are underway to establish official GMPs for pharmaceutical excipients, one driven by a directive of the European Commission and the other by the International Pharmaceutical Excipient Council (IPEC), which operates in Europe, the United States and Japan. For aerosol component supplies, unofficial industry GMP guides are already available, though there is no apparent effort to make them official at this time.

Already, two independent initiatives are underway to establish official GMPs for pharmaceutical excipients

European Commission Considers Excipient GMPs

In 2004, the European Commission amended 2001/83/EC on medicinal products for human use. Amended Article 46(f) established that marketing authorization holders are required to use as starting materials only active substances fabricated *in accordance with the detailed guidelines on GMP for starting materials.* The amendment also states: *This point shall also be applicable to certain excipients, the list of which as well as the specific conditions of application shall be established by a Directive adopted by the Commission in accordance with the procedure referred to in Article 121(2).*

The latter portion of the amendment refers to the "Comitology Procedure." At the 2008 PDA/EMEA Joint Conference in Budapest, Hungary, the European Commission's **Sabine Atzor,** Administrator Pharmaceuticals, Pharmaceutical Unit, Enterprise and Industry Directorate-General, defined comitology as a task for the Commission to establish a directive with an advisory committee of the member states. If there is disagreement regarding the directive, the European Parliament and Council become involved to produce further legislation.

The Commission launched a public consultation process in 2004 to explore possible approaches to a directive for excipients. "As you can imagine," Atzor said, "we received a variety of proposals both from regulators and from industry." Commentators advocated a range of solutions, from little support for new legislation to extensive lists of excipients that should be covered in future directives. In between those two extremes were proposals to follow a risk-based approach to the regulation of excipients.

Based on the feedback, the Commission chose the risk-based approach, and used the lists of excipients submitted during consultation to devise categories of excipients based on risk. The following categories of excipients were chosen:

1. Excipients prepared from materials derived from a TSE relevant animal species (excluding lactose)
2. Excipients derived from human/animal material with a potential for viral contamination risk
3. Excipients claimed to be sterile (or sold as sterile) and used without further sterilization
4. Excipients with the claim "endotoxin or pyrogen controlled"
5. Propylene glycol
6. Glycerol ➤

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The Commission also sought to determine the current status of the use of quality guidelines, quality system requirements, GMPs, ISO standards, etc., with respect to excipients. Working with various industry organizations, a questionnaire was distributed to various excipient suppliers and users.

The Commission drafted a GMP conditions for the manufacture of excipients, which could serve as the basis for a future GMP directive. This document closely resembled the Commission's current GMP, but included a chapter specific on the obligations of the holder of the manufacturing/import authorization.

The public consultation period took place from March to July 2007.

The Commission asked participants in the consultation to consider five disparate policy options:

1. Legislation based on the draft GMP principles for certain excipients
2. Guidelines based on existing industry GMPs, such as those previously prepared by IPEC
3. Identification of "certain excipients" to be subject to GMP by applying risk management tools
4. Self-regulation by industry for applying GMP principles based on risk
5. Status quo

The Commission contracted Europe Economics to evaluate the data. The firm issued its final report, *Excipients Impact Assessment Report—Final,* on Dec. 19, 2007. The Impact Assessment concludes that *there have been no reported cases of fatalities in the EU/EEA as a result of faulty excipients.* In addition, it can be seen that the estimated cost of any of the policy options significantly exceeds the potential benefits.

Finally, the report states, *The European Commission's IA guidelines require that the status quo be considered as a serious option, and in the present case (despite some support from established excipient manufacturers for increased regulation) this is supported by the information reviewed in this report.*

Official Excipient GMPs Supported by Industry Groups

A footnote to this conclusion explains that formal excipient GMPs have *been on the cards for quite some time, but the plans have drawn a mixed response from industry.* The European Fine Chemicals Group (EFCG), the footnote states, issued a position paper in September 2007 *fully backing the plans to enforce GMP regulations on excipient manufacturers.*

EFCG's position paper defines three categories of excipients based on risk: common excipients, specific excipients and novel excipients.

The Impact Assessment concludes that there have been no reported cases of fatalities in the EU/EEA as a result of faulty excipients.

"Common Excipients" is defined as *widely used pharmaceutically inactive substances which are appropriately evaluated for safety using available standards and intentionally included in a drug delivery system.* For these, EFCG proposes the establishment of GMP requirements based on the amended U.S. Pharmacopeia Chapter <1078>, "Good Manufacturing Practices of Bulk Pharmaceutical Excipients," which combines GMP principles found in guides for excipients by most notably the World Health Organization and IPEC-Pharmaceutical Quality Group (PQG).

In supporting *a concerted, legal European standard for* common excipients, EFCG calls for the following practices to be enforceable:

1. The formal release of every batch based on validated or compendial methods
2. Close monitoring of suppliers and manufacturing processes
3. Assurance of the traceability and execution of comprehensive change control agreements along the entire supply chain
4. Assurance of hygienic excipients manufacture
5. Minimization of known quality risks of excipients

Lastly, EFCG advocates the sharing of *appropriate stability data and comprehensive and appropriate product information* with excipient users for the purposes of finished product registration.

"Specific excipients" is defined by EFCG as *pharmaceutically inactive substances which are associated with an increased risk potential and, therefore, require an elevated degree of safety management.* EFCG defines "novel excipients" as new chemical entities, excipients with novel use and all novel biological excipients. For both categories, EFCG endorses proposed European Commission Directive 2001/83.

IPEC also advocates creation of formal GMPs. As reported in the January-February 2008 edition of *International Pharmaceutical Quality,* IPEC's interaction with the FDA Center for Drug Evaluation and Research Pharmaceutical Ingredient Safety Task Force has led to the idea of an ICH guideline on excipient GMPs as a companion to Q7A. **Arthur Falk,** PhD, head of IPEC's International Pharmaceutical Excipients Auditing organization, confirmed the group's support for ICH action at an FDA ICH planning meeting last year, as long as they are appropriately differentiated from API GMPs.

At the February PDA/EMEA Joint Conference, **Janeen Skutnik,** Director/TL Regulatory Monitoring, Pfizer Global Manufacturing, reviewed differences between excipients and APIs that should be accounted for in any GMPs (see table on this page). Her review of the scope of excipient supplies sheds

light on the enormity of the challenge facing the European Commission with its directive and other health authorities mulling the possibility of official excipient GMPs.

For one, she noted, there is no single excipient industry. Instead, excipients derive from a "diverse collection of materials from many origins," with over 1200 in use in marketed pharmaceutical products (excluding those used for colors and flavors). Of those, 30% have official pharmacopeial monographs. Suppliers of excipients include manufacturers of chemicals, foods and petroleum, as well as quarries.

"There are a variety of sourcing issues such as very remote primary sources and massive extended distribution chains," she explained. "And if you follow any of the situations such as the Haiti glycerin, such as the pet food issue that happened in the United States, a lot of these issues are stemming from that supply chain and a lack of knowledge and understanding—as well as some of the criminal acts that occurred—that really prevent us as pharmaceutical manufacturers from always knowing and understanding the full story." She continued, "Contact with the original manufacturer is sometimes very difficult and in some cases it is nonexistent. If you are talking about a mined material, there is no manufacturer for something you extract from a mine."

Excipients are typically evaluated for safety, but are not approved by the authorities in the United States, Europe or elsewhere. "We don't submit applications to approve the use of an excipient," Skutnik said, but "we actually add them to our formulations to serve several roles: processing aids, actually protecting supporting or enhancing stability, bioavailability and a lot of cases patient acceptability to allow the formulation to be delivered to the patient. They serve a role in product identification. And actually now they are even being looked at to help in the area of counterfeits with regard to our medicines in terms of physical markers, and really enhancing any other attribute of the overall safety or effectiveness of our drug products."

GMPs and quality expectations for excipients must balance a fine line in areas like purity, Skutnik said. Should expectations go too far, as Van Trieste alluded to in the case of glass manufacturers, many excipient manufacturers can opt to stop supplying drug companies because the volume of business is too small.

"Unlike APIs, excipients are not usually manufactured specifically for us. Historically we have had a lot of challenges in working in the pharmaceutical industry when various standards come out, whether they are pharmacopeial standards, whether they are expectations from regulators, in working with suppliers because we are a very small percentage of their market." Skutnik pointed to cellulose derived excipients where the total cellulose market is 240 million tons annually, but the pharmaceutical portion is merely 50,000 tons or .02%.

When it comes to purity, drug manufacturers and regulators must understand the difference between excipients and APIs. Acknowledging that not everyone might agree with her, Skutnik stated that inactive substances will have inactive impurities.

"One thing we have seen as a challenge over the years, and I can say this on behalf of IPEC," she said, "is we have a lot of pharmaceutical companies who are asking excipient manufacturers to eliminate all impurities in their materials. Now for people who have experience in formulation…what we

Appropriate GMPs for Excipients

At the February PDA/EMEA Joint Conference, Janeen Skutnik, Director/TL Regulatory Monitoring, Pfizer Global Manufacturing, reviewed differences between excipients and APIs that should be accounted for in any GMPs. The following table from her slides demonstrates expected GMP requirements for finished products (column 1) and the proposed corresponding requirement for excipients (column 2).

API GMP (EU)	Excipients GMP
• Responsibilities of the Quality Unit can not be delegated	• Responsibilities can be delegated with appropriate controls
• Release of Raw Materials by the Quality Unit	• Procedures for Raw Material approval and release
• Detailed & specific documentation requirements	• Requirements to suit products & manufacture
• Full label reconciliation required	• Procedures for control & destruction of excess
• DQ / IQ / OQ / PQ	• Commissioning
• Full 3 batch validation programs	• Demonstrate consistent operation by capability studies or similar
• Full cleaning validation studies	• Design & justify cleaning methods
• Detailed requirements to establish & monitor impurity profiles	• Identify & set limits for impurities
• Full stability programs (3 lots & 1 per year)	• Historical data or evaluation program

call impurities from a pharmaceutical perspective are really essential minor components. If you remove or over purify those excipients, that material will no longer work in a formulation. So it is something that we need to be very careful with because we are going to end up with products that we cannot actually use or sell or in some case you might not even be able to compress the tablet."

Aerosol Component GMPs

The IPEC/PQG guide for excipients is not the only industry GMP guide available for pharmaceutical suppliers. The International Phamaceutical Aerosol Consortium (IPAC-RS) published a GMP guide for orally inhaled and nasal drug product (OINDP) components in 2006.

The Consortium, comprised of inhalation and nasal drug product manufacturers, reached out to component suppliers to develop the guide. Participants represented the following companies: Valois, Rexam, Boehringer Ingelheim, Pfizer, Abbott, 3M, Teva, Novartis, Sanofi Aventis, Novo Nordisk and West Pharmaceutical Services.

The guideline meets the growing need for better control of OINDP components as pharmaceutical manufacturers implement quality by design (QbD). According to the Consortium, component quality significantly impacts quality of finished OINDPs and CMC tests. Particularly important aspects are change control and extractables. IPAC moved forward with its document in the absence of a suitable alternative.

The working group that developed the guideline operated under the following two premises:

1. Quality practices vary widely between component suppliers
2. OINDP pharmaceutical manufacturers each have different expectations and audit component suppliers using different standards

IPAC touts the guideline's benefits as giving regulators more confidence in OINDP container closure systems and device components; improving relations between suppliers and drug manufacturers; reducing supply chain "events"; facilitating consistent, high quality components; setting clear understanding of expectations; and improving quality systems.

Components covered by the document include pressurized meter dose inhalers (metal and plastic) and multi/single dose and refillable dry powder inhalers. The FDA and the European authorities already specify regulations and guidances that cover such products. However, the regulators focus solely on the device/component/formulation nexus produced by pharma, not the suppliers providing various critical components like metering valves, gaskets, nebulizers, pumps, etc.

The push for strong quality management systems has opened FDA's eyes to problems with the DMF system.

The IPAC guide fills the regulatory gap, and is a tool to help companies work with suppliers up and down the supply chain to improve quality. The document incorporates IPAC's own guidelines, ISO 9001: 2000 and the PQG PS 9000:2001. IPAC purports that the document is in alignment with the U.S. pharmaceutical GMPs.

