Science • Technology • Quality • Regulatory • Community

PDA Letter

November/December 2006

Volume XLIII • Issue #10

In This Issue…

The Ultimate Connection: PDA's Joint Regulatory Conferences Facilitate Dialogue and Understanding

This past September and October, PDA provided its members and the industry at large with not one, but two joint regulatory conferences—the ultimate opportunity to connect with major health authorities.

First, we convened the 17th annual PDA/FDA Joint Regulatory Conference in Washington, D.C., Sept. 11–15. This meeting has become an important tradition within the pharmaceutical and biopharmaceutical industries and draws attendees from around the world. About 1,000 professionals attended the conference, exhibition and Training and Research Institute courses this year.

A month later—Oct. 10–13—PDA began what it hopes becomes an equally important tradition: the PDA/EMEA Joint Conference, Exhibition and Courses. We held the premiere meeting in the EMEA's home city of London, and over 400 industry and regulatory professionals attended. Representatives from the European Commission, EMEA and other regulatory agencies throughout the European Union provided overviews of the intricate European legislative and regulatory systems.

Both events boasted diverse attendance by sector (industry and government) and nationality. Out of the 400+ professionals in attendance in London, over 40 represented various health authorities from Europe—EMEA, Sweden, Germany, Ireland, Italy, France, Hungary, Netherlands, Czech Republic, United Kingdom, Malta, etc.—and from other parts of the globe—South Korea. In Washington, more than 30 representatives of the U.S. FDA were present to network with conference attendees, who came from places as far away as Japan, Taiwan, South Korea and Australia, and from many not-so-well-known U.S. locales like Dublin, Ohio; Billerica, Mass.; Liberty Corner, N.J.; and Mystic, Conn.

In this issue, we feature articles that recount highlights from these two important PDA events. Turn to page 17 to learn more about the first-ever PDA/EMEA conference and pages 18 and 23 to view a report from the 17th annual PDA/FDA conference. In addition, this month's "In Focus" spotlights these two events, beginning on page 36.

PDA
Parenteral Drug Association

Connecting People, Science and Regulation[SM]

Houston, We Have a Solution

PDA Training and Research Institute

Houston Training Course Series

February 12-14, 2007
Houston, Texas, USA

Eight Training Programs to Help You Maximize Efficiency

- Compliance Auditing of Cleanrooms and Controlled Environments
- Design Control
- Effective Quality Assurance Auditing
- Making the Grade with the FDA
- Q7A: Understanding the History, Intent and Application of ICH Q7A – *The International API Good Manufacturing Practice Guidance*
- Preparing for an FDA Pre-Approval Inspection
- So You Want to Do a Media Fill… **NEW COURSE!**
- Visual SOPs

Venue

Doubletree Hotel Houston Downtown
400 Dallas Street
Houston, Texas 77002-4777
USA
Tel: +1 (713) 759-0202
Fax: +1 (713) 759-1166

www.pdatraining.org
+1 (410) 455-5800

Web Seminars

PDA Parenteral Drug Association

Get the latest science, technology and regulatory information presented to you, live, from the convenience of your computer.

Designing a Cleaning and Disinfection Program in GMP Controlled Environments

November 15, 2006 | 1:00 p.m. – 2:30 p.m. EST

This presentation outlines how one would set up, validates and implements a successful cleaning and disinfection program and mirrors the training presented to FDA's CDER and CBER divisions.

Speaker: Art Vellutato, Jr., V.P. of Technical Support Operations and one of the two founders of *Veltek Associates, Inc.*

Investigations of Sterility Test Failures

November 21, 2006 | 1:00 p.m. – 2:30 p.m. EST

This presentation will include information allowing the participants to establish an initial checklist that can be customized to their facility's need.

Speaker: Scott V.W. Sutton, Ph.D., Pharma Consultant, Microbiology, *Vectech Pharmaceutical Consultants, Inc.*

A Critical Evaluation Of Compendial Water Systems Exhibiting The Absence Of Bacteria

November 30, 2006 | 1:00 p.m. - 2:30 p.m. EST

Four specific examples of the compendial designation of water with the anti-microbial agent, Added Substance and/or a Foreign Substance/Impurity as defined in the General Notices Section of USP, will be presented with system design overview, operating conditions, and data.

Speaker: William V. Collentro, Senior Consultant, *Water Consulting Specialists, Inc.*

Did you miss these PDA Fall Conferences?

- 2006 PDA/FDA Joint Regulatory Conference
- The Universe of Pre-filled Syringes and Injection Devices Forum

Don't worry, you can order selected sessions online and on-demand for the price of one web seminar.

Train your entire staff for one price.
Member US$ 395 | Nonmember US$450

www.pda.org/webseminars

Table of Contents

Cover art: PDA connected industry with FDA and EMEA in September and October.

Coming Next Month...
Risk Management/ Assessment

PDA
Parenteral Drug Association

Connecting People, Science and Regulation™

PDA Emerging Manufacturing and Quality Control Technologies Global Conference

January 29-31, 2007
San Diego, California

Register before January 15th and save!

Get a first-hand look at new and emerging manufacturing and quality control technologies designed for the pharmaceutical and biopharmaceutical industries. Company representatives will be on hand to explore the use of new innovations as potential tools to drive continuous process improvement while increasing manufacturing efficiency.

www.pda.org/emerging

President's Message

Bob Myers

PDA had another very successful year in 2006, our sixtieth! The aggregate volume of our various products and services offered to the membership (events, courses, technical pubs, etc.) increased by 10% over the previous year. Over the last two years, our volume has grown by 35%. Next year, our goal is an additional 15% increase in products and services, resulting in 50% combined growth for years 2005-2007.

This growth means PDA is providing programs, courses, publications and other products and services that our members require in order to improve their skills, increase their knowledge and advance their careers. Much of our growth in 2006 came in Europe, where our new staff led by **Georg Roessling** met the challenge of providing a valuable line-up of programs throughout the year. The crowning achievement of the year in Europe was the fantastic PDA/EMEA Joint Conferencce—the first of what we anticipate will become an annual event. Over 400 industry professionals turned out in London for courses, exhibits and the conference. Georg and his team—**Jim Lyda** and **Volker Eck**—have helped to expand the Association's influence and relevance throughout Europe.

In the United States, the Annual Meeting in Anaheim and the PDA/FDA Joint Regulatory Conference in Washington were the largest of many successful meetings and courses. Just this October, nearly 500 professionals visited Bethesda, Md., to attend PDA's prefilled syringes conference—the third and largest conference on this topic we have sponsored to date. Our volunteer members and sponsors provide the resources we need to provide high-quality programming, and our very own **Wanda Ballard-Neal** (Programs and Meetings) and **Nahid Kiani** (Sales) are responsible for the excellent venues, networking activities and exhibits that accompany these meetings.

The Training and Research Institute had another successful year as well, and you can read VP of Education **Gail Sherman's** year-end-review on page 46.

Our plan for 2007 includes significantly more programs, meetings and educational opportunities. While many of these events might not be as large as those in 2006 in terms of total attendance, we will have 30 meetings globally versus 17 in 2006. Many more conferences will be offered in Europe to better serve our growing membership there. Early next year, we will make announcements regarding a number of new programs, so keep checking the *PDA Letter,* the *Connector* and the website.

We worked hard to enhance our sterilization and technical report program. Sterilization is one of PDA's core strengths, and Technical Report No. 1: *Moist Heat Sterilization* is one of the Association's most well-known and practical technical publications. The process of revising this nearly 30-year-old document has been a long one, and one of the goals I assigned to Sr. VP of Scientific and Regulatory Affairs **Rich Levy,** PhD, was to expedite this process and have a new version out by early 2007. I'm pleased to announce that this process is on track, and we anticipate TR-1 to publish in early 2007. We published two technical reports in 2006—six since January 2005. We anticipate publishing five to six TRs in 2007 on practical and relevant topics.