IPAC states that the voluntary use of the guideline has been strong, and unlike the excipient groups, does not envision advocating for official GMPs. The Consortium is considering working with ISO to have the OINDP component GMP guideline incorporated into ISO 15378:2006, Primary Packaging Materials for Medicinal Products. In addition, IPAC is investigating working with ASTM to convert the guideline into a standard.

FDA Expects QMS to Cover Supply Chain

In the United States, the FDA is under pressure to do more to ensure the quality of active ingredients. Taking on the challenge of regulating other component types, no matter how critical, is one the FDA cannot absorb under current resource constraints. As such, the Agency has been pushing for pharmaceutical firms to adopt strong quality systems and to use such systems to tighten controls over their disparate suppliers.

In addition, FDA is taking a hard look at the Drug Master File (DMF) system. DMFs are used by drug companies and suppliers to provide important information to FDA that they choose not to share with their customers. The Agency does not approve DMFs and only reviews them upon reference in a drug marketing application. Currently, 22,000 DMFs are filed with FDA, and the Agency reports about half have either never been reviewed or have not been reviewed in the last 10–20 years.

The push for strong quality management systems has opened FDA's eyes to problems with the DMF system. For instance, DMFs complicate control of supplier and component quality and can thwart QbD efforts. The current DMF process is not conducive to a holistic approach to quality.

As such, FDA is reaching out to industry to modernize DMFs. The desired state for DMF activities, according to the Agency, would see vendors and drug manufacturers depend more on quality systems than the DMF, use quality agreements to support product quality efforts, and better identify and manage confidential/proprietary information.

While FDA recognizes that DMFs cannot be entirely removed from the process, it wants to see them used for only the most critical quality information. Even still, FDA wants to know from DMF holders, what information is included in the master files that pharmaceutical companies do not need.

GMPs Not Likely in Near Future for Non-API Components

The Excipients Impact Assessment Report in Europe does not necessarily mean the European Union will forego legislation for the application of GMPs to certain excipients. In concluding her remarks at the PDA/EMEA Joint Conference, European Commission's Atzor noted that excipients could be discussed in a communication paper on the future of pharmaceuticals, which is expected to publish in 2008. While there is "no big motivation" to move forward with the 2004 legislation as a result of the consultation, she noted that the EC is "currently reflecting on what the best options and solutions will be for the future."

Pfizer's Skutnik noted there is "a lot going on" in terms of excipient GMPs, and she stressed the need for a global solution.

"For most places around the world," she said, "there currently are no regulations with regard to excipients, just as there weren't many, many years ago for APIs….It is not the case where we have only excipients coming from China for U.S. products or excipients coming from Europe for the African market. We are using the same excipients, so we need to make sure we create solutions that really address the situation and the markets we are currently using."

The likelihood of a regulatory GMP oversight of other drug components is even more remote.

Responding to the glass scenario presented by Amgen's Van Trieste at the PDA/FDA QS workshop, FDA's Trautman acknowledged the problem facing drug and biopharmaceutical companies. It is a "huge issue" for the medical device industry as well, she said.

FDA has weighed its options when it comes to tightening control over the supply chain. The bottom line is, however, the Agency does not have the authority to regulate many supply types. "And ultimately," Trautman asserted, "we feel it is not our job. You as the finished product manufacturers have the responsibility."

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China Media Coverage Discounts Quality Efforts by Industry, Regulators, continued from cover

Five months later in December, members of the Bush Administration traveled to China for a third Cabinet-level meeting of the U.S. China Strategic Economic Dialogue with the aim of targeting drugs, medical devices, food items and farming feed. As a result of the meetings, two Memorandum of Agreement (MoA) were reached on medical product and food product safety. The MoA on the Safety of Drugs and Medical Devices expresses the understanding that there are "mutual benefits of protecting public health through improved cooperation…with regard to monitoring and regulating the safety of drugs and medical devices." The signatories to the MoA are the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China.

The purpose of the agreement is to establish methods of cooperation between the U.S. and China that will provide the FDA with additional information about products exported from China to the U.S., provide SFDA with increased sharing of information about products exported from the United States to China, and encourage further regulatory cooperation between the parties regarding drug and medical device regulation.

According to the U.S. Department of Commerce, the "[SFDA] will provide the FDA information regarding the certification status of medical devices, finished drug products, active pharmaceutical ingredients and excipients against SFDA standards. The two sides will begin implementation by focusing on a list of designated export products SFDA must certify and trace to a registered producer, and on a list of products for export from the United States for which HHS/FDA will share with SFDA open-source information."

To enhance the safety of products sold in the United States, Chinese authorities implemented two programs, both subject to an audit by the HHS. The first requires exporters to the United States to register with SFDA and agree to annual inspections to ensure their goods meet U.S. standards. The SFDA will notify HHS of companies that fail inspection and why; the SFDA uses a system that traces products from the source of production manufacture to the point of exportation.

The General Principles in the Memorandum of Agreement on the Safety of Drugs and Medical Devices:

A. The Parties shall engage in regulatory cooperation regarding the export of Drugs, Excipients, and Medical Devices from the customs territory of China to the United States and Drugs, Excipients and Medical Devices produced in the United States and exported to the customs territory of China as set out in Article VI and as further defined in Work Plans to be agreed upon by the Parties

B. The Parties shall engage in information-sharing to improve their mutual understanding of, and to gain great confidence in, each Party's regulatory system as set out in Article V and as further defined in Work Plans to be agreed upon by the Parties. As specified in Article V, each Party shall share relevant information with the other Party, including on relevant laws, regulations, areas of jurisdiction and public health and safety

C. The Parties shall engage in regulatory cooperation regarding improving the authenticity, quality, safety, and effectiveness of Drugs, Excipients, and Medical Devices as set out in Articles IV and VI and as further defined in Work Plans to be agreed upon by the Parties

D. The Parties shall commit to annual meetings between senior Agency leaders to discuss and evaluate progress under this agreement, among other things

Second, the new certification requirements will ensure products exported from China to the United States meet U.S. standards. Once SFDA confirms a shipment meets HHS requirements, it issues a certificate that carries a unique identifying number, which it in turn files.

Also in the agreement, each party will notify the other within 48 hours of the emergence of significant risks to public health related to product safety, recalls and other situations. HHS can request a timely investigation regarding any covered product if there is reason to believe it could pose a health or safety risk.

Leavitt said in a statement that information sharing is a critical aspect of the agreements. "Chinese authorities have pledged to provide timely notification to U.S. regulators under a wide range of circumstances, including the failure of a facility to meet inspection requirements and the suspension or revocation of a manufacturer's certification status. Inspectors from HHS' Food and Drug Administration will also gain broader access to Chinese production facilities and on an expedited basis."

The agreements are important, Leavitt continued, because "the United States has a good system to assure the safety of imports today, but it is not adequate for the future. This year alone, [the U.S.] will import $2 trillion worth of goods into this country from 825,000 importers, through more than 300 points of entry. Also, analysts expect that volume of trade to continue to grow sharply. To keep up with the pace of global commerce, we need a fundamental shift, from trying to catch unsafe products as they come in, to building quality and safety into products before they reach our borders."

Trade with China is Growing, Important

According to various sources, including *The Wall Street Journal,* China has emerged in recent years as the world's largest supplier of APIs.[5] In 2005, China had $4.4 billion, or 14% of the world's $31 billion market for APIs.

Besides its economic importance, the political importance of trade with China is always evident. According to the Congressional Research Service Report for Congress, *China's Trade with the United States and the World,* updated on Jan. 4, 2007, "allowing trade with China to develop, is part of the overall U.S. strategy of engagement with the People's Republic of China. The rationale behind engagement is that working with China through economic, diplomatic, informational and military interchanges helps the United States to achieve important national security goals such as preventing nuclear proliferation, defeating global terrorism, defusing regional conflicts, fostering global economic growth and championing aspirations for human dignity."

The U.S. is China's largest overseas market and second largest source of foreign direct investment on a cumulative basis. In 2004, China replaced Germany and the United Kingdom to become the fourth largest market for U.S. goods and remains the fastest growing major U.S. export market.

Evolving Regulatory System

China is establishing regulatory programs that more closely resemble the West, and is reaching out for assistance. Over the last year, there have been a series of bilateral meetings between the U.S. and Chinese health departments to focus on the safety of Chinese exports and the possibilities for more cooperation, information exchange and the establishment of stronger regulations and enforcement infrastructure in China, according to the November/December issue of *International Pharmaceutical Quality* (IPQ).

The upcoming *PDA/FDA Co-Sponsored Conference Series on Quality Systems* in Beijing and Shanghai is further evidence of China's openness to reform. The conferences will provide information regarding global regulatory expectations for the design, management and inspection of modern quality systems. They will also focus on the challenges faced by virtual, small and large companies in developing and implementing robust quality systems. Application to drug substance and drug product—including biotechnology facilities—will be presented.

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FDA Cannot Police All Markets

Transforming and modernizing the Chinese system is key, because the FDA cannot provide adequate policing worldwide. Commissioner of Food and Drugs, Andrew C. von Eschenbach, MD in testimony to the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations on Nov. 1, 2007, said "FDA performs over 200 foreign drug manufacturing inspections per year. Exercising FDA's regulatory authority abroad can be difficult." FDA has reported that China only received 4% of foreign inspections in FY 2007, which is out of line with the country's status as world's largest API supplier.

The situation will only compound itself as Chinese manufacturers move steadfastly into the finished dosage realm. In 2007, FDA approved the first generic drug from China—the AIDS treatment nevirapine. According to sources like *The Wall Street Journal,* this is just the tip of the iceberg.[6]

In May 2007, as reported in the January/February 2008 issue of the IPQ, CDER's office of compliance established a Pharmaceutical Ingredient Safety Task Force to recommend measures industry can take to anticipate and prevent problems with raw material supplies. IPQ also outlines other Agency activities to bolster its foreign inspection program, including IT modernization. The Bush Administration's 2009 budget proposes additional personal for FDA, but it is unclear whether Congress will approve the funding which will derive from increased user fees.

Time will tell if these regulatory patches will improve the situation. One thing is for certain, a change is needed to prevent more health incidents and further unwanted attention on the industry and the FDA.

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Quality & Regulatory Snapshot

A Glimpse Into the PDA Regulatory Comments Process

Bob Dana, PDA

To be or not to be: that is the question. Famous lines penned by William Shakespeare. How do they apply to PDA and this months Quality and Regulatory Snapshot? Good question.

At PDA, the question is more properly stated as "to comment or not to comment." Have you ever wondered how PDA decides when commenting on regulatory proposals is appropriate and when it isn't? This month, PDA commented on three such regulatory proposals: ICH Annex 2 and Annex 3 to Q4B and the FDA's proposed changes to the drug GMPs. How did these comments get developed, reviewed and approved?

PDA staff review public information sites, such as the *U.S. Federal Register* and European sites on a daily basis to learn of new regulatory proposals. When a notice of the availability of such proposals is published, our Regulatory Affairs and Quality Committee (RAQC) is asked to provide recommendations as to whether PDA should offer comments on the proposal. Depending on the individual proposal, our Biotechnology Advisory Board (BioAB) and/or our Science Advisory Board (SAB) are also asked to weigh in with their recommendation. As this is being written, our RAQC and the Advisory Boards are considering whether PDA should comment on a draft guidance published by FDA entitled *Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products.*

If the RAQC and Advisory Board members recommend commenting, they are asked to provide the names of persons who might be willing to serve on the task force which will develop the draft PDA comments. In addition, we maintain a data base of members who have expressed an interest in volunteering and we routinely use that list to help populate the task forces.

Task forces generally number between eight and twelve members, and include a cross section of members with varied and appropriate technical and regulatory expertise. Once the task force has been constituted and a leader selected, the real work (fun?) begins. Time frames for the preparation of regulatory comments include fixed deadlines and, at least in the United States, tend to be relatively short. The process of developing comments and getting them approved generally involves a brief period of intense activity. Task forces typically do their work using teleconferences and are asked to have draft comments completed and ready for consideration four to six weeks before the deadline for submission to the regulatory agency. This timing means they generally have less than a month to do their work.

Once the draft comments are complete and submitted to PDA staff (generally to me), they undergo a series of reviews. A preliminary screening takes place to ensure the positions put forth by the task force are consistent with PDA policies and historical perspectives and that the tone of the comments is positive and constructive. Generally, this is not a problem, but we do try to be sensitive to how our comments might be perceived. As a child, I always heard from my parents that "it's not what you say, it's how you say it," and I still remember some of the lessons I learned when I forgot that advice.

The next step is to formally send the comments to the RAQC and if necessary, the appropriate advisory board(s). Members of these groups are asked to review the draft comments and

decide to either approve, approve with comment, approve with mandatory revision or disapprove them. Changes recommended in members' ballots are reviewed with the task force and PDA staff, and as necessary, the draft comments are edited. When final approvals are received from RAQC and the advisory board(s), the comments and a cover letter suitable for transmitting them to the regulatory agency are submitted to PDA's Board of Directors for their review and disposition. Assuming the Board approves the comments, PDA President **Bob Myers** signs the cover letter and the comments are then submitted to the regulatory agency. A copy of the comments and the cover letter are placed in the Quality and Regulatory section of the PDA website, and the cover letter is reproduced in the next issue of the *PDA Letter.*

So that's the process. It ensures the positions advocated by PDA reflect those of a wide cross section of our members. Most of the time, it goes pretty smoothly. Of course, there are times when the decision to comment or not can be controversial and sometimes there can be some lengthy discussions about the content of the comments themselves. Still, at the end of the day, PDA prides itself on preparation of scientifically sound comments on regulatory proposals, focused on issues which have the potential to significantly impact the regulatory arena for years to come. It's just another example of PDA connecting people, science and regulation.

If this sounds like something you'd like to participate in, please send in a volunteer form to **Hasanna Howe** at howe@pda.org or **Iris Rice** at rice@pda.org, and we'll your name into our volunteer database. Then you too can have the opportunity to help shape the future of the pharmaceutical industry.

And don't forget—we welcome your input, feedback and suggestions on the Quality and Regulatory Snapshot at any time. Just submit them to snapshot@pda.org.

2008 North America Event Calendar

Please visit www.pda.org for the most up-to-date event, lodging and registration information.

Conferences

March 11–14, 2008
2008 PDA Pharmaceutical Cold Chain Conference and Training Course
(Conference, Course and Exhibition)
Bethesda, Maryland

April 14–18, 2008
PDA 2008 Annual Meeting
(Conference, Courses and Exhibitions)
Colorado Springs, Colorado

April 16–17, 2008
Quality Requirements for Phase 0/1 Pharmaceutical Development Studies—A PDA Workshop
(Immediately following the PDA 2008 Annual Meeting)
Colorado Springs, Colorado

May 13–16, 2008
PDA Risk Management and Aseptic Processing Conference and Training Course
(Conference and Course)
Bethesda, Maryland

May 19–23, 2008
2008 PDA Biennial Training Conference
(Conference, Courses and Exhibition)
New Orleans, Louisiana

June 12-13, 2008
Current Best Practices in Biotech Manufacturing
(Conference and Exhibition)
Northern California

June 26–27, 2008
Technical Report No.1, 2007 Revision
Montreal, Canada

September 8–12, 2008
2008 PDA/FDA Joint Regulatory Conference
(Conference, Courses and Exhibition)
Washington, D.C.

October 6–7, 2008
The Universe of Pre-filled Syringes & Injection Devices
(Conference and Exhibition)
San Diego, California

October 20–22, 2008
PDA's 3rd Annual Global Conference on Pharmaceutical Microbiology
(Conference, Courses and Exhibition)
Chicago, Illinois

Training

Lab and Lecture events are held at PDA TRI, Bethesda, Maryland unless otherwise indicated.

Lab Courses

March 17–20, 2008
Downstream Processing: Separation, Purification and Virus Removal

March 26–28, 2008
Pharmaceutical Water System Microbiology

May 19–21, 2008
Cleaning Validation

June 4–6, 2008
Developing a Moist Heat Sterilization Program within FDA Requirements

June 9–13, 2008
Pharmaceutical and Biopharmaceutical Microbiology 101

August 4–8, 2008
Rapid Microbiological Methods

October 2–3, 2008
Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

Lecture Courses

May 13–14, 2008
Elements of Risk Management

June 11–13, 2008
Environmental Monitoring Database and Trending Technologies

Course Series

June 2–4, 2008
Raleigh Training Course Series
Raleigh, North Carolina

October 21–23, 2008
New Brunswick Training Course Series
New Brunswick, New Jersey

Chapters

March 12, 2008
New England
Dinner Meeting and Tour of Massachusetts Biologics Laboratory

March 25, 2008
Metro Chapter
3rd Annual PDA Metro Chapter Day Symposium

March 26, 2008
Capital Area Chapter
Preparing for the Pre-Approval Inspection (PAI): What to do BEFORE the Investigator Arrives

April 3, 2008
New England
Business and Organizing Committee Meeting

June 13, 2008
Southeast Chapter
Eighth Annual PDA Southeast Chapter Golf Social

August 13, 2008
New England
Business and Organizing Committee Meeting

September 17, 2008
New England
Facility tour and Glass Defects Meeting

October 8, 2008
New England
Business and Organizing Committee Meeting

November 12, 2008
New England
Facility tour and Cleaning Validation

December 10, 2008
New England
Business and Organizing Committee Meeting

Web Seminars

April 3, 2008
Building Quality Into Your Commissioning and Validation While Reducing Cost and Time to Market
Online

May 8, 2008
Qualifying Operatiors in their Jobs
Online

May 22, 2008
Responding to FDA-483's

Europe/Asia-Pacific Event Calendar

Please visit www.pda.org for the most up-to-date event, lodging and registration information.

Europe

April 1–2, 2008
2008 PDA Compendial Forum
In cooperation with:
The European Pharmacopeia,
The Japanese Pharmacopeia and
The United States Pharmacopeia
(Conference and Exhibition)
Frankfurt, Germany
Training Course: March 31, 2008

June 3–5, 2008
2008 PDA Virus and TSE Safety Forum
In cooperation with Paul-Ehrlich-Institut, FDA and European Health Authorities
(Conference and Exhibition)
Berlin, Germany

June 24–25, 2008
2008 PDA/EBE Biopharmaceutical Development and Manufacturing Meeting Global Challenges in Europe
(Conference and Exhibition)
Dublin, Ireland
Training Courses: June 26–27, 2008

September 23–24, 2008
2008 Pharmaceutical Freeze Drying Technology
(Conference and Exhibition)
Brussels/Wavre, Belgium
Training Course: September 25, 2008

October 7–8, 2008
2008 PDA Conference on Quality by Design
(Conference and Exhibition)
Frankfurt, Germany
Training Course: October 9–10, 2008

October 14–15, 2008
2008 PDA Visual Inspection Forum
(Conference and Exhibition)
Berlin, Germany
Training Courses: October 16–17, 2008

November 4–5, 2008
Pharmaceutical Cold Chain Management
(Conference and Exhibition)
Berlin, Germany
Training Courses: November 6–7, 2008

Asia-Pacific

April 21–22, 2008
PDA/FDA Co-sponsored Conference Series on Quality Systems
Beijing, China

April 24–25, 2008
PDA/FDA Co-sponsored Conference Series on Quality Systems
Shanghai, China

November 11–12, 2008
Japan Chapter
PDA Japan Annual Meeting

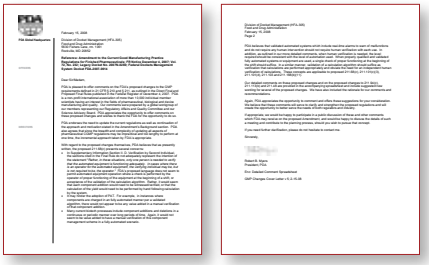
Chapters

April 22–23, 2008
Japan Chapter
API GMP committee symposium

November 11–12, 2008
Japan Chapter
PDA Japan Chapter Annual Meeting

PDA's Comments Endorse Incremental GMP Revisions

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



February 15, 2008

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Reference: Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals; FR Notice December 4, 2007; Vol. 72, No. 232; Legacy Docket No. 2007N-0280; Federal Dockets Management System Docket FDA-2007-0614

Dear Sir/Madam,

PDA is pleased to offer comments on the FDA's proposed changes to the GMP requirements defined in 21 CFR § 210 and § 211, as outlined in the Direct Final and Proposed Final Rules published in the Federal Register of December 4, 2007. PDA is a non-profit international 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 global workgroup of our members representing our Regulatory Affairs and Quality Committee and our Science Advisory Board. PDA appreciates the opportunity to offer comments on these proposed changes and wishes to thank the FDA for the opportunity to do so.

PDA endorses the need to update the current regulations as well as continuation of the approach and motivation stated in the Amendment's Background section. PDA also agrees that since the breadth and complexity of updating all aspects of pharmaceutical CGMP regulations may be impractical and too lengthy to perform at one time, the incremental approach taken by FDA is appropriate.

With regard to the proposed changes themselves, PDA believes that as presently written, the proposed 211.68(c) presents several concerns:

In Supplementary Information Section II. D. Verification by Second Individual, the sections cited in the Final Rule do not adequately represent the intention of the statement "Rather, in these situations, only one person is needed to verify that the automated equipment is functioning adequately. In cases where there is an operator for the automated equipment, the verifying individual may be, but is not required to be, the operator." FDA's proposed language does not seem to permit automated equipment operation where a check is performed by the operator of proper functioning of the equipment at the beginning of a shift, or acceptance of the validation of the calculation algorithm. Rather, it would seem that each component addition would need to be witnessed/verified, or that the calculation of the yield would need to be performed by hand following calculation by the system.

It may hinder the adoption of PAT. For example, in instances where components are charged in an fully automated manner per a validated algorithm, there would not appear to be any value added in a manual verification of that component addition.

Many current biotech processes include component additions and deletions in a continuous or periodic manner over long periods of time. Again, it would not seem to be value added to have a manual verification of this component management scheme in a fully automated scenario.

PDA believes that validated automated systems which include real-time alarms to warn of malfunctions and do not require any human intervention should not require human verification with each use. In addition, as outlined in our more detailed comments, when human verification is needed, the level required should be consistent with the level of automation used. When properly qualified and validated fully automated systems or equipment are used, a single check of proper functioning at the beginning of the shift should suffice. In a similar manner, validation of a calculation algorithm should suffice as verification that calculations are performed appropriately and obviate the need for an independent human verification of calculations. These concepts are applicable to proposed 211.68(c), 211.101(c)(3), 211.101(d), 211.103 and 211.188(b)(11).

Our detailed comments on these proposed changes and on the proposed changes to 211.94(c), 211.113(b) and 211.48 are provided in the accompanying spreadsheet and include suggested new wording for several of the proposed changes. We have also included the rationale for our comments and recommendations.

Again, PDA appreciates the opportunity to comment and offers these suggestions for your consideration. We believe that these comments will serve to clarify and strengthen the proposed regulations and will create the opportunity to better serve the needs of both regulators and industry.

If appropriate, we would be happy to participate in a public discussion of these and other comments which FDA may receive on the proposed Amendment, and would be happy to discuss the details of such a meeting and contribute to the planning process, should you wish to pursue that concept.

If you need further clarification, please do not hesitate to contact me.

Sincerely,

Robert B. Myers
President, PDA

2008 PDA/FDA Joint Regulatory Conference

Harmonization, Implementation, and Modernization: Achieving a Future Vision

September 8-12, 2008
Washington, D.C.

Conference	September 8-10
Exhibition	September 8-9
Courses	September 11-12

www.pda.org/pdafda2008

The US Food and Drug Administration (FDA) announced the Good Manufacturing Practices (GMPs) for the 21st Century initiative in 2002, giving the industry its first glimpse of the future of regulatory oversight for pharmaceutical production. The intent of the original initiative was to offer the industry the necessary tools to provide more post-approval flexibility, making continual improvement less of a regulatory burden, and to promote better self-regulation to improve regulatory compliance status.

In the five years that have passed since the announcement, regulatory health authorities and industry have partnered by harmonizing requirements and implementing new systems for assuring and maintaining pharmaceutical quality. The 2008 PDA/FDA Joint Regulatory Conference will provide examples of how these new approaches have been successfully implemented. In addition, the conference will examine what is working well and where the industry and regulatory health authorities still need to work to achieve modernized quality systems.

PDA is also offering an exhibition during the conference. The PDA Training and Research Institute (PDA TRI) will host courses immediately following the conference to complement what you learn at the meeting.

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.