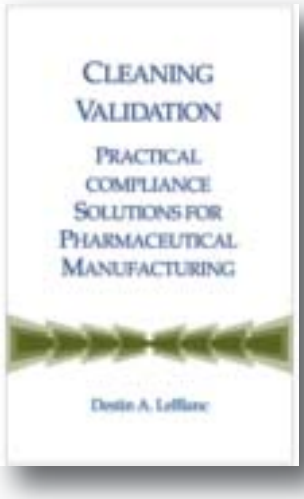
Another exciting development has been the consolidation of TRI and the PDA Headquarters in Bethesda. The first stage of the consolidation took place in August when we moved the HQ from 3 Metro Center to Bethesda Towers. Now, plans are in place to build a state-of-the-art training lab, cleanroom and lecture area on the first floor of our new location. We were delighted to work with **Vectech Pharmaceutical Consultants, Inc.** in designing the facility (see Gail Sherman's message in the October *PDA Letter*). I am extremely pleased to announce that **Fedegari Autoclavi SPA** has pledged to donate a state-of-the-art autoclave to the facility, which will allow us to create a number of new steam sterilization courses based on the revised TR-1. We expect the new TRI facility to open in June 2007.

All of these developments made PDA's sixtieth year special. We worked hard this year to recognize our proud past and those contributors who haved helped PDA grow over the years. The excellent feedback we received from the members throughout the year helps us plan for the future needs of our community.

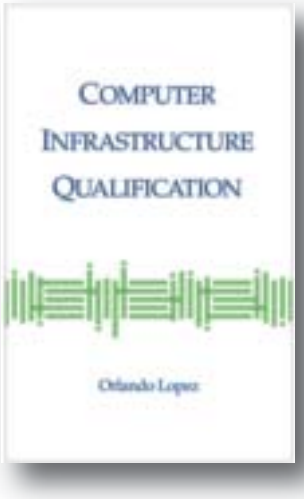
I am looking forward to next year and beyond!

PDA Parenteral Drug Association *Bookstore*

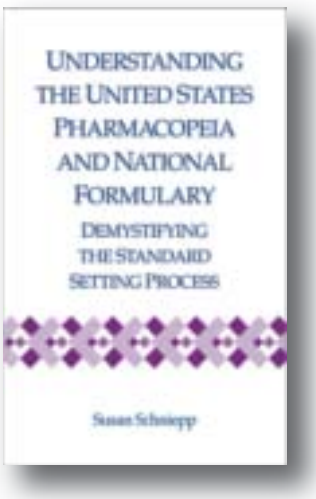
New PDA/DHI Publications



Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing
By Destin A. LeBlanc
Item No. 17253



Computer Infrastructure Qualification: For FDA Regulated Industries
By Orlando Lopez
Item No. 17251



Understanding the United States Pharmacopeia And National Formulary: Demystifying The Standard Setting Process
By Susan Schniepp
Item No. 17250

2006 December Clearance Stock Sale

30% Off
PDA Technical Reports (Sale applies to hardcopy versions only)

30% Off
PDA Archive on CD-ROM (Item no. 01101)
PDA Technical Archive CD-Rom 2005 Update (Item no. 01002)

Please remember to enter or include the coupon code: DEC06/30 when ordering online or on mail/fax orders. (no refund is granted)

Sales period: December 1, 2006 – December 31, 2006.
(All payments must be received on or before December 31, 2006)

ISO/IEC 17025:2005 and Pharmaceutical Testing Laboratories

M.L. Jane Weitzel, Watson Laboratories

Have you heard of ISO/IEC 17025:2005, general requirements for the competence of testing and calibration laboratories? If you are responsible for a laboratory operation in the pharmaceutical industry, this is a valuable document for you to understand.

Why do you need to know about ISO/IEC 17025?

ISO/IEC 17025 represents a complete, detailed, and internationally recognized quality management system (QMS) for laboratories. ISO/IEC 17025 refers to QMS simply as the "management system." Developing a laboratory quality system to meet the requirements of ISO/IEC 17025 ensures the QMS's consistency, completeness and uniformity. It also ensures the technical requirements unique to a laboratory are met.

The applicability of ISO/IEC 17025 to testing laboratories in the pharmaceutical testing area is demonstrated by the number of regulatory laboratories accredited to it. In 1999, the U.S. FDA adopted ISO/IEC 17025 to drive the quality systems for its labs. Now, all the regional labs have been audited to ISO/IEC 17025 and most have received their accreditation. Health Canada's Health Products and Food Branch Inspectorate laboratory is also accredited under ISO/IEC 17025.

ISO/IEC 17025 describes a laboratory QMS in greater detail than GMP regulations. More detail is given on how to establish traceability for a test result; traceability is more than using a U.S. Pharmacopeia standard. The standard clarifies that each test result should be accompanied by its measurement uncertainty so the end user of the data can make informed decisions using the data. The requirement to demonstrate technical proficiency is spelled out in the standard.

A laboratory QMS aligned with ISO/IEC 17025 will ensure the laboratory's test methods are well understood, preventing unnecessary testing and unneeded investigations. The exercise of estimating measurement uncertainty enables the laboratory to ensure the test method is fit for use and to possibly identify improvements for the method. Properly defining traceability ensures the laboratory's test results can be compared to those test results generated in other laboratories. All these benefits result in a more efficient and effective laboratory—a real business saving.

What does accreditation to ISO/IEC 17025 mean?

A laboratory accredited to ISO/IEC 17025 incorporates an overall system for technical and quality management, which results in benefits observed in daily laboratory practices. The laboratory's quality system and test methods are evaluated by an independent accrediting body and its technical competency is demonstrated through proficiency testing. The accreditation demonstrates a commitment to continuous improvement and to demonstrating technical capability. Additionally, accreditation ensures confidence in test results.

ISO/IEC 17025 includes requirements for both the quality system and the test methods. Testing laboratories that comply with this international standard will therefore also operate in accordance with the principles of ISO 9001 quality management systems. Although both ISO 9001 and ISO/IEC 17025 define management system requirements, only ISO/IEC 17025 can be used to demonstrate the technical competence specific to laboratories.

The utility of the standard is its emphasis on the technical requirements unique to laboratories. These requirements include:

- Personnel
- Accommodation and environmental conditions
- Test methods and method validation
- Uncertainty of measurement
- Equipment
- Measurement traceability
- Sampling
- Handling of test items
- Ensuring the quality of test results
- Reporting the results

The laboratory accreditation process involves assessing the quality management system and technical competence of laboratories in accordance with the requirements of ISO/IEC 17025. Before becoming accredited, laboratories are assessed, test procedures are witnessed and reviewed and QMS and technical records are evaluated.

Guides have been developed to assist in understanding and implementing ISO/IEC 17025 in pharmaceutical test laboratories. One such guide is published by AOAC INTERNATIONAL, titled *AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals*. The guide is available from AOAC (www.aoac.org).

PDA & 17025:2005

The usefulness and relevance of ISO/IEC 17025 to testing laboratories in the pharmaceutical industry is becoming more apparent each day. It is a topic PDA should follow more closely.

ISO and IEC

ISO: International Organization for Standardization

IEC: International Electrotechnical Commission

PDA Parenteral Drug Association

Global PAT Conference

Hyatt Regency Bethesda
Bethesda, Maryland
May 21-22, 2007

Call for Papers/Exhibitors

Dear Friends and Colleagues:

The PDA Global PAT Conference Program Planning Committee invites you to submit an abstract for presentation (approximately 30 minutes) at the PDA Global PAT Conference in Bethesda, Maryland, May 21-22, 2007. We are looking for **case studies** detailing all aspects of a Process Analytical Technology (PAT) development and implementation project, including:

- Strategies for developing a meaningful business case, risk and opportunity evaluations
- Approaches to regulatory submissions for PAT applications (FDA and EMEA)
- Working within your organization to implement PAT: The business case; Impact on roles (Quality/Regulatory/Manufacturing); Overcoming organizational obstacles
- Use of PAT in the development interface in support of quality-by-design principles
- Implementation in manufacturing for legacy products and pipeline products
- Developing the PAT toolbox for implementation across multiple applications
- Improve product quality and operator safety via process containment
- Reduce the Burden of Offline Laboratory Testing: In-process and end product
- Use of data-rich experiments and chemometrics
- Qualification requirements for PAT

All submitted abstracts will be reviewed by the Program Planning Committee for inclusion in the meeting or for poster presentation.