Europe

EMEA Anticipates Revising Chapter 5 of GMP Guide by end of '08 or early '09

The European Medicines Agency (EMEA) has issued a statement updating stakeholders as to the status of efforts to revise Chapter 5, Part 19, of its GMP guide. The section concerns "dedicated facilities." After receiving feedback from Member States via a survey on the topic, EMEA decided it was necessary for the guide to identify those products in which the use of dedicated facilities is mandatory.

According to EMEA in the January statement, the topic has been the subject of a significant amount of debate within the drafting group and the GMP/GDP Inspectors Working Group, including discussions with interested parties at various forums. As a consequence the timeframes originally established by EMEA in a February 2005 concept paper for the various steps in the revision of the guidance have not been met.

EMEA also is working on clarifying the words "certain" and "exceptional cases" as used in Chapter 3, Section 6 concerning "production area."

EMEA chose to release the status statement due to the heavy public interest in the revisions.

EU revises *Manufacture of Sterile Medicinal Products*

The revision of Annex 1, Volume 4, *Manufacture of Sterile Medicinal Products* has now been released to the public.

According to the European Union, the revision to the annex was necessary to align the clean room classification table with ISO standards.

The revised Annex 1 provides supplementary guidance on the application of the principals and guidelines of GMP to sterile medicinal products.

The guidance has been updated in four main areas: classification table for environmental cleanliness of clean rooms and associated text, media simulations, bioburden monitoring and capping of freeze-dried vials.

The new annex should be implemented by March 1, 2009, except for the provisions on capping free-dried vials, which will take place in March 1, 2010.

European Commission Revises GMP Guidelines

The European Commission is reviewing existing GMP provisions, as an implementation measure related to the International Conference on Harmonisation (ICH) Q9 guideline on quality risk management.

The ICH Q9 guideline has been implemented with the new Annex 20. It should be noted that the new annex is not intended to create any new regulatory expectations, but rather provides an inventory of internationally acknowledged risk management methods and tools together with a list of potential applications at the discretion of manufacturers.

The European Medicines Agency Changes Submission Process

The European Medicines Agency (EMEA) announced on Feb. 5, 2008 that it plans to implement only electronic submissions of information in support of marketing authorization applications. Implementation of the Electronic Common Technical Document (eCTD) will be the ultimate required format for electronic submissions in response to the centralized procedure.

According to the EMEA, by the end of the 2009 deadline, the European Regulatory Network must have the infrastructure and processes in place to handle electronic-only eCTD to successfully support the related decision making processes for medicinal products within the European Union.

EU and Health Products and Food Branch of Health Canada Agree to Confidentiality Agreement

Regulatory experts from the European Union and Health Products and Food Branch of Health Canada in December 2007 agreed to a confidentiality arrangement; a press release concerning the matter was published on Jan. 11, 2008.

According to the European Medicines Agency, this agreement will allow them to exchange confidential information about the authorization and safety of medicines

The new confidentiality arrangement builds on the EU and the Health Products and Food Branch of Health Canada's previous cooperation and will allow the exchange of information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved.

The types of information that will be shared include position papers on future legislation and/or regulatory guidance documents; scientific advice on product development given to companies to promote innovation; assessments of applications for marketing authorizations and information about the safety of marketed medicines to better protect public health.

North America

U.S. FDA Releases Draft Guidance for Manufactures of Cellular and Gene Therapy Products

The U.S. FDA has published a draft guidance providing manufacturers of cellular and gene therapy products with recommendations on the validation of growth-based Rapid Microbiological Methods (RMM) for sterility testing of their products.

The draft guidance, *Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products,* addresses considerations for method validation and for the determining equivalence of an RMM to sterility assays. It also applies to somatic cellular therapy and gene therapy products.

The FDA will accept comments on the draft guidance until May 12, 2008.

The U.S. FDA Welcomes Comment on Proposed Information Collection Activity

In the Jan. 28 *Federal Register,* FDA announced an opportunity for comment on the estimates that they used for a proposed information collection activity.

Specifically, the information gathering pertains to exporters of human and animal drugs, biologics, devices, foods and cosmetics which may not be sold in the U.S. These exporters are required to maintain certain records to comply with requirements in the Food, Drug and Cosmetic Act.

Based on historical data, the Agency estimates an annual burden of 39,120 hours to comply with these requirements. Interested persons have until March 28, 2008 to comment.

FDA's CDER Plans 40 New Guidances in 2008

The U.S. FDA's Center for Drug Evaluation and Research posted a list of guidance for industry projects it plans to develop in 2008. Out of the 40 planned, six will cover chemistry issues and eight compliance issues.

The U.S. FDA Publishes Final Guidance on PMA Bioresearch Monitoring Program

In the Jan. 8 *Federal Register,* FDA announced the availability of a guidance entitled *The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program*.

The guidance provides premarket approval application (PMA) applicants with information about the bioresearch monitoring (BIMO) review process. This includes a BIMO evaluation of clinical and nonclinical information in the PMA and certain PMA supplements as well as preapproval BIMO inspections.

Comments can be addressed on this guidance to the FDA at any time.

The U.S. FDA Publishes Final Guidance on Medical Device PMA Review and Inspection

In the Jan. 8 *Federal Register,* FDA announced the availability of the guidance, *The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.* The document explains the process involved with the review of the manufacturing section of a PMA and the inspection of the manufacturing operations. This guidance is also applicable to the review of manufacturing information in certain PMA supplements.

Comments can be addressed on this guidance to the FDA at any time.

Feedback on Information Collection for Formal Dispute Resolution Guidance Requested

The U.S. FDA requested public feedback regarding the collection of information related to the guidance, Formal Dispute Resolution, in the Jan. 22 *Federal Register.* Published in January 2006, the guidance maps FDA's process for resolving scientific and technical relating to cGMP. The guidance provides procedures that encourage, open and prompt discussion of disputes and lead to their resolution.

Comments are due by March 24. FDA is requesting comments specifically on the following: "whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected and ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate and other forms of information technology."

Since the guidance was published, the Agency figures two manufacturers will submit approximately two requests annually for a Tier 1 dispute resolution and that there will be one appeal of these requests to the Dispute Resolution Panel (required for a Tier 2 resolution). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a Tier 1 resolution and approximately 8 hours to prepare and submit each request for a Tier 2 resolution, as well as an annual reporting burden of 68 hours.

Volunteer Spotlight

If one day you go to the beach and you look out in the water and see a surfer that looks like Art Vellutato, Jr., it probably is.

Art Vellutato, Jr.

Company: Veltek Associates, Inc. and Aseptic Processing, Inc.

Title: VP Technical Support Operations and Sr. Consultant

Education: Engineering, Albright College, 1985
MBA, University of Pennsylvania, Wharton School of Business, 1989

PDA Join Date: 1985

Areas of PDA Volunteerism:
Faculty Member of PDA TRI for the Aseptic Processing Course and Coordinator/Trainer for the Disinfection Course

Chairman of the Cleaning and Disinfection Task Force

President of the Delaware Valley Chapter of PDA

Exhibit Committee Chairman

Interesting Fact about Yourself:
If one day you go to the beach and you look out in the water and see a surfer that looks like Art Vellutato, Jr., it probably is. One of my main hobbies is surfing. I have surfed across the globe since I was ten.

Why did you join PDA and start to volunteer?
I joined PDA in 1985. At that time, PDA was a premier location to network with QA/QC professionals in the pharmaceutical and biotechnology industry. For years that was how I met most of the essential contacts who helped me become experienced in industry technology and grow our business to the successful level that it is today.

Of your PDA volunteer experiences, which stand out the most?
Having the opportunity to volunteer as a planning committee member and become the President of the Delaware Valley Chapter of PDA coupled with being a faculty member at PDA TRI are two experiences within PDA that I have greatly enjoyed. I find networking with our local professionals and training industry personnel rewarding.

How has volunteering through PDA benefited you professionally?
Through my volunteering efforts, I have had the opportunity to grow in my knowledge of the industry, its requirements and operational needs. This has enabled me to tailor products and services that will be invaluable to the professionals who must daily deal with the struggle to produce safe and effective drug products for the world.

Which member benefit do you most look forward to?
I find that the opportunity to serve on technical committees stands above the other PDA benefits. The opportunity to share technical methodologies with other industry professional for the betterment of the industry in terms of writing guidelines and technical reports is rewarding in itself.

Which PDA event/training course is your favorite?
As a faculty member of the PDA TRI, I personally like teaching the Cleaning and Disinfection Course. Here I have the opportunity to train students in an intense curriculum about a subject matter that would never be equaled in training at their own organizations. The balance between training students and personally consulting with them to improve their operations is without a doubt a way in which I feel I can considerably contribute to the industry as a whole.

What would you say to someone considering PDA membership?
The multitude of services and opportunities that exist within PDA are enormous. The organization provides a multitude of mechanisms to become involved, to network and to either become involved or to stay in touch with the growth of virtually every QA/QC or Validation subject in the industry.

2008 PDA Annual Meeting

EXHIBITORS

Last updated 2/7/08

April 14-18, 2008

Colorado Springs, Colorado

AAI Pharma
abc Laboratories, Inc.
ABM Janitorial Services
Accugenix, Inc.
AES - Chemunex, Inc.
Agilent Technologies
Ahura Scientific, Inc.
Althea Technologies, Inc.
American Pharmaceutical Review (Russell Publishing)
American Stelmi Corporation
Anhydro A/S
Applied Biosystems
ARAMARK Cleanroom Services
Asahi Kasei Medical America, Inc.
Aseptic Technologies
Associates of Cape Cod, Inc.
ATCC
BD Medical - Pharmaceutical Systems
Benchmark Products
BEPC, Inc.
Berkshire Corporation
Bio-Concept Laboratories, Inc.
Biocorp
Biologics Consulting Group, Inc.
bioMerieux Industry, Inc.
BioPharm International
BioProcess International/ BioExecutive International
BioReliance
Bioscience International
Biotest
BioVigilant Systems Inc.
BOC Edwards Pharmaceutical Systems
Brightwell Technologies, Inc.
Celsis, Inc.
Charles River Laboratories
Cirrus Pharmaceuticals, Inc.
Commissioning Agents, Inc
Compliance Software Solutions, Corp.
Contec, Inc.
Contract Pharma Magazine
DPT Laboratories
Draxis Pharma
Drumbeat Dimensions, Inc.
Duoject Medical Systems, Inc.
DuPont Qualicon
Eisai Machinery U.S.A., Inc.
Ellab, Inc
EMD Chemicals, Inc.
FDA.com
Fluid Imaging Technologies
FP Developments
Garvey Corporation
Gavin Pharmaceutical Services
General Physics Corporation
Genesis Packaging Technologies
Gerresheimer AG
Hardy Diagnostics
Hach Ultra
HECHT Anlagenbau GmbH
Helvoet Pharma, Inc.
HiMedia Laboratories Pvt. Limited
HRA Research
Hyaluron Contract Manufacturing
IMA North America, Inc.
Invensys Validation Technologies
ISPE
JM Hyde Consulting, Inc.
Lancaster Laboratories
Lighthouse Instruments, LLC
Linac Technologies
Lonza, Inc.
Maas & Peither AG Gmp-Publishing
Masy Systems, Inc.
Metall + Plastic
MetricStream
Microbiology International
MIDI, Inc.
Millipore Corporation
Mission3
Moda Technology Partners
Molecular Epidemiology, Inc. (MEI)
NextDocs Corporation
Nicomac, Inc.
Novatek International
OMPI of America
Optima Group Pharma
Overlook Industries, Inc.
Pace Analytical Life Sciences
Pall Life Sciences
Parenteral Drug Association (PDA)
Particle Measuring Systems
PDA Bookstore
PDA Training and Research Institute
Pharmaceutical Formulation & Quality (PFQ)
Pharmaceutical Technology
Pharmaceutics International, Inc. (PII)
PharmaSys, Inc.
Pharmasystems Inc.
PharmEng Technologies, Inc.
PML Microbiologicals
ProPharma Group
PTI Inspections Systems
Rap-ID
Rapid Micro Biosystems
Raven Labs
Remel, Inc.
RJ Lee Group, Inc.
Rommelag USA, Inc.
Sartorius Stedium North America, Inc.
SGD Pharmaceutical Glass
Sharp Corporation
Skan US, Inc.
SL Pharma Labs, Inc.
Sparta Systems, Inc.
Sterigenics
STERIS Corporation
SynTegra LLC
Talecris Biotherapeutics, Inc.
ThermoScientific
TriboGlide
Uhlmann Packaging Systems/Visiotec
Vectech Pharmaceutical Consultants, Inc.
Veltek Associates, Inc.
Vetter Pharma-Fertigung GmbH & Co. KG
Walker Barrier Systems
West Pharmaceutical Services

2008 PDA Annual Meeting

Feeding the Future:
Annual Meeting New Member Breakfast and Volunteer Luncheon

Colorado Springs, Colo. • April 14–18 • www.pda.org/annual2008

Hassana Howe, PDA

New Member Breakfast

Monday, April 14, 2008
7:30 a.m.–8:30 a.m.

Welcome new PDA members! If you joined PDA on or after Oct. 1, 2007, you are invited to kick-start your PDA membership by attending the complimentary New Member Breakfast hosted on-site at the PDA 2008 Annual Meeting. This is a wonderful opportunity to learn more about PDA and to meet other new members, board members and staff.

Volunteer Luncheon

Tuesday, April 15, 2008
12:45 p.m.–1:45 p.m.

All members are welcome to join the complimentary PDA Volunteer Luncheon at the 2008 PDA annual meeting to learn how PDA volunteer opportunities can help 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.

Working for a common goal will lead to the advancement of science, technology and training, as well as, the development of your own technical and leadership skills by getting involved with PDA. There are many different levels of involvement, so come join us for lunch to learn more!

To attend either of these events or ask questions, please contact me at +1 (301) 656-5900, ext. 119 or howe@pda.org.

Pick Up a Pin, Win a Prize or Just Say "Hi" Visit the PDA Booth #704

Julia Onder, PDA

The PDA membership booth at the upcoming 2008 PDA Annual Meeting will be an exciting stop in the exhibition hall. Enjoy networking with peers and PDA staff members, pick up your PDA membership pin and learn about the new PDA events and benefits being offered in 2008. Be sure to get your exhibition passport stamped and refer a colleague to PDA to win exciting prizes.

And as always, a helpful PDA staff member will be on hand to answer your questions. We look forward to seeing you.

For more information on the 2008 PDA Annual Meeting please visit www.pda.org/annual2008.

Learn more at the PDA booth about our **"Refer a Colleague Campaign"** and be entered into a drawing to win a **$50.00 American Express Gift Card.** For more details, please visit the booth.

2008 PDA Annual Meeting

Science Driven Manufacturing: The Application of Emerging Technologies

THE BROADMOOR
COLORADO SPRINGS

April 14-18, 2008

Colorado Springs, Colorado

Conference	|	April 14-16, 2008
Exhibition	|	April 14-15, 2008
Career Fair	|	April 14-15, 2008
Courses	|	April 17-18, 2008

The PDA Annual Meeting is dedicated to advancing the careers of pharmaceutical and biopharmaceutical professionals by focusing program content on science and technology innovation, offering extensive formal and informal networking opportunities and providing a forum to contribute to and influence the advancement of science and regulation in the industry.

Highlights of this year's conference program include:

- Concurrent sessions organized by three tracks: Manufacturing Sciences, Biotechnology Sciences, Quality Sciences
- Keynote presentations by Linda Armstrong Kelly, the mother of Lance Armstrong, who credits her as the unsung hero who assisted him in his triumph over cancer; and Shelley Morrison who plays Rosario on the hit NBC series *Will and Grace* and who has survived two bouts of cancer.
- Novel manufacturing technologies that enhance patient safety
- New contaminants: Implications, detection and exclusion

Complementing the conference are PDA Training and Research Institute (PDA TRI) courses, an exhibition and PDA's 4th Annual Career Fair.

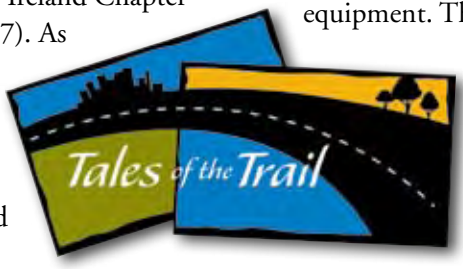
www.pda.org/annual2008

PDA℠
Parenteral Drug Association

A Business Travel Newbie Takes First Trip to Meet PDA Members

Emily Hough, PDA

Being the junior member of the Science and Technology department, I was excited to have my first opportunity to meet PDA members and volunteers by attending the New England Chapter tour and meeting (Jan. 23), the Metro Chapter dinner (Jan. 24) and the Ireland Chapter conference (Feb. 7). As the very first business trip of my young career, I was ecstatic! Little did I know what was in store for me!



Everything was going smoothly with my trip from Maryland to Massachusetts for the the New England Chapter Facility Tour and Dinner Meeting on PDA TR-42, *Process Validation of Protein Manufacturing,* until I touched down in Boston. The plan was to quickly collect my luggage so I could get to the hotel in time to prepare for the Chapter tour of the Shire Human Genetic Therapies research facility in Lexington. But to my dismay, my bag wasn't there! After conferring with the airline, I was told that my luggage would be returned to me before I had to ship out the next day to New Jersey. So on I went to my hotel with my laptop, briefcase and airline travel case to my next stopping point, the hotel.

Instead of preparing for the tour of the Shire facility, I tracked down the nearest shopping center, but ran out of time to actually buy what I needed. Thankfully, I was already wearing a suit.

In spite of a directionally-challenged taxicab driver, I arrived at the tour on time. I joined over thirty people at the Shire facility, which manufactures drugs for genetic diseases. As someone who has to write and edit articles about the industry, this was beneficial to see an actual research lab and analytical equipment. The facility houses five groups of researchers—Bioanalytics, Protein Expression and Purification, Cell Biology, Physiology, and Histology—along with support staff and senior research management.

Most of Shire's products, both those that are commercialized and those in development, are based on a technology known as enzyme replacement therapy. **Chris Masterson**, Senior Director, Quality Assurance, said they were holding the tour in conjunction with the Chapter event because his firm "has a great story to tell, and nobody knows the story."

PDA member **Greta Davis** was kind enough to drive me from Shire's facility to the featured event at the Hilton in Waltham where Chris, **Kelley Boutin** and **Peter Levy** spoke to over 100 attendees. Peter's speech elucidated the process of developing TR-42. PDA's **Ta-Méla Jeffries** also attended in her ongoing effort to reach out to the various chapters.

After the event, I met with some members of the New England Chapter, including president **Louis Zaczkiewicz.** When I told Louis about my lost luggage and my concern that I might have to wear the same shirt two days in a row, he generously offered me a PDA New England chapter shirt! Fortunately, I would not have to explain to the Metro Chapter the next day why I was wearing a New England Chapter shirt, because my luggage arrived later that night.

With luggage in hand and my first PDA chapter event in the bag, I was off the next day to Somerset, N.J., to meet Metro Chapter president **Nate Manco** and PDA's **Trevor Swan,** who like Ta-Méla, was attending the chapter's dinner to interact with chapter members. The next morning everything was going according to plan. I left for the station with enough time to spare but somehow I missed the train. Luckily enough, the next train wasn't too far behind.

PDA's Who's Who?

Naomi Baer, Sr. Application Specialist, Millipore Corporation and Metro Chapter President-Elect

Noel Bagnall, Development Director, Genzyme

Harold Baseman, Principal and Chief Operating Officer, ValSource LLC

Kelley Boutin, Sr. Recruiter, Shire Human Genetic Therapies

Phil Broderick, Administration Associate, Biologics & Legal, Elan Corporation

Anthony Cundell, PhD, Director, Schering-Plough

Greta Davis, Validation Manager, Bristol-Myers Squibb Medical Imaging

Anne Greene, Phd, Lecturer, Dublin Institute of Technology

Frank Hallinan, Director, Wyeth Biotec Ireland and Ireland Chapter President

Tom Hodgkinson, Validation Manger, Genzyme

Ta-Méla Jeffries, Coordinator of Membership Services and Chapters, PDA

Robert Johnson, Analytical Compliance Scientist, GlaxoSmithKline

Peter Levy, Principal, PL Consulting LLC

Paul Logue, Vice President, Elan Corporation and Ireland Chapter Secretary

Nate Manco, Director, ECO Animal Health and Metro Chapter President

Chris Masterson, Sr. Director, Shire Human Genetic Therapies

Declan Quinlan, Sr. Manager, Genzyme

Georg Roessling, PhD, Sr. Vp. PDA Europe

Kevin Schreier, Process Manager, Jacobs

Kevin Smyth, Process Manager, Jacobs

Trevor Swan, Sr. Coordinator of Membership Services and Chapters, PDA

Louis Zaczkiewicz, Sr. Engineer, Hyaluron Contract Manufacturing and New England Chapter President

Anthony Cundell, PhD, presented the keynote talk, entitled *Microbiological Examination Test Implementation.* During the pre-talk "Meet and Greet," Trevor and I had a great time talking to members about PDA and hearing from **Robert Johnson,** GlaxoSmithKline, about the Chapter's exciting plans.

Trevor said that he learned a lot from Anthony's presentation and from networking with Nate and Metro Chapter President-Elect **Naomi Baer** after the event.

Following my trip to the American Northeast, I was off to the PDA Ireland Chapter conference, *Trends in Aseptic Processing—A Risk Management Approach,* at the University College Dublin (UCD). Prior to departing, several Chapter members, including Elan Corporation's **Phil Broderick,** helped me find lodging near the University.

Chris Masterson, Shire HGT

Having learned my lesson, I packed a carry-on bag with essential clothes along with my suitcase, which was fortunate because the airline with which I had made reservations switched my flight to the airline which had lost my luggage when traveling to Massachusetts! When I arrived in the lovely city of Dublin I had all my luggage and was ready to meet with the Chapter leaders and event speakers (and enjoy some sightseeing).

The night before the conference, Elan Coporation's **Paul Logue** organized an impressive dinner (for a newbie at least) at the Four Season Hotel for conference speakers and selected chapter members. This dinner helped the speakers learn more about the Ireland Chapter and its goals. In attendance were Ireland Chapter president **Frank Hallinan, Kevin Schreier, Kevin Smyth, Hal Baseman, Declan Quinlan, Noel Bagnall, Tom Hodgkinson** and **Anne Greene,** who told me of the Ireland Chapter's very ambitious plans to start a student chapter. **[Editor's note:** The New England Chapter has formally announced plans to start the first PDA student chapter. See the February *PDA Letter,* p. 38.**]**

The event took a full day and was held at the William Jefferson Clinton Auditorium at the UCD. PDA's

Georg Roessling, PhD, in his closing remarks said the Ireland Chapter was a "powerhouse" and he felt the leadership was "strong" and very "dedicated." **[Editor's note:** See related article, page 52.**]**

It was quite clear to me as I left Ireland that PDA Chapter events are a valuable tool for fulfilling member needs at the local level. I am now, more than ever, eager to visit chapters and get feedback from our members.

I would like to thank everyone that I met on my travels and those who helped me. I felt very welcome at each and every event I attended!

Shire Human Genetic Therapy manufactures drugs for genetic diseases

Tulsa Scott, Commissioning Agents, Inc.

(l-r) James Cataldo, MassBioLabs and Jack Campion, UMass Biologics Lab

Linda Perez, Superior Controls, Inc.