Visit www.pda.org/pat to submit your abstract.
Abstracts must be received by Friday, December 15, 2006 for consideration.

Please include the following information and follow the steps identified in the Abstract Manager.
Submissions received without full information will not be considered.

- Title
- Presenter's biography
- Additional authors
- Full mailing address
- Email address of the presenter and co-presenters
- 2-3 paragraph abstract, summarizing your topic and the appropriate forum (case study, discussion, traditional, panel, etc.)
- Target audience (by job title/department)
- Audience take-home benefits
- Key learning objectives

Commercial abstracts featuring promotion of products and services will not be considered. Upon review by the program committee you will be advised in writing of the status of your abstract after January 15, 2007. PDA will provide one complimentary registration per presentation. Additional presenters are required to pay appropriate conference registration fees. All presenters are responsible for their own travel and lodging, with the exception of health authority speakers.

ATTENTION EXIBITORS

PDA is seeking vendors who provide excellent products/services in support of this conference.
Space is limited and is on a first come, first serve basis.
To reserve your space, please contact Nahid Kiani at Kiani@pda.org or +1 (301) 656-5900 x 128.

Recent Sci-Tech Discussions: Stopper Inoculation, EMEA PQRs and Quality Agreements

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.

QUESTION 1

A colleague of mine has asked me about the regulatory basis for why we do direct stopper inoculation versus spore strips in sterilization validation of stoppers. I am aware that the resistance of spore populations is substrate dependent, and replied to my colleague that this is the reason we use direct inoculation for stoppers at our facility. I am convinced there is a scientific basis for direct inoculation, but what is the regulatory basis? I would appreciate an answer on this topic from any of the members of this mailing list.

Respondent 1: The regulatory basis for this requirement is that it is good science and cGMP, i.e., other folks are doing it. Of course, if one doesn't do it and relies on spore strips, one might find oneself putting a nonsterile product on the market, which could kill hundreds or thousands before you are aware of it. Folks like your colleague…seem to be of the opinion that every tiny requirement is documented in the regulations/guidance, which of course is impossible, and they have the view that if it [is not] documented there, then it is not required. Tell him/her there is nothing in the regulations about paying his salary in full or on time. I usually find this puts an end to such nonsense. There is an article by Jeanne Moldenhauer and Sandra Rubio on this topic….Can't remember the title, but if my good friend Jeanne is watching, maybe she can elucidate. May be worth seeing if there is anything in the USP.

Questioner: Thanks for the reply [Respondent 1]. I agree with your frustration. Knowing that the resistance of endospores is substrate-dependent, and that the resistance of endospores on stoppers is typically higher than the resistance of endospores on strips, the scientifically sound approach is to use direct inoculation. As far as I am concerned, good science should equal good compliance.

Respondent 2: The article [Respondent 1] had suggested is "Effect Of Rubber Stopper Composition, Preservative Pretreatment And Rinse Water Temperature On Moist Heat Resistance Of B. Stearothermophilus Atcc., 12980" PDA *Journal of Pharmaceutical Science and Technology,* Vol:49 No.1, Jan/Feb 1995. I hope it helps.

Respondent 3: You might also want to review the drafts of PDA's Technical Report No. 1.

Respondent 4: This is an interesting topic and one that I have had some exposure to (working in Validations). My problem is that we have a rubber stopper (Chloro Butyl) which we sterilize for 30 minutes at 122°C, and have done for years. We run for 15 minutes at a 121.7°C half-cycle validation to prove sterilization (using BI ampoules). When we spiked the stoppers with B. stearo endospores (where the stock suspension has a D Value of 1.8), we ended up with a spiked stopper where the D value is now 3.7 leaving an estimated total kill time of around 37 minutes. Of course, this cannot be validated via the current half cycle without increasing the approved production cycle to 60 minutes at 122°C. In my opinion, 60 minutes at 122°C would be an incredible level of overkill. This leaves the following scenario: Do we push the cycle to 60 minutes and risk having issues with stopper flow/machine ability? Or is there another way of validating the kill of these Spiked Stoppers (Fraction - Negative etc.) without having to change our production cycle parameters? Any information on the best approach, etc. would be very useful.

Respondent 3: You might try changing to a combined biological indicator bioburden based sterilization model, which would reduce the cycle time.

Questioner: This is a situation in which a half-cycle approach is not necessarily the best approach. Pre-washed and siliconized stoppers should have a low bioburden to begin with. I would suggest a mixed bioburden/biological indicator approach in this case. What do others think about this?

Respondent 5: This is a situation where you should consider one of [my] rules of life. For the past more than 25 years, I have conducted or participated in training programs for the drug and biotech industry. This has given me an opportunity to interact with a great many capable industry scientists. I have learned a lot by listening to participants in my courses…The rule of life in this situation is: When very intelligent people have difficulty finding an answer to a question, then the question is wrong and it is time to change the question. So, what should be a more appropriate question in your situation? One of the topics that I was responsible for teaching is development and validation of sterilization cycles. You can make a legitimate case that ➤

PDA Parenteral Drug Association Bookstore

Bestsellers

Environmental Monitoring, Volume I, Volume II and Protocol CD
Edited by Jeanne Moldenhauer, PhD

Item No. 17239 PDA Member $530 Nonmember $659

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
by James L. Vesper
Item No 17219 PDA Member $210 Nonmember $260

PDA Archive on CD-ROM – PDA Archive Retrieval Index (2006 version)
Item No. 01101 PDA Member $395 Nonmember $590

Encyclopedia of Rapid Microbiological Methods, Volume I, II, III,
edited by Michael J. Miller, PhD
Item No. 17252 PDA Member $730 Nonmember $899

The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance
by Siegfried Schmitt, PhD
Item No. 17234 PDA Member $225 Nonmember $279

Successfully Validating ERP Systems (and other large, configurable applications)
by David Stokes
Item No. 17245 PDA Member $250 Nonmember $309

Filtration Handbook Series
by Maik W. Jornitz and Theodore H. Meltzer, PhD
Item No. 17262 PDA Member $420 Nonmember $525

Pocket Code of Federal Regulations GMP Guide – 2006 Edition
Item No. 13004 PDA Member $4 Nonmember $10

Laboratory Validation: A Practitioner's Guide (20% OFF)
edited by Jeanne Moldenhauer, PhD
Item No. 17201 PDA Member $295 Nonmember $369

Risk-Based Software Validation: Ten Easy Steps
by David Nettleton and Janet Gough
Item No. 17256 PDA Member $200 Nonmember $249

To Order: +1 (301) 656-5900 www.pda.org/bookstore

the D value of the BI microbe is the critical parameter in this situation. If you follow this strategy, then this leads to some questions/options. What you should do is provide justification for the approach you have applied to your situation, because your approach seems correct. You could do a study of bioburden of the stoppers, identify the microbes you recover and do a D value study of the actual bioburden microbes. Then design a bioburden-based cycle.

This would not be my choice. I would suggest staying with the approach you have used. I would anticipate that the sterilized stoppers would pass the sterility test. You could do a study of the bioburden of sterilized stoppers. I would anticipate that you would get zero recovery. You could design a "stress test" by suspending the sterilized stoppers in growth media and demonstrate "no growth." In dealing with quality and compliance issues, industry scientists forget the first [of my rules] of achieving quality and regulatory compliance, which is: Quality compliance begins and ends with good science. Quality compliance will provide a basis for regulatory compliance. Industry professionals, regulatory professionals and scientists often look at such issues on the basis of conventional approaches or what FDA did to or accepted for another company. But the reality is that each situation is unique to a specific product, a specific company and specific operation within the company. If you provide adequate scientific justification, regulatory agencies will deal with it and accept it. You may be called upon to provide clarification and answers, but you should be able to do that. There is another quirk of compliance that you should note. If enough companies do the wrong thing, the wrong test or the wrong procedure, then it becomes "current practice" and next it becomes a regulatory requirement because it is the general industry "current practice." An appropriate scientific study, with justification based on sound science and sound data analysis, will win over an unrealistic current practice. So go for it. Stay with your current practice. Develop the supporting data, if needed, to argue for it. Good luck.