Please Welcome the Following Industry

Darcy Adee, DSM Pharmaceuticals

Faiz Ahmed, CIBA Vision Sterile Manufacturing

Erling Albrectsen, Novo Nordisk

John Albright, Celsis

Noelani Alcoba, MedImmune

Andrea Ambrosio, Grifols

Caralyn Andres, Charles River Laboratories

Fola Ayoola, Lifecell

Golnaz Badie, Grifols Biologicals

Stephen Badolato, Mission LLC

Mohan Bal, Amylin

Caroline Bansal, Sanofi Pasteur

Adam Barrios, DesigneRx Pharmaceuticals

Peter Basdeckis, Astellas Pharma US

Susan Batten, Ben Venue Laboratories

Igor Bercik, State Institute for Drug Control

Deirdre Bermingham, Pharmaceutical Process Engineering

Richard Berry, Genzyme

Eli Bjornson, Alpharma AS

Mickaela Blake, Schering Plough Research Institute

Claude Bonde, Novo Nordisk

Richard Brook, Clarkston Consulting

Helene Brough, Shire

Dave Bryan, GlaxoSmithKline

Diane Burgess, University of Connecticut

Peter Calcott, Calcott Consulting

Pierre Caloz, Merck Serono

Philip Capone, Sartorius-Stedim Biotech

Myra Coddens, Abbott Labs

Edward Connolly, CIS-US

Wilbur Conway, Ben Venue Laboratories

Brian Cruz, Alcon Laboratories

Kathleen Curreri, Sartorius Stedim Biotech

Karen Cusi, Amgen

Karla D'Agostino, Cadbury Schweppes

Niki DeBoer, MAST Biosurgery

James Decker, Pfizer

Richard Denk, Hecht Anlagenbau

Tracey DeSantis, Elan Drug Delivery

Weill Dominique, Sterigene

Matthew Dorsey, Boehringer Ingelheim Vetmedica

Thibaud Du Merle, Bristol-Myers Squibb

Brian Edmonds, Merck

Michael Ehasz, AAI Pharma

Angela Elliott, Bayer Healthcare Pharmaceuticals

Daniel Falkenheim, Baxter BioPharma Solutions

Michael Fleming, Sanofi Pasteur

Sylvie Fokin, Rohm and Haas Company

Jessica Foley, PAREXEL International

Bill Foley, Waters Corporation

Christopher Furman, Talecris Biotheraputics

Kazunori Furuichi, sanofi aventis

Bruce Gardner

Magdalena Gay Segura, Ben Venue Laboratories

Dan Gee, Massbiologics

Patty George, Teva Parenteral Medicines

Sandra Gohil, Baxter Healthcare

Melissa Golias, Laureate Pharma

Edgar Gomez Aguirre, Hyaluron Contract Manufacturing

Garaldine Goumans, GSK Biologicals

Brad Green, Laureate Pharma

Thomas Greenwood, Wyeth Biotech

Edward Griffin, Accugenix

Leigh Grygotis Cherry, Merck

Andres Ernesto Guerra, Probiomed SA de CV

Robert Guertler, Alcon Laboratories

Nora Hannaford, Shire HGT

Darrin Hansen, BTF Precise Microbiology

Jibin Hao, Millipore Corporation

Christina Harper, Sartorius Stedim Biotech

Lisa Hart, Amgen

Jake Hayes, Merial

Joan Heim, Invitrogen Corp

Martin Heinrich, MDS Nordion

Michael Hibbard, Amgen

Keiichi Hirai, Daiichi Sankyo

Daniel Hoch, Protocol Link

Joseph Horvath, Millennium Pharmaceuticals

Kimberly Hubbard, Pharma-Ed Resources

Gary Hutchinson, Amgen

Yoshiya Ikeda, API

Joe Jacobson, Fort Dodge Animal Health

Martin Jakobsson, BioInvent International AB

Lars Jansson, NNE Pharmaplan AB

Canping Jiang, Bristol-Myers Squibb

Ganiyu Jimoh, Covidien

Jay Jolly, Bristol-Myers Squibb

Shiota Kazuma, Godo Shusei

James Kelly, Ben Venue Laboratories

Hirotaka Kemmei, Astellas Toyama

Milad Khan, Merial

Soo Kim, Xencor

Lim Kim Eng, SciGen

Tara King, Hematech

Kenneth Kleinhenz, Cytori Theraputics

Jeanette Kopp, Covidien Healthcare

Janos Kovacs, IVMP Directorate of Veterinary Medicinal Products

Erasmus Kuhlmann, Bayer Healthcare Pharmaceuticals

Maya Kumano, Kringle Pharma

Jay Lad, Skanska Pharmaceutical Group

Robert Laughner, Cook Urological

Thaddeus Law, Mylan Pharmaceuticals

Melissa Leaf, CSL Behring

Leaders to the PDA Community

Michael Leatherman, Eli Lilly
Norman Lee, Amgen
Corinne Lehmann, Sanofi Chimie
Jeffrey Lehmer, Amgen
Ingrid Lesaca, Genentech
Sara Lewis, Baxter Healthcare
Jen-kuei Liu, Applied Biosystems
Myra Lu, AMO (Hangzhou)
Wade Maley, Mylan Pharmaceuticals
Dale Mason, Hollister Stier Labs
Kazuya Matsuo, Abbott Laboratories
Norbert Matzanke, Ferring
Jon McCabe, STERIS
Jenny Mellquist, Hematech
Andrea Mesaros, Ben Venue Laboratory
Eri Mieno, Sanwa Kagaku Kenkyusho
Asako Mikawa, Chugai Research Institute
Erik Millick, Baxter BioPharma Solutions
Erika Molignano, Genzyme Corporation
Brian Morgan, Baxter Healthcare
Petra Mullerova, Uskvbl
Jim Nadlonek, Amylin Pharmaceuticals
Chen Nan, Shanghai Ritai Medicine Equipment
Louisa Nash, Pfizer
Thalia Nicas, Eli Lilly
Michael Nielsen, Alpharma
Astrid Nielsen, Novo Nordisk
Peter Nilsson, Getinge
Kei Nishimura, UCB
Karolina Nordin, AstraZeneca
Kazue Noro, Otsuka
Grainne O'Donovan, Wyeth
Shiho Ono, Novartis
Stephen Pace, Radian
Richard Paiva, Hyaluron
Thomas Pamukcoglu, SAFC
Hye Mi Park, Celltrion
Jayesh Patel, Roche
Parul Patel, FDA
April Peters, Baxter Healthcare
Joseph Prinzo, Management Recruiters of Woodbury
Cheryl Ptasienski, Alsco Cleanroom Services
Zankhana Punwani, Schering Plough
Lana Radosevic, Bayer Healthcare
Dasa Radosova, Uskvbl
Sumeet Rastogi, Bayer HealthCare
Suma Ray, Sartorius Stedim Biotech
Cheri Redman, Bausch and Lomb
Jacob Rietkerk, Centocor
Kim Riley, Shire HGT
Jonathan Ringham, Array Biopharma
Courtney Rogers, Merial
Ryan Ruiz, Genentech
Gabriela Ruja, National Medicines Agency
Rosa Sabie, Teva
Machelle Sanders, Biogen Idec
Helmi Sandifer, Sirna Therapeutics
Shin Sangsu, Boryung Pharm.
Go Sarara, National institute of Advanced Industrial Science and Technology (AIST)
Yoshinori Sato, Teijin Pharma
Margaret Savage, Wyeth Biotec
Michael Scheckelhoff, Commissioning Agents
Kenneth Schenk, Bristol-Myers Squibb
J. Evan Schone, Merck
Douglas Schwetke, AAIPharma
Peter Shao, Jazz Pharmaceuticals
Andrew Sheppe, Middlesex Community College
Kenneth Shrout, ProPharmaGroup
Samanta Siderius, GSK - R&D Shared Services Library
Veerle SILLIS, Pfizer Manufacturing Belgium NV
Mary Sliwkowski, Genentech
Charlie Slovensky, Merial
Jeremiah Smith, Genentech
Kevin Smyth, Jacobs Engineering
Gopalam Somasekhar, Wyeth
Jonathan Sorid, Centocor
Claudia Stampfli, Lonza
Peter Stathis, OncoMed Pharmaceuticals
Audny Stenbraten, Statens Legemiddelverk, Avd for Tilsyn
David Stephon, Adolor Corporation
Rebecca Street, GlaxoSmithKline
Byron Suprenant, CSL Behring
Karen Sutch, RJ Lee Group
Nuala Sutton, Wyeth Biotech
Iolanda Teodor, Baxter Healthcare
Steve Thill, Hematech
Pascal THOMAS, Millipore
Zachery Thompson, Merial
Chihiro Umio, Astellas Toyama
Leon VanWormer, Sartorius Stedim Biotech
Irma Vicente, Wyeth
Varonique Vonlanthen, UCB Pharma.
Geneane Walsh, Sartorius Stedim Biotech
Joy Whitsett, Arena Pharmaceuticals
Anne-Mette Wittekind, Alpharma
Leah Wong, RMC Pharmaceutical Solutions
Russell Wong, Bayer HealthCare
Steven Wong, Lifecell
Jung Woo, The Texas A&M University System Health Science Center
Sin-ichiro Yoshida, Maruho
Guangtao Zhao, Shanghai Haichang Medical Plastic Factory
Steve Zhou, Microbiotest

If your information appears inaccurate in this list, please visit www.pda.org to update your profile or email changes to info@pda.org.

PDA Technical Report No. 1, Revised 2007

June 26-27, 2008 | Montreal, Canada

Join members of the PDA Task Force on Technical Report No. 1 and industry representatives at the *PDA Technical Report No. 1, Revised 2007, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control* meeting in Montreal, Canada, to discuss the updated recommendations in the latest revision.

Visit www.pda.org/tr1 for more information and to register.

February Top 10 Bestsellers

1. **Encyclopedia of Rapid Microbiological Methods, Volume I, II and III**
   Edited by Michael J. Miller, PhD
   Item No. 17252, PDA Member $730, Nonmember $899
2. **Bioprocess Validation: The Present and Future**
   By Trevor Deeks, PhD
   Item No. 17248, PDA Member $225, Nonmember $279
3. **Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics**
   By Scott Sutton, PhD
   Item No. 17242, PDA Member $210, Nonmember $260
4. **PDA Technical Report 1, Revised 2007, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control**
   Item No. 01001, PDA Member $150, Nonmember $250
5. **Essential Microbiology for QP Candidates**
   Edited by Nigel Halls with Appendix from Bruce Vernon
   Item No. 17265, PDA Member $225, Nonmember $279
6. **PDA Archive on CD-ROM – PDA Archive Retrieval Index** - 30% Off
   Item No. 01101, PDA Member $395, Nonmember $590
7. **Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple**
   By James L. Vesper
   Item No. 17219, PDA Member $235, Nonmember $289
8. **Microbiology, and Engineering of Sterilization Processes, Twelfth Edition 2007**
   By Irving J. Pflug, PhD
   Item No. 13008, PDA Member $225, Nonmember $275
9. **Ethylene Oxide Sterilization: Validation and Routine Operations Handbook**
   By Anne F. Booth
   Item No. 17276, PDA Member $200, Nonmember $249
10. **Risk-Based Software Validation: Ten Easy Steps**
    By David Nettleton and Janet Gough
    Item No. 17256, PDA Member $200, Nonmember $249

www.pda.org/bookstore

Tel:+1 (301) 656-5900 | Fax:+1 (301) 986-1361

Chapter Contacts

The following is a list of the PDA Chapters, organized by the regions of the world in which they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and his or her email address. Where applicable, the Chapter's website is listed. More information on PDA Chapters is available at www.pda.org/chapters.

Asia-Pacific

Australia
Contact: Anna Corke
Email: acorke@medicaldev.com
www.pdachapters.org/australia

India
Contact: Darshan Makhey, PhD
Email: dmakhey@hotmail.com

Japan
Contact: Katsuhide Terada, PhD
Email: terada@phar.toho-u.ac.jp
www.j-pda.jp

Korea
Contact: Woo-Hyun Paik, PhD
Email: whpaik@hitel.net

Southeast Asia
Contact: K. P. P. Prasad, PhD
Email: prasad.kpp@pfizer.com

Taiwan
Contact: Shin-Yi Hsu
Email: shinyi.hsu@otsuka.com.tw
www.pdatc.org.tw

Europe

Central Europe
Contact: Andreas Wenng, PhD
Email:
andreas.wenng@chemgineering.com
www.pdachapters.org/centraleurope

France
Contact: Philippe Gomez
Email: philippe.gomez@sartorius.com
www.pdachapters.org/france

Ireland
Contact: Frank Hallinan
Email: hallinf@wyeth.com
www.pdachapters.org/ireland

Israel
Contact: Raphael Bar, PhD
Email: rbar@pharmos.com
www.pdachapters.org/israel

Italy
Contact: Stefano Maccio, PhD
Email: stefano.maccio@ctpsystem.com
www.pdachapters.org/italy

United Kingdom
Contact: Siegfried Schmitt, PhD
Email: siegfried.schmitt@parexel.com
www.pdachapters.org/unitedkingdom

North America

Canada
Contact: Patrick Bronsard
Email: patrick.bronsard@snclavalin.com
www.pdachapters.org/canada

Capital Area
Areas Served: MD, DC, VA, WV
Contact: Allen Burgenson
Email: allen.burgenson@lonza.com
www.pdachapters.org/capitalarea

Delaware Valley
Areas Served: DE, NJ, PA
Contact: Art Vellutato, Jr.
Email: artjr@sterile.com
www.pdadv.org

Metro
Areas Served: NJ, NY
Contact: Nate Manco
Email: natemanco@optonline.net
www.pdachapters.org/metro

Midwest
Areas Served: IL, IN, OH, WI, IA, MN
Contact: Peter Noverini
Email: peter_noverini@baxter.com
www.pdachapters.org/midwest

Mountain States
Areas Served: CO, WY, UT, ID, NE, KS, OK, MT
Contact: Sara Hendricks
Email: scarry@att.net
www.pdachapters.org/mountainstates/

New England
Areas Served: MA, CT, RI, NH, VT, ME
Contact: Louis Zaczkiewicz
Email: zaczkiewicz@pdachapters.org
www.pdachapters.org/newengland

Puerto Rico
Contact: Manuel Melendez
Email: manuelm@amgen.com
www.pdachapters.org/puertorico

Southeast
Areas Served: NC, SC, TN, VA, FL, GA
Contact: Patrick Sabourin
Email: patrick.sabourin@novartis.com
www.pdachapters.org/southeast

Southern California
Areas Served: Southern California
Contact: Saeed Tafreshi
Email:
saeedtafreshi@inteliteccorporation.com
www.pdachapters.org/southerncalifornia

West Coast
Areas Served: Northern California
Contact: John Ferreira
Email: jferreira@banzigersystems.com
www.pdachapters.org/westcoast

2008 PDA Annual Meeting

Meet Familiar and New Colleagues at the PDA 2008 Annual Meeting

Networking Events Includes Fun Run/Walk and Horseback Riding

The PDA 2008 Annual Meeting offers an expanded array of networking activities designed to bring you face-to-face with your peers, as well as industry and regulatory leaders, to share ideas, exchange information and make valuable contacts. There are even events for the whole family to enjoy!

Visit www.pda.org/annual2008 for information on how to register and any additional fees for the following events.

Saturday, April 12

Guided Mountain Horseback Ride

1:00 p.m.–4:30 p.m.

Experience unique western horseback riding, cross old mining claims and see breathtaking mountain views—only 20 minutes from the Broadmoor!

Sunday, April 13

Fun Walk/Run Event

8:00 a.m.–10:30 a.m.

Proceeds benefit the Lance Armstrong Foundation

Join your friends, family and colleagues for a 3K walk and 5K run around the vast grounds of the Broadmoor and past the entrance of the North Cheyenne Canyon and Seven Falls.

2nd Annual PDA Golf Tournament at the Broadmoor (West Golf Course)

10:00 a.m.–11:30 a.m. Tee Times

Challenge your colleagues and other conference attendees to a round of golf on the West Golf Course, the Broadmoor's most difficult course.

Monday, April 14

New Member Breakfast

7:30 a.m.–8:30 a.m.

If you joined PDA on or after Oct. 1 2007, you are invited to attend the New Member Breakfast hosted on site. RSVP by March 21, 2008 by contacting **Hassana Howe** at +1 (301) 656-5900 ext. 119 or at howe@pda.org.

Ready, Paint, Fire

10:00 a.m.–12:30 p.m.

Create your own masterpiece at the pottery painting extravaganza!

Annual Graduate Research Symposium and Student Poster Sessions

11:00 a.m.–12:45 p.m.

Learn about the current research being conducted by bio/pharmaceutical science students. You may find your next employee among them!

Pikes Peak Cog Railway

11:00 a.m.–3:30 p.m.

Sit back, relax and take in the splendors of Colorado as the highest cog railway in the world takes you through hidden valleys, past groves of quaking aspens and over the tundra at timberline.

Tuesday, April 15

Cheyenne Mountain Zoo

10:00 a.m.–1:30 p.m.

The Cheyenne Mountain Zoo is America's "highest" zoo, at 6,800 feet on 50 acres, with more than 700 diverse and exotic creatures.

Rocky Mountain High Gala Reception

5:15 p.m.–7:00 p.m.

Enjoy a night of great food, dancing and entertainment with your friends and colleagues at this western themed gala event. Immerse yourself in the western atmosphere as you rejoice in that "Rocky Mountain High."

Monday, April 14 and Tuesday, April 15

Exhibit Hall Networking Event

Monday, April 14: 10:00 a.m.–7:00 p.m.
Tuesday, April 15: 10:00 a.m.–4:00 p.m.

Join us in the Exhibit Hall to network with company representatives to learn about the future of the industry during refreshment breaks, networking receptions and prize drawings.

PDA's 4th Annual Career Fair (open Monday and Tuesday)

Monday, April 14: 10:00 a.m.–5:15 p.m.
Tuesday, April 15: 10:00 a.m.–4:00 p.m.

Representatives from industry-leading companies around the world come in search of qualified, potential employees to fill highly desired bio/pharmaceutical positions.

Quality Requirements for Phase 0/1 Pharmaceutical Development Studies—A PDA Workshop

Colorado Springs, Colo. • April 16–17 • www.pda.org/annual2008

Vince Mathews, QA Consultant, Eli Lilly

In March 2004, the FDA published a report entitled *Innovation Stagnation—Challenge and Opportunity on the Critical Path to New Medical Products.* In this report, the FDA expressed concern that there was a slowdown in innovative medical therapies reaching patients partly due to the difficulty of predicting the ultimate success of novel candidates. It was recognized that better tools are needed to identify successful products and eliminate impending failures more efficiently and earlier in the development process. In January 2006, the FDA subsequently published the *Guidance for Industry, Investigators, and Reviewers—Exploratory IND Studies.* In this document, the FDA discusses approaches for utilizing exploratory IND studies to help identify promising candidates and eliminate those lacking promise.

Immediately following the PDA 2008 Annual Meeting in Colorado Springs, Colo. PDA will host a workshop to address approaches for performing early phase development studies that are used to increase the overall efficiency of new product development. This workshop will bring together medical, scientific and quality personnel to explain these techniques, existing quality/GMP regulations, and suggested quality approaches to ensure patient safety while facilitating early phase development.

David Jacobson-Kram, PhD, Senior Scientist, CDER, FDA will address the utilization of early phase studies, and individual sessions will then be held on some of the early phase approaches being utilized including:

- Compounding
- Radiochemicals
- Microdosing
- Challenge Agents
- Biomarkers

Each session is designed to provide an overview of the material, technique or strategy, identify any existing regulatory requirements, highlight quality/cGMP considerations associated with its use, and share current and recommended practices.

The workshop will conclude with a presentation on Phase I GMP requirements, and a panel discussion which will include the individual speakers.

For more information and to register, visit www.pda.org/annual2008.

2008 PDA/FDA Joint Regulatory Conference to Address Globalization and Modernization

Washington, D.C. • September 8–10 • www. pda.org/pdafda2008

John Finkbohner, PhD, Director, MedImmune

This year's PDA/FDA Joint Regulatory Conference is titled, *Harmonization, Implementation, and Modernization: Achieving a Future Vision.* The aim of the conference is to provide examples of how industry and regulatory leaders have successfully implemented new approaches resulting from the GMP's for the 21st Century Initiative.

In 2002, the U.S. FDA began a number of activities under this initiative intended to offer industry the tools to provide more post-approval flexibility, making continuous improvement less of a regulatory burden, and promoting better self-regulation to improve compliance status for members of regulated industry. As the new paradigms in quality by design (QbD), design space, and risk management approaches to implementing change have taken root, industry continues to look at means to improve implementation for specific production platforms and to gain insights by sharing lessons learned through recent experience. In the five years that have passed since the announcement, regulatory health authorities and industry have partnered by harmonizing requirements and implementing new systems for assuring and maintaining pharmaceutical quality.

The conference will examine what is working well and where the industry and regulatory health authorities still need to collaborate to achieve modernized quality systems. The conference will provide a venue for industry and regulatory health authority experts to explore how to successfully achieve the future vision of a science and risk-based approach to product quality incorporating an integrated quality systems approach in pharmaceutical production. The opportunity for face-to-face dialogue on these issues provides pharmaceutical industry professionals an invaluable venue for direct information exchange with policy makers.

The plenary sessions planned for this conference will offer presentations from senior FDA officials. Presentations will address the activities occurring to foster globalization through examining the current state of multiple harmonization efforts and set the stage for the concurrent sessions which offer more in-depth discussions of critical topics. On the last day, FDA will provide focused updates highlighting current compliance and agency initiatives that are intended to advance the goals of the GMP's in the 21st Century programs.

Conference attendees can be assured that they will walk away with a full understanding of the current status of initiatives intended to move the modernization of regulatory oversight forward.

Concurrent sessions will focus on a variety of topics under three parallel tracks. Topics in development include a number of sessions under the umbrella of the product lifecycle focusing on:

- Product development
- Pharmacovigilance and product complaints
- Supply chain
- Updates to the use of drug master files
- Change management and reporting of post-approval changes
- Updates on the experiences under the FDA CMC pilot program
- The potential for lessening the regulatory oversight burden

A second track will focus on quality systems. Topics in this track will include the impact of the EU clinical directive and the potential revision to Annex 13, as well as the overview of updates to EU Annex 1.

Presentations touching on a number of harmonization activities will also be discussed, such as:

- The Transatlantic Initiative on Administrative Simplification in Pharmaceuticals
- The Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- Pharmacopoeial harmonization
- Activities of the Global Harmonization Task Force

The third concurrent track will focus on issues of enhanced importance in present day operations including:

- Management of emerging markets
- Import safety
- Product authentication (anti-counterfeiting)
- Nanotechnology
- Advances and challenges in combination products
- Updates related to follow-on biologics
- Expanding product areas such as stem cell and gene therapy products

We hope you will be able to join us at the *2008 PDA/FDA Joint Regulatory Conference* and take advantage of this unique opportunity to interact on current issues and hot topics with worldwide regulatory health authorities.

For more information on the 2008 PDA/FDA Joint Regulatory Conference, please visit www.pda.org/pdafda2008.

The Industry's Preeminent Training Conference in New Orleans

New Orleans, La. • May 19–21 • www.pda.org/training2008

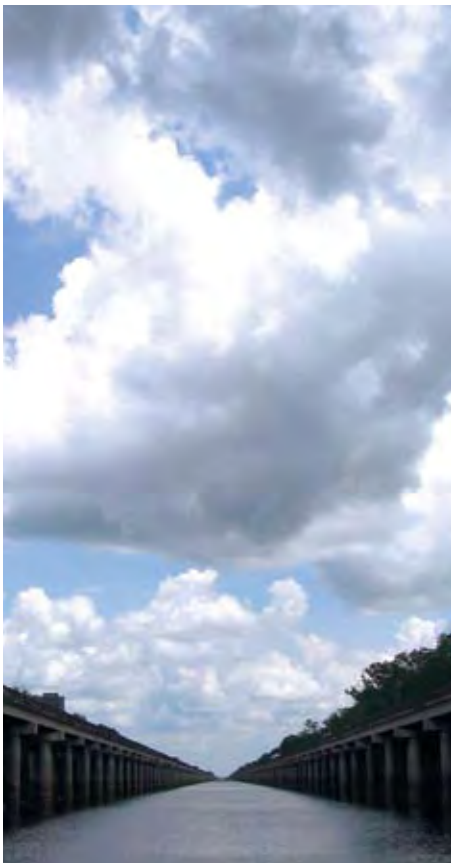
Rick H. Rogers, Training Manager, Covidien

International compliance trainers representing every facet of the bio/pharmaceutical industry will be congregating at the 2008 PDA Biennial Training Conference and two day TRI training course. If you are a trainer in the pharmaceutical, medical devices or a related industry or if you have a responsibility for any aspect of compliance training at your organization, this is the one conference you don't want to miss. This conference, which expects as many as 300 professionals to attend, attracts a significant percentage of the trainers, training management and Quality Affairs (QA) representatives from our industries.

This year's conference is the seventh in an unbroken series of conferences that have been offered every two years since 1996. The conference is administered by PDA's oldest and longest running standing Program Planning Committee, which this year is being chaired by **David Fant,** David Fant Associates, one of the most senior and well known GXP Trainers in the industry.