Respondent 3: Getting no growth on a sterility test is very different from getting a PNSU of 10^2-6. You can get no growth long before you achieve the desired sterility assurance levels.

Respondent 5: Good point. I was working backwards. After you sterilize using a given cycle, what additional data can you collect to support your sterility cycle design? One is already assuming that

the sterilization cycle design is correct, one can assume that you have achieved required Sterility Assurance Level (SAL). I think Respondent 4 is using an appropriate approach to design the sterilization cycle. Sometimes, people can get into unnecessary complications by being incorrectly rigid in interpreting what constitutes regulatory compliance. The key issue is validity of the sterilization cycle. Besides BI ampules, what additional data should one consider to further support the cycle design?

Respondent 3: There are also a variety of articles published by Tom Berger and Mike Korczynski on this topic. Pfizer [Monique Reisterer] gave a presentation at [the 2006 PDA Annual Meeting]…on specific stopper formulations and the potential to group formulations.

QUESTION 2

The requirement to perform product quality reviews (PQRs) for APIs under ICH Q7A (section 2.5 of the EMEA document) are quite different than those PQR requirements outlined in The new Chapter 1 (Quality Management) of the EU GMP Guide (section 1.5).

The latter document applies to all licensed medicinal products. Medicinal products have been defined as a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Therefore could you define an API as a medicinal product? If so, wouldn't the latter document apply to APIs when it comes to requirements for what should be part of your PQR?

Respondent 1: Yes. APIs are covered by Annex 18 of the EMEA guidance on GMP. I believe it may now be called Part II of the guidance. This means all of the other parts of the guidance are applicable including the need for APQR. The only part of GMP which does not apply is the need for a qualified person (QP) release, *but* the QP releasing the finished product *must* confirm that APIs were manufactured in accordance with GMP, etc.

QUESTION 3

Is it usual practice to enter into formal quality agreements with API and excipient vendors?

Respondent 1: Yes, for APIs and increasingly for excipients. I recommend you read my recent publication "Managing Microbiological Quality of Pharmaceutical Excipients" that appeared in the November-December 2005 *PDA Journal of Pharmaceutical Science and Technology.*

Respondent 2: Not only is it usual practice, it is essential! This is for many reasons, and under the new EU regs, I would suggest that your QP would be very unhappy without this sort of agreement because he/she is now required to take responsibility for the API being manufactured under GMP.

Respondent 3: The recent discussion on Quality Agreements prompts me to ask a related question: Who signs the Quality Agreement and what is the relationship with a supply contract?

I have seen the agreements incorporated as an exhibit in the supply contract without any signatures on the agreement itself. I have also seen them as separate agreements signed by the heads of quality at the sponsor and supplier. I like this concept in that it reinforces the point that the sponsor's QA is delegating defined quality system responsibilities to the supplier's QA unit. However, it can cause confusion with the contract which may have very similar language in it. A third version is to incorporate the QA agreement, with QA signatures, as an attachment to the contract. Any preferences?

Respondent 2: I suspect that it all depends on where you are based. I believe that in Europe the most common format is to have separate agreements. This could even run to three, a commercial agreement, for example for the purchase of an MA, a supply agreement and a quality agreement. Also possible is that the quality agreement could be included in the supply agreement, or even distributed between the two. In the United States I believe it tends to be one agreement. All this is based on fairly limited experience.

Respondent 4: For the EU (EEA) the guidance requirement (and therefore the legal requirement) is that the contract giver and contract acceptor will have an "agreement" as to who is responsible for what. Often it is overlooked by the powers that be as they comfort themselves in the knowledge that the contract is in place. Alas the contract in my experience is nearly always restricted to commercial issues and it doesn't address the GMP need as above.

My preference if for a commercial contract signed by the lawyers, etc., that INCLUDES a reference to a separate document detailing the responsibilities for the contract giver and contract acceptor as required by GMP. As this latter element involves GMP, it should be signed by QA chaps as well as other appropriate personnel. This is a current hot potato with European regulators.

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. Any PDA member can join one or more Interest Group by updating their member profile (www.pda.org/pdf/join_IG_instruction.pdf). Please go to www.pda.org/science/IGs.html for more information.

North American Interest Groups

Section Leader	Frank Kohn, PhD *FSK Associates*	David Hussong, PhD *U.S. FDA*	Don Elinski *Lachman Consultants*	Sandeep Nema, PhD *Pfizer Inc.*	Robert Dana *PDA*
Section Title	**Biopharmaceutical Sciences**	**Laboratory and Microbiological Sciences**	**Manufacturing Sciences**	**Pharmaceutical Development**	**Quality Systems and Regulatory Affairs**
Related IGs and Group Leaders	**Biotechnology** Group Leader: Jill Myers *BioPro Consulting* E-mail: jmyers@bioproconsulting.com **Lyophilization** Group Leader: Edward H. Trappler *Lyophilization Technology* E-mail: etrappler@lyo-t.com **Vaccines** Group Leader: Frank S. Kohn, PhD *FSK Associates Inc.* E-mail: fsk@iowatelecom.net	**Analytical Labs/ Stability** Group Leader: Rafik H. Bishara, PhD *Eli Lilly & Co.* E-mail: rafikbishara2@yahoo.com **Microbiology/ Environmental Monitoring** Group Leader: Jeanne E. Moldenhauer, PhD *Vectech Pharm. Consultants, Inc.* E-mail: jeannemoldenhauer@yahoo.com **Visual Inspection of Parenterals** Group Leader: John G. Shabushnig, PhD *Pfizer Inc.* E-mail: john.g.shabushnig@pfizer.com	**Facilities and Engineering** Group Leader: Chris Smalley *Wyeth Pharma* Email: smallec2@lwyeth.com **Filtration** Group Leader: Russ Madsen *The Williamsburg Group, LLC* E-mail: madsen@thewilliamsburggroup.com **Pharmaceutical Water Systems** Group Leader Theodore H. Meltzer, PhD *Capitola Consulting Co.* E-mail: theodorehmeltzer@hotmail.com **Sterile Processing** Group Leader: Richard Johnson *Fort Dodge Animal Health* E-mail: johnson@fdah.com	**Clinical Trial Materials** Group Leader: Vince Mathews *Eli Lilly & Co.* E-mail: vlm@lilly.com **Combination Products** Group Leader: Michael Gross *QLT Inc.* E-mail: mgross@qltinc.com **Packaging Science** Group Leader: Edward J. Smith, PhD *Wyeth Pharmaceuticals* E-mail: smithej@wyeth.com **Process Validation** Group Leader: Harold Baseman *ValSource, LLP* E-mail: halbaseman@adelphia.net	**Inspection Trends/ Regulatory Affairs** Group Leader: Robert L. Dana *PDA* E-mail: dana@pda.org **Quality Systems** Group Leader: David Mayorga *Global Quality Alliance, LLC* E-mail: david@gqaconsulting.com

European Interest Groups

Related IGs and Group Leaders	**Biotech** Group Leader: Roland Güenther *Novartis Pharma AG* E-mail: roland.guenther@pharma.novartis.com	**Visual Inspection of Parenterals** Group Leader: Markus Lankers, PhD *Rap.ID GmbH* E-mail: markus.lankers@rap-id.com	**Filtration** Group Leader: Roger Seiler *Sartorius SA* Email: roger.seiler@sartorius.com **Production and Engineering** Group Leader: Philippe Gomez *Sartorius SA* Email: Philippe.gomez@sartorius.com **Prefilled Syringes** Group Leader: Thomas Schoenknecht, PhD *Bünder Glas GmbH* Email: tschoenknecht@gerresheimer.com	**Combination Products** Group Leaders: Alexandra Schlicker, PhD *F. Hoffman La Roche AG* E-mail: alexandra.schlicker@roche.com Georgios Imanidis, PhD *University of Basel, Pharmaceutical Technology* E-mail: georgios.imanidis@unibas.ch	**Nanotechnology** Group Leader: D F Chowdhury *Aphton BioPharma* E-mail: Fazc@aol.com **Technology Transfer** Group Leaders: Volker Eck, PhD *Nerviano Medical Science S.r.l* E-mail: Volker.eck@nervianoms.com Zdenka Mrvova *Zentiva* E-mail: mrvova@leciva.cz

Worried about who's looking over your shoulder?

Relax. PDA's Career Center is 100% Confidential

- Create, edit and store your anonymous resume and cover letter for free
- Reveal as little or as much personal information as you like
- Search and apply to a variety of pharmaceutical and biopharmaceutical jobs ranging from entry level to executive level
- Receive e-mail job alerts that notify you of newly added jobs specifically matching your search criteria so you never miss out on an opportunity

PDA℠
Parenteral Drug Association

Connecting People, Science and Regulation℠

www.pda.org/careers

HAZARD AREA MICROBIAL MONITORING

SMA *MICROPORTABLE* CFM LITERS MADE FOR PHARMACEUTICAL AND BIOTECH OPERATIONS

A rechargeable battery operated microbial air sampler for determining the level of existent viable contaminants in aseptic manufacturing operations.

- *Mirror Finished 316L Stainless Steel Construction*
- *Calibrated Flow interchangeable to Liters or CFM*
- *Dual Flow Rate of 1.0 CFM (28.3 Liters) or 5.0 CFM (141.5 Liters)*
- *Rechargeable Battery (8 hour continuous operation)*
- *Automatic Shutoff after sample*
- *Flat Panel control pad*
- *Small size: 10 ½" h x 6 ½" w, 8.8 lbs.*
- *Uses standard 100mm Agar Plates*
- *Uses our autoclavable standard SMA Atrium Top*
- *Preset Volume Sample Control*
- *Includes Recharge Kit*
- *Easy Carry Handle*
- *Battery Low Warning Light*
- *CE Certified*

Class 1 Division 2 Hazard Safe

SUPERIOR PRODUCTS • SUPERIOR IDEAS • SUPERIOR SOLUTIONS

vai
Veltek Associates, Inc.
(610)-644-8335
www.sterile.com

INNOVATIVE CLEAN ROOM PRODUCTS

European Regulatory Process Mapped at 1st PDA/EMEA Joint Conference

400+ Professionals Attend Inaugural Event

Walter Morris, PDA

Through a web of treaties and legislation, the federal system known as the European Union has resulted in the standardization of governance among the growing number of member states. For the pharmaceutical and biopharmaceutical industries, this has meant standardization of marketing authorization regulation and enforcement, coordinated by the European Medicines Agency (EMEA).

Over 400 professionals representing industry, government and academia attended the first PDA/EMEA Joint Conference, Exhibition and TRI Courses in London, Oct. 10-13. They experienced a program designed to provide a comprehensive overview of the entire European regulatory system for bio-/pharmaceuticals, starting at the top with a discussion of the legislative and regulatory processes, continuing down to inspections and GMPs, drilling down further to member state implementation, and then delving into very specific elements of the regulations.

The opening plenary session, "Understanding the EU Regulatory Framework," laid out the foundation on which GMP in the European Union is based. Speakers expounded on how law-making occurs at the EU level and how it is implemented in the member states. They also outlined the roles of the Union's various review and oversight organizations (e.g., EMEA, EU Commission and EDQM). Finally, the session dealt with inspections.

Following opening remarks by program planning committee members, **Martin Terberger,** Head, Pharmaceuticals Unit, European Commission, gave the first presentation—called "Legislation and How it is Made"—of the conference. His goal was to introduce attendees to the system of European legislation, an "ambitious task because everybody will agree that in Europe we have a quite complex system of issuing legislation," he said.

A topic worthy of a "whole conference," Terberger did an exemplary job of providing an introduction to the EU legislative process in 20 minutes.

The entire system of governance under the European Union is specified in a series of treaties, or what Terberger called the "foundation of all we are doing in Brussels." These treaties form the three pillars of the Union: the European Communities (EC), the Common Foreign and Security Policy and the Police and Judicial Cooperation in Criminal Matters.

Terberger outlined the areas of the Union relevant to pharmaceutical manufacturers. "Pharmaceutical regulation takes place under the first pillar,

continued on page 20

PDA and EMEA: Meet Again?

During their opening remarks, members of the program planning committee expressed optimism about the quality of the program and about the PDA/EMEA conference becoming an annual event.

Committee member David Cockburn, Inspections Sector, EMEA: "The high number of attendees at this first event demonstrates the high level of interest that there is within the GMP community in the topics under discussion on the agenda. One of the primary aims of the conference is to create a better understanding of the European pharmaceutical framework in the GMP area, which can be considered fairly complex."

Committee co-chair Anders Vinther, CMC Biopharmaceuticals: "When Tim Marten and I and all the people at PDA a couple of years ago started talking about maybe having a PDA/EMEA joint conference, what we hoped to create was an event where people would be updated on what is happening in terms of regulations, what is the European regulatory framework, what is happening in terms of new guidelines, inspection trends and so on—also to create an event where people would have a chance to network and speak to colleagues in industry and colleagues in the regulatory agencies. And when you finish the meeting hopefully you will say, 'Now I feel I'm really up-to-date with everything that is happening in Europe in the regulatory and quality area.' We hope that is the feeling you will have when you leave this conference tomorrow….This is going to be a fantastic meeting!"

Committee co-chair Tim Marten, AstraZeneca: "I'd like to welcome you all to this first—I hope—PDA/EMEA conference. Those of you who have been to the United States and seen the PDA/FDA conference know that it is a fantastic opportunity to interact with regulators from the FDA. And here, it is even better because we have regulators from virtually every European member state health authority represented, so you have the opportunity to interact with so many different people. So I'm really pleased to see so many people here today."

PDA President Bob Myers following the conference: "PDA could not have been more pleased with the results of our inaugural PDA/EMEA Joint Conference. I know everyone within PDA and the members of the program planning committee would like for this event to become a regular one."

2006 PDA/FDA Conference: Kellogg School Professor Links Quality to Upper Management

Walter Morris, PDA

If you are still not convinced of the importance of quality management in the manufacturing operation, you did not hear **Daniel Diermeier,** PhD, IBM Distinguished Professor of Regulation and Competitive Practice, Kellogg School of Management, Northwestern University, present at the 2006 PDA/FDA Joint Regulatory Conference.

In the opening session called "Strategically Applying Regulations and Quality Management in the Business Environment," Diermeier captivated the more than 600 "hard" scientists in attendance with his "social science" analysis: "Quality in Healthcare—Anticipation and Management." The session was moderated by **Paul Allen,** VP, Managing Partner Life Sciences, Clarkston Consulting. In the second presentation of the session, Deputy FDA Commissioner for Policy **Scott Gottlieb,** MD, provided an overview of FDA's "Critical Path Initiative."

Diermeier demonstrated great skill at taking common sense observations about public perceptions towards quality in different industries to make a compelling case for strong quality management within the pharmaceutical industry. He noted that of all the common consumer industries, none requires high-quality products across product lines and producers like the drug industry. Diermeier stated that industries such as automobiles, hotels and furniture don't require a consistent high level of quality for all consumers. For example, certain consumers of automobiles accept potentially lower quality cars (Fiat according to Diermeier), while others demand much higher quality cars (Mercedes-Benz or Jaguar according to Diermeier). For pharmaceuticals, on the other hand, all consumers expect high-quality drugs.

Diermeier also discussed how important it is for pharmaceutical companies to manage the public perception of the quality of their products. He stated that quality and/or compliance problems can rapidly spin out of the company's control, unless the firm manages the situation at a very early stage.

In Object 1 below, Diermeier exhibits how managerial control over an adverse event decreases rapidly after the situation is "triggered":

Object 1

To demonstrate the importance of quality perception management, Diermeier cited a case involving Bausch & Lomb from earlier this year. The U.S. Centers for Disease Control and Prevention linked a surge in fungal infections to the company's **ReNu Moisture Loc** contact lens solution. "Within 48 hours Bausch & Lomb's stock price dropped 21%, and the drop was sustained," Diermeier reported. The situation resulted in "$637 million in destroyed shareholder value."

Diermeier advised the companies to do a better job of monitoring and understanding qualitative information about their products. While investment in QA/QC is usually very high, companies often fail to recognize early warnings coming out of the mass media and new online sources (e.g., blogs, message boards) that a quality or safety problem is impacting a product.

The conference's second plenary session provided a unique opportunity for audience members to discuss strategic quality management principles with Diermeier and two industry CEOs: **Josh Boger,** PhD, Vertex Pharmaceuticals Incorporated and **Guy Villax,** Hovione. Paul Allen moderated the discussion.

Both Diermeier's and Gottlieb's presentations with slides, as well as the entire discussion session with the CEO's are available "On-Demand," at **www.pda.org/webseminars/ondemand.html.**

Daniel Diermeier, Northwestern University

Let Our Expertise Be Your Safety Net

We're Texwipe®. We're Here to Help.

The technical expertise at ITW Texwipe is your assurance of the most reliable contamination control for your cleanroom. Our broad line of consumables includes the right product for your specific application.

When you specify Texwipe, we support you with training, educational tools and protocol recommendations.

Whether you operate a Class 1 or Class 100,000 cleanroom in a sterile or an industrial environment, our products ensure your operation runs as it should. We help you reduce your cost of ownership by providing the right products to optimize your cleaning protocols.

Visit our website to find the optimum solutions for your specific applications. Or call us. We're Texwipe. We're here to help.

Dry Wipers • Pre-Wetted Wipers • Swabs • Sterile Products • Stationery • Mops

ITW Texwipe®

Quality. Consistency. Support.

	North America	Europe	Asia
Tel	201 684 1800	+45 87 400 220	+65 6468 9433
Fax	201 684 1801	+45 87 400 222	+65 6468 6772
E-mail	info@texwipe.com	europe@texwipe.com	asia@texwipe.com

www.texwipe.com

Intricate European Regulatory Process Mapped at 1st PDA/EMEA Joint Conference, continued from page 17

which is the European Community, and this is basically…the area of the internal market—the free movement of goods—that we want to regulate." Under the auspices of the EC, legislation concerning public health is issued pertaining to goods moving within the Union, both domestic and imported.

Four specific legal instruments are established by the treaties giving the EC the power to regulate public health. "This is very important for you to understand how far different legal instruments are binding directly and how far they need transposition from member states," said Terberger.

Four Legal Instruments in the EU

Regulations: binding precise rules that allow no discretion for interpretation

Directives: binding general rules that require transposition into member state law

Decisions: binding precise rules applicable to specific situations/entities

Recommendations and opinions: nonbinding opinions of the EC

The regulations are directly binding and applicable in all member states. "In this way, they have to be precise enough to be directly applied by industry and by citizens," explained Terberger. "So actually they don't give large freedom or discretion for interpretation, at least they shouldn't."

Directives are binding to member states, but have to be transposed by member states into their national law, a "separate legal act." Terberger noted that directives are normally issued because member states "insist to have this discretion in the transposing act" and/or because the substance of the directive should be "less distinct and less precise than in a regulation. So member states actually have to transpose it in order to give it the necessary level of detail and to instruct citizens and enterprises clearly what they have to do."

Decisions are based on secondary legislation and are directly binding to those parties (companies, individuals, etc.) for whom they are based. There is no second act of transposing and no discretion. Finally, recommendations and opinions are used infrequently with respect to pharmaceuticals.

Following this overview, Terberger reviewed how the various instruments are used to regulate the industry. The EMEA and the current centralized procedure were created with regulation 726 in 2004—"the basis of everything EMEA is doing." Directives 2001/83 established the various types of decentralized procedures for human drugs (2001/82 for veterinary products). The instrument of a decision is used for all marketing authorizations issued at the central level. "These marketing authorizations are authorized by the European Commission," Terberger explained, "following the scientific advice we get from EMEA."

Like the U.S. FDA, EMEA provides guidance to industry. There are several types of guidelines, including commission guidelines based directives or regulations and technical and scientific guidelines issued by EMEA. The latter, said Terberger, represent interpretations of legislation and are "more precise, quite voluminous, establish clarity between EMEA and enterprises."

After Terberger's presentation on the legal foundations for drug regulation in the European Union, **Emer Cooke,** Head, Inspection Sector, EMEA, provided more specific details on the regulatory bodies overseeing the industry in her talk "Regulatory Framework and Key Players."

The regulatory framework for pharmaceuticals includes 46 national health authorities and a network of about 4,000 experts throughout Europe. EMEA also works closely with the European Commission, the Parliament and Council.

Within EMEA, two committees hold primary responsibility for pharmaceuticals—the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use. In addition, there are committees responsible for medicinal products intended for the treatment of rare diseases and for herbal products.

EMEA's responsibilities include the evaluation of centralized authorized products, variations and renewals. The Agency also provides arbitration when problems arise at the decentralized level. "We are also responsible for sampling and testing centrally authorized products," said Cooke, and for the "supervision of GMPs."

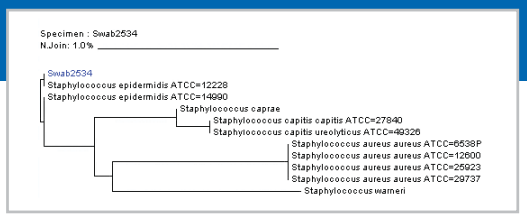
National health authorities, called "competent authorities," maintain a lot of responsibility. "Really in the GMP regulatory framework, the key players are the national competent authorities," declared Cooke. "National competent authorities are responsible for, among other things, issuing and supervising national marketing authorizations. They are responsible for pharmacovigilence, inspections and testing….In the area of clinical trials, they are responsible for authorization of many clinical trials on their territory. In the area of manufacturing, they are responsible for authorization and supervision of manufacturing in their territories."

Cooke stressed the importance of cooperation among the various competent authorities: "I want to point out how important it is within the European network for competent authorities to work together, and this importance has been recognized by the creation of large number of fora at which the competent authorities get together to deal with specific ➤

Attend a Free MicroSeq® System Seminar
For more information, please visit
www.microseq.com

The right answer, every time.

Identify thousands of microbial species with the highest level of accuracy.
The MicroSeq® Microbial Identification System automatically identifies bacterial and fungal species with one standardized procedure. It doesn't matter if the organisms are gram negative or gram positive, healthy or unhealthy, dead or alive. The MicroSeq system gives you unprecedented speed, accuracy, and reproducibility—without the ambiguity common to phenotypic or biochemical identification methods.



Results in less than 5 hours

- Simplified workflow
- Validated libraries contain over 2800 species
- Automated sequencing and identification
- Based on gold standard 16S sequencing
- Includes features to assist with 21 CFR Part 11 compliance

For fast, definitive microbial identification, visit **www.microseq.com**.

Applied Biosystems

25 YEARS ADVANCING SCIENCE

aspects of the regulations and supervision of medicinal products."

David Cockburn, Principal Scientific Administrator, EMEA, concluded the opening session with "Inspections and How They Occur."

In defining the inspection process, Cockburn stressed the word *equivalence*: "No matter who actually does the inspection, it will look very similar [and] standards are very similar. All inspections conducted by the EMEA and the national competent authorities are equivalent."

Inspections are conducted on behalf of the EMEA and the member state carrying out the inspection, noted Cockburn. "Member states accept each other's conclusions."

Equivalence of inspections among the various competent authorities comes from "a series of community documents—a compilation of community procedures—which lay down various procedures connected with GMP inspection and related activities. The inspections are carried out in accordance with those procedures, transposed into national procedures."

The various competent authorities utilize a "common format" for GMP certificates issued, for inspection reports and for logging data into databases.

National competent authorities currently are expected to inspect sites within their jurisdiction once every three years. "Generally," said Cockburn, "we are looking for a two-year cycle."

Risk management principles are applied in decisions about whether to inspect or not. "There are some elements of risk management already in the community procedures on inspection planning," explained Cockburn, "but with the advent of ICH Q9—which not only applies to industry, it applies to regulatory authorities as well—there is work now going on to better link quality risk management to the inspection process."

Cockburn reviewed inspection triggers. These include: {{bullets}}

Applications to competent authorities for manufacturing authorization

Variations to manufacturing authority

Routine inspection

Marketing authorizations

The next plenary session delved deeper into the European regulatory framework with two presentations on member states' implementation of the EU GMPs and a talk from an industry representative on the private sector's role in developing regulatory controls. A report on these talks will appear in the next issue of the *PDA Letter.*

Participate in PDA: Write and/or Review Technical Reports

Authors: PDA is seeking content experts globally to participate on three new Task Forces starting January 2007 to draft Technical Reports on the following subjects:

- Sterilizer Systems: Design, Commissioning, Operation, Validation and Maintenance
- Steam in Place
- Validation of Dry Heat Processes Used for Sterilization and Depyrogenation

Reviewers: PDA is seeking content experts globally to review and provide comment/feedback on the following Technical Report drafts:

- Filtration of Liquids Using Cellulose-Based Depth Filters
- TR No. 14: Validation of Column-based Separations
- Biological Indicators for Sporicidal Gassing Processes: Specification, Manufacture, Control and Use

If you have not already participated on a PDA Technical Report, please be prepared to offer a short biographical sketch outlining your areas of expertise and interest pertinent to the development of this project. For more information on how to participate, contact Genevieve Lovitt-Wood at glovitt@mindspring.com. We encourage you to offer your time, skills and expertise to any of these projects!

2006 PDA/FDA Conference: FDA Compliance and Inspection Trends Session Draws Standing Room Only Audience

Walter Morris, PDA

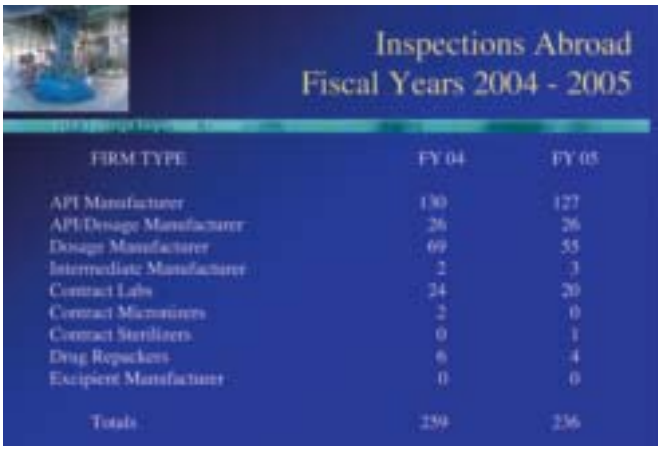
It seemed that all of the participants at this year's conference packed into the break-out session room to hear an update on FDA Compliance Inspection Trends. Three members of CDER's Office of Compliance (OC) presented data and answered questions during the session: **Rick Friedman**, Team Leader, Guidance and Polic; **Edwin Rivera Martinez,** Chief, Investigations and Preapproval Compliance Branch; and **Joseph Famulare**, Acting Deputy Director, OC. The session was not entirely dedicated to FDA inspection data. **Jacques Morenas,** French Health Products Safety Agency, spoke about the Pharmaceutical Inspectorate Convention/Scheme (for which he serves as current chair).

Rivera Martinez presented data from CDER's human drugs foreign inspection program for FDA fiscal years 2004 and 2005. Data for FY '06 was not complete because the U.S. government's fiscal year does not end until Sept. 30.

Foreign inspections, like all FDA inspections, are conducted mainly by field investigators operating out of the Agency's Office of Regulatory Affairs (ORA). GMP recommendations for establishments referenced in applications are made by the Investigations and Preapproval Compliance Branch in CDER's compliance office. Overseas inspection findings are evaluated by the Foreign Inspection Team (FIT) within the Investigations and Preapproval Compliance Branch. FIT is a cadre of compliance officers specially dedicated to the review of foreign FDA 483s, inspection reports and company responses to investigator observations. The group also drafts warning and untitled letters issued following inspections and makes recommendations for automatic detention of pharmaceutical products entering the United States because of adulteration.

In breaking down the foreign inspection numbers by manufacturer type (see Object 1), Rivera Martinez was surprised to see that API facilities comprised only 50% of the sites inspected in FY '04 and 54% in FY '05.

"For many years, a lot of folks have said that a large percentage of our inspection overseas is of API manufacturers," said Rivera Martinez. "I was rather surprised, at least in 2004, API manufacturing inspections only comprised 50%." In past years, he noted, "75 or 70% of our inspections were of API manufacturers."



Object 1

Rivera Martinez was also surprised a manufacturer of an API intermediate had been inspected. This atypical case, he explained, probably was the result of a "for-cause" investigation: "FDA does not routinely inspect manufacturers of intermediates, unless of course when we are conducting the API inspection, say they start from step 1, right from the API starting material, and proceed to the intermediate steps and produce the API. In those circumstances, we would probably cover all of the steps in the production of the API. We would not specifically schedule anybody to go overseas just to cover an intermediate manufacturing process unless we have a specific reason to do so."

Similarly, field investigators very rarely inspect excipient manufacturers, but FDA did visit one in FY '03. "I want to say that FDA does not routinely conduct inspections of excipient manufacturers," stated Rivera Martinez. "We have the regulatory authority to do so under the Food, Drug and Cosmetic Act, but we exercise discretion there. Basically we rely on drug manufacturers under the 211 provisions of controlling and qualifying [his or her] raw material suppliers in order to ensure the quality of the excipients."

continued on page 26

FDA Inspection Types

PAI: Preapproval inspections are conducted because a company has filed a marketing application.

For Cause: For cause inspections are conducted because the Agency has a specific reason—usually an indication that there is a problem—to audit a facility.

GMP Surveillance: FDA routinely conducts GMP surveillance inspections. These are now "systems inspections," as mapped out by Compliance Policy Guide 7356.002.

PDA Calendar of Events for North America

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

Conferences

December 6-7, 2006
2006 ISPE/PDA Joint Workshop: Challenges of Implementing ICH Q8 and Q9 — Practical Applications
(Conference and Exhibition)
Washington, D.C.

December 8, 2006
Evaluating the Impact of the Final Out of Specification (OOS) Guidance - A PDA Workshop
Washington, D.C.

January 18-19, 2007
PDA/USP: Workshop on Residual Solvents
Bethesda, Maryland

January 29-31, 2007
PDA Emerging Manufacturing and Quality Control Technologies Global Conference
(Conference and Exhibition)
San Diego, California

March 19-23, 2007
2007 PDA Annual Meeting
(Conference, Courses and Exhibition)
Las Vegas, Nevada

May 21-22, 2007
Quality by Design (QbD)
Bethesda, Maryland

May 22-23, 2007
PDA Global PAT Conference
Bethesda, Maryland

September 24-28, 2007
2007 PDA/FDA Joint Regulatory Conference
(Conference, Courses and Exhibition)
Washington, D.C.

October 29-31, 2007
Visual Inspection Conference
Bethesda, Maryland

November 2007
Extractables/Leachables
Bethesda, Maryland

Training

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

Laboratory Courses

November 15-17, 2006
Cleaning Validation

January 22-26, 2007
Aseptic Processing Training Program
Session 1, Week 1

February 7-9, 2007
Environmental Monitoring Database and Trending Technology

February 12-16, 2007
Aseptic Processing Training Program
Session 1, Week 2

March 1-2, 2007
Environmental Mycology Identification Workshop

March 5-7, 2007
Fundamentals of Pharmaceutical Filtrations and Filters

March 12-16, 2007
Aseptic Processing Training Program
Session 2, Week 1

March 28-30, 2007
Cleaning Validation

April 16-20, 2007
Aseptic Processing Training Program
Session 2, Week 2

Course Series

February 12-24, 2007
Houston Training Course Series
Houston, Texas

Chapters

November 15, 2006
PDA Southern California Chapter
Dinner Meeting
La Jolla, California

November 16, 2006
PDA West Coast Chapter
Dinner Meeting
Location to be determined

November 29, 2006
PDA Delaware Valley Chapter
Dinner Meeting
Malvern, Pennsylvania

November 29, 2006
PDA New England Chapter
Afternoon Workshop — Contract Manufacturing
Location to be determined

November 30, 2006
Mountain States Chapter
Dinner Meeting
Longmont, Colorado

Europe/Asia-Pacific

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

Europe

November 9-10, 2006
PDA Italy Chapter
PDA/EMEA Update and PQR Course (in Italian)
Milan, Italy

November 23-24, 2006
PDA Italy Chapter
PDA/EMEA Update and PQR Course (in Italian)
Rome, Italy

December 5-6, 2006
Process Validation of Protein API Manufacturing
Berlin, Germany

December 6-7, 2006
PDA Biotechnology Meeting
New Techniques of Sterilization and Contaminant Removal
Paris, France

January 31-February 1, 2007
Designing a Cleaning and Disinfection Programme for a GMP Sterile Manufacturing Environment
Vienna, Austria

February 5-6, 2007
Rapid Microbiology Methods: Make Them Work - Get Them Approved
Verona, Italy

February 6-7, 2007
Pharmaceutical Anti-Counterfeiting
Berlin, Germany

February 7-9, 2007
Rapid Microbiology Methods: Make Them Work - Get Them Approved - Training Course
Verona, Italy

February 12-13, 2007
Challenges of Implementing ICH Q8 and Q9 - Practical Applications
Co-sponsored by PDA and ISPE
Brussles, Belgium

March 26-27, 2007
Continuous Improvement Applications in the Pharmaceutical Industry and the Impact of ICH Q10
Verona, Italy

May 8-9, 2007
Aseptic Manufacturing
Milan, Italy

June 11, 2007
PDA/ISPE/AFI
Bologna, Italy

Asia-Pacific

November 13-17, 2006
2006 PDA Asia-Pacific Congress
(Congress, Courses and Exhibition)
Tokyo, Japan

November 16-17, 2007
Basics of Biopharmaceutical Sterilizing Filtration
Tokyo, Japan

November 16-17, 2007
Quality Programs - The Road to Continuous Improvement
Tokyo, Japan

November 16, 2007
Risk Assessment in Manufacturing
Tokyo, Japan

November 17, 2007
GMP Requirements for the Manufacture of Clinical Trial Materials
Tokyo, Japan

2006 PDA/FDA Conference: FDA Compliance and Inspection Trends Session Draws Standing Room Only Audience, continued from page 23

Overall, the types of manufacturing sites visited were "quite consistent" in FY '04 and '05, he noted. "In other years we have had some significant changes in these percentages. But generally, most of our inspections overseas are of API manufacturers, dosage and both API and dosage manufacturers."

FDA has modified its strategy regarding the type of inspection conducted at foreign sites in order to conserve resources yet ensure sites abroad are routinely inspected. Rivera Martinez pointed out that "most inspections overseas are driven by the preapproval inspection program," but investigators are asked to conduct systems-based inspections (FDA compliance program 7356.002 for drug products or 7356.002 for APIs) in conjunction with the PAI audit, time permitting.

Rivera Martinez expounded further: "So generally the inspection is initiated because of a pending application, a preappoval inspection….Generally the folks in ORA will try to plan time so that the investigator will also conduct a systems-based inspection. What does this do for us? Well, we can use the information from the systems-based inspection for other application reviews in the future. And in this way, we might not have to send an investigator six months or eight months later to conduct another preapproval inspection because the systems-based inspection has been performed and the facility has been found satisfactory."

Following his presentation, Rivera Martinez was asked if FDA could explain the reason for the discrepancy in the length and depth of foreign inspections compared to domestic inspections. The questioner noted that foreign inspections are typically shorter and not as in-depth.

One consideration, he said, is the fact that the foreign inspection team is comprised of well-trained, more experienced investigators. "So when they go out and do an inspection, they are also not expected to do a full inspection. They just need to observe enough to give them a good indicator of where the firm is in terms of compliance. In other words, they also don't have to document as much because it is an inspection overseas. There are different requirements in terms of documentation [needed in order] to bring a regulatory case on the domestic side versus a foreign."

Rivera Martinez also noted that the FIT in the OC was created several years ago to ensure uniformity in the foreign inspection program. "By creating the Foreign Inspection Team and having a specific group—five to six compliance officers who are only dedicated essentially to reviewing foreign inspection reports, [FDA has] a very well-integrated group, and they very much think alike. So we've been able to establish quite a bit of uniformity over the years."

OC's Friedman added: "By and large, the international cadre members are more advanced in their inspection skills. To get on the international cadre you have to have training and a certain amount of experience before you can start doing international inspections."

Friedman also stated that the threshold for regulatory action is lower for foreign plants than for U.S.-based facilities. "The threshold under the Act for foreign firms is a showing of 'appearance of adulteration.' And also, the tools that we have at our disposal—including import detention—are more streamlined for a violative foreign firm. For a domestic firm, we have to go through a less expeditious legal system to carry out an injunction or seizure."

OC's Famulare covered recent compliance trends in his presentation "CDER Compliance Update."

The inspection data he presented came from a sample of 1,176 citations contained on FDA 483s issued from February 1, 2004 to July 31, 2004. The most frequent citations were related to 21 CFR 211.110 (a), production/process validation (57 out of 1,176, 4.85%). Discrepancies (21 CFR 211.192) were the next most frequent investigator observation (55 out of 1,176, 4.68%). See Object 2 for the remainder of the "top 10 citations."

Famulare broke down the inspection data by GMP syste. The system most frequently cited was the laboratory system, (276 out of 1,176, 24%), followed by the quality system (263, 22%) and the production system (256, 22%).

Famulare also presented the top ten reasons for drug product recalls in FY

Top 10 Citations

Citation	Total Number	Percentage of All Citations
211.100(a) Production / Validation	57	4.85%
211.192 Discrepancies	55	4.68%
211.067(b) Equip. Cleaning / Maint.	35	2.98%
211.166(a) Instru. Calibration	34	2.89%
211.160(b)(4) Lab Controls	33	2.81%

1176 Citations

Object 2

Joseph Famulare, CDER

Edwin Rivera Martinez, CDER

Rick Friedman, CDER

'06—an incomplete analysis because the fiscal year had not ended. Famulare noted that a "compelling" finding is "the very high number of Class 1 recalls," which had reached 31 by September. "We have had years when there have been only one or two," he said.

Several factors contributed to the atypical number of Class 1 recalls in FY '06, according to Famulare. "One was FDA follow up on large compounding pharmacies with manufacturing scale" operations in FDA-registerd facilities. The Agency received reports of contaminated products serious enough to impact consumers. The problems resulted from the firms' failures to follow aseptic processing standards and forced a large number of Class 1 recalls.

Famulare concluded his talk with an overview of several initiatives within the compliance office that might soon bear fruit, including its involvement with the Pharmaceutical Inspectorate and revisions to several past guidances. He also foreshadowed the release of two guidances that were published subsequent to the PDA/FDA conference, quality systems and out-of-specification results (see "Regulatory Briefs," p. 33).

Regarding the Pharmaceutical Inspectorate, which is being assembled under the auspices of FDA's 21st century GMP initiative, Famulare said it "is coming along." Right now, CDER has a memorandum of understanding with ORA "to have about 45 almost fully dedicated CDER drug inspectors." The first class of these investigators is in the process of achieving Level III certification."

FDA is "deep into the throes of formulating a new Part 11 regulation," declared Famulare. Language for the revised Part 11 is still in the process of

continued on bottom of page 31

RAQC "Open Air"

Jim Lyda, PDA

Taking advantage of the balmy Washington weather, the PDA Regulatory Affairs and Quality Committee (RAQC) scheduled an informal meeting on the outdoor balcony of the Renaissance Hotel during the 2007 PDA/FDA Joint Regulatory Conference. The occasion was a "get acquainted" visit with Jacques Morenas, Assistant Director, Inspections, French Health Products Safety Agency and current chairman of the Pharmaceutical Inspection and Cooperation Scheme (PIC/S). Morenas earlier gave a well-attended presentation during the conference on the operations of PIC/S, including training activities, membership and future goals. PIC/S, based in Geneva, Switzerland, has a long history of supporting inspectorate training and development and harmonization of inspection procedures. PIC