The 2008 PDA Biennial Training Conference will feature the widest offering of professional information available anywhere to trainers in the industry. FDA speakers are on the agenda to present the latest in compliance training topics as well as to answer questions from attendees. The conference also will feature a one-day exhibit by more than a dozen vendors and consultants providing goods and services to trainers.

Thirty concurrent sessions of referred presentations are slated to be offered during the three day conference. The



vast bulk of these concurrent sessions will be delivered by practitioners from the industry-every day trainers-who will be presenting their expertise on topics covering the whole range of training related issues. Everything from current best practices to classroom training techniques will be covered.

One of the most significant aspects of the conference for attendees is the chance to meet and network with others from the industry who share interests in training issues. Ample time is built into the conference for attendees to meet and share their experiences. In addition, the conference offers social events that are always well received by the attendees, including a Paddlewheels Riverboat Cruise.

This year also represents the fourth straight conference where excellence in training will be acknowledged with the awarding of the PDA Trainers' Choice Awards. These awards are given to the finest training activities in several categories submitted by trainers from the industry. The Program Planning Committee selects finalists for the awards in each category, and conference attendees vote for the winners. Awards are presented at the final luncheon of the conference.

Winning the PDA Trainers' Choice Award represents the highest achievement for any trainer in our industry.

And as if that were not enough, PDA TRI is conducting two days of training classes on Thursday and Friday of that week, May 22–23. The classes feature eight different training offerings, four of which are brand new. The most up-to-date information will be available at these sessions, which include topics covering:

- Challenges for GxP Training for the 21st Century
- FDA Inspection Readiness for a Training Systems Audit
- Qualifying Your SMEs as Trainers
- Training for Performance
- Train the Trainer: Deviation Investigations and Investigation Report Writing
- When "Off the Shelf" Just Won't Do
- A Manager's Role in Training
- Core Competency-Based Curricular Approach to Training in Regulated Industry

For more information and to register, visit www.pda.org/training2008.

Working for You Behind the Scenes: PDA's Registration Staff

Emily Hough, PDA

You probably have never thought about it. You merely looked at what conference you wanted to attend, entered your PDA ID number and weeks later attended the conference. But did you ever think about what it took to get you there?

Behind the scenes is **Patresa Day**, Assistant Manager, Registration & Customer Accounts Representative and **Andrea Viera**, Sr. Registration Customer Accounts Specialist. Their job is to provide support to PDA conference, course and membership event participants by facilitating their registration process in the U.S. and in Europe.

Andrea Viera and Patresa Day in front of TRI

On a daily basis, they ensure that the online registration process for PDA open events is active and user friendly to members and non-members alike. When the system that supports the registration process restrains them from giving the customer service that PDA would like to extend to members and supporters—Patresa and Andrea take over and answer the questions and concerns that come in from registrants promptly.

Andrea, who was newly promoted to her position, said that she enjoys "being able to assist registrants by making the process as easy as possible to maintain [the registrants'] focus on the event and not the payment process."

They both receive registration forms by fax and process them manually. They also prepare badges for the registrants weeks in advance to ensure that the check-in process is as smooth as possible.

Patresa, who has worked at registration for a year and a half, says that "it is nice to know that the registration team is helping PDA to educate and inform its members on their job requirements."

For Registration Questions, contact:

Patresa Day
Assistant Manager, Registration & Customer Accounts Representative

+ 1 (301) 656-5900 ext 115
day@pda.org

Andrea Viera
Sr. Registration Customer Accounts Specialist

+ 1 (301) 656-5900 ext 220
viera@pda.org

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Visit us at the PDA 2008 Annual Meeting in Colorado Springs, CO April 14–15, 2008—Booth #219

Training in Europe

Gail Sherman, PDA

TRI TALK

I thought that I would take a bit of time to talk about our initiatives in Europe for 2008 and 2009. Europe is a blank page for TRI at this point, and I think there are lots of opportunities to move into uncharted areas.

Once again, the training offered at the PDA/EMEA conference has proved to be hugely successful for Europe and for TRI, even though training materials sat in customs during the actual courses. As a matter of fact, I am hoping for lots of educational programs in Europe in 2008. In January, I met with the PDA European staff and we decided to add training to almost all of the conferences being planned in Europe in 2008. We looked at the conference topics, and are in the process of contacting instructors and developing training programs for each. Check the PDA website at www.pda.org/calendar for future training in Europe.

We will be offering our short aseptic processing training in Basel in April and are looking for an alternate location for December. We are also planning a European Course Series to coincide with this expanded training. The Practical Aspects of Aseptic Processing course will be held for four or five days starting in December. We are also looking for other sites in Europe to conduct this and similar training in the future. So does anyone have an idle cleanroom and a working fill line?

On the volunteer side, the TRI Education Advisory Committee is looking for new members and would love to have someone who can represent the European industry and training for that industry. We are planning a short survey of needs, and would like to be sure that outside of the U.S. needs are met as well. While some of our courses do "cross the pond" there are others that need to be developed specifically for EU regulations and GMP issues. So, in that light–if you have been waiting for us to ask you to teach, here's the invitation–give me a call!

We will be working on our 2009 programs on both continents soon, so if you have ideas, please let me know. As a member based organization, it is important to listen to our members' needs.

See you at the Annual Meeting in Colorado Springs—and maybe at a European conference or two in the coming year. I look forward to continuing already existing relationships and hope to work with others in the coming years.

Kazakh Health Authority Training

The following photos were generously supplied by the Kazakhstan health officials who attended the November TRI training.

PDA president Bob Myers models traditional Kazakh headgear (aiyr kalpak) and an overcoat (shapan) with Kazakhstan nationals who attended training at PDA earlier in the year

Before You Depart Colorado, Consider TRI Classroom Training

Colorado Springs, Colo. • April 17–18, 2008 • www.pdatraining.org/annual2008

Tim Morris, PDA

Every year following the PDA Annual Meeting, the PDA Training and Research Institute offers a complete collection of lecture courses—a perfect way to compliment the experienced gained from attending the conference sessions. This year will be no different, as PDA TRI boasts 11 courses in Colorado Springs.

Last year, TRI had an overwhelming response to the courses held in Las Vegas. We hope to carry on that trend in Colorado Springs by continuing to provide in-depth learning experiences that cater to you and your fellow colleagues. The selection of courses this year reaches a broad range of topics, so you will likely find one of the eleven training opportunities to be highly valuable to your career and company goals.

One of TRI's new 2008 courses is also making an appearance in Colorado Springs: *Mycoplasma in the Biotech and Pharmaceutical Industries.* Led by **Wayne Garafola,** Sartorius Stedim Biotech, this course will introduce attendees to mycoplasma organisms and discuss where they come from, how to detect them, why they are a concern and how to avoid them. Students will also learn to identify current FDA/EU guidelines concerning the isolation and culturing of mycoplasma organisms. This topic closely relates to the Mycoplasma track being offered at the annual meeting this year.

Three of the training courses held at last year's meeting in Las Vegas are returning in 2008: *Development of Qualification and Validation Protocols—A Risk Management Approach, Risk Estimation in Aseptic Processing* and *A Comprehensive Guide to OOS Regulations.* These courses proved popular in 2007 and have been updated in 2008 to include new information on the topics, giving students an intimate setting coupled with the expert knowledge and experience of **Harold Baseman**, **Klaus Haberer,** PhD and **Lynn Torbeck**.

Of course, all of our instructors for the Annual Meeting courses are proven experts in their fields and have successfully provided training over the past year in various PDA venues, including the Institute's new facility in Bethesda and on the road at various conferences and course series. If you plan on attending the 2008 PDA Annual Meeting, then rounding out your stay with one of the many TRI courses will allow you to return to your company better served, better equipped, and better prepared to face the current and future challenges that lie ahead. And it's convenient!

Jim Lyda, PDA, wears a Kazakh cap and poses with members of the Kazakhstan pharmaceutical industry

PDA Ireland Chapter presents:
Trends in Aseptic Processing—A Risk Management Approach

Emily Hough, PDA

The PDA Ireland Chapter on February 7 held their event at the William Jefferson Clinton Auditorium, University College Dublin. Eight Industry experts discussed a range of aseptic processing trends, and a number of suppliers showed off their goods and services, including Biomérieux Industry, MSC, Millipore and Jacobs.

Kristen Evans gave a thought provoking speech on *Process Simulations for New Aseptic Facilities.* Evans, waxed philosophically, stating that "Science has the problem of induction: No matter how much evidence we have for a conclusion, the conclusion could still conceivably be false."

PDA's Who's Who?

Noel Bagnall, PhD, Technical Development Director, Genzyme

Harold Baseman, Principal and Chief Operating Officer, ValSource LLC

Kristen Evans, Director of Global Quality Compliance, Amgen

Una Hearty, PhD, Associate Director/Quality Head, Wyeth

Tom Hodgkinson, Validation Manager, Genzyme

Kevin Schreier, Process Manager, Jacobs

Kevin Smyth, Process Manager, Jacobs

Phil Templeton, Managing Director, Aseptic Technology & Design Ltd

Harold Baseman challenged the audience in his lecture, *Introduction of PDA's Quality Risk Management for Aseptic Processing Technical Report,* to consider why industry needs a technical report on quality risk management of aseptic processing. He reviewed the benefits of managing the risk of aseptic processes, how QRMs add value to product and process and what the final result should be.

Kevin Smyth and **Kevin Schreier** in their presentation, *Minimizing Risk in Aseptic Facility Design and Delivery,* spoke about defining risk to the delivery of the final project. They spoke about risk mitigation and lessons that had been learned from recent local projects. According to Smyth and Schreier, the definition of risk is "the possibility of something bad happening." They said that the end product should equal what is focused on in the beginning of the project.

Tom Hodgkinson, delivered, *Development & Application of Risk Management at Genzyme Ireland.* He said that validation to a validation engineer is the "process wherby documented evidence is provided demonstration, with a high level of assurance, that a process is robust and reproducible."

Phil Templeton's lecture entitled, *Design, Commissioning and Qualification of an Aseptic Fill Finish Facility* concluded with operational considerations for isolators, RABBS and conventional cleanrooms.

Noel Bagnall's, *Start Up of an Aseptic Process,* gave valuable advice, "never put off until tomorrow what you can do today." He also mentioned that you never have enough spares, because as soon as you need one of something, that is the something that you can't find.

Una Hearty's presentation entitled, *Risk Based Approach to Qualification,* educated the audience about quality risk management and which tool to use for specific tasks within the aseptic processing domain.

The full day educational conference was broken up periodically for breaks and for a luncheon, so attendees could have an opportunity to seek out presenters for one-on-one time, as well as the chance to network. For more information on the Ireland Chapter and its upcoming events visit www.pdachapters.org/ireland.

(l-r) Michael Morris, IMB; Kristen Evans, Amgen; Tom Hodgkinson, Genzyme; Harold Baseman, ValSource; Georg Roessling, PDA; Una Hearty, Wyeth

2008 Europe Event Calendar

APRIL

2008 PDA Compendial Forum: Future Directions of the Pharmacopoeias (in cooperation with PH. Eur., JP and USP)

- Conference/Exhibition: April 1–2 | Frankfurt, Germany
- Training Course: March 31

JUNE

2008 PDA Virus & TSE Safety Forum

- Conference/Exhibition: June 3–5 | Berlin, Germany

PDA/EBE Biopharmaceutical Development and Manufacturing Meeting Global Challenges in Europe

- Conference/Exhibition: June 24–25 | Dublin, Ireland
- Training Courses: June 26–27

SEPTEMBER

2008 Pharmaceutical Freeze Drying Technology

- Conference/Exhibition: September 23–24 | Brussels/Wavre, Belgium
- Training Course: September 25

OCTOBER

Quality by Design

- Conference/Exhibition: October 7–8 | Frankfurt, Germany
- Training Courses: October 9–10

2008 PDA Visual Inspection Forum

- Conference/Exhibition: October 14–15 | Berlin, Germany
- Training Courses: October 16–17

PDA/ISPE Workshop with PIC/S

- Workshop: October 22 | Geneva, Switzerland

NOVEMBER

Pharmaceutical Cold Chain Management

- Conference/Exhibition: November 4–5 | Berlin, Germany
- Training Courses: November 6–7

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- ✓ ***Effectiveness Check***
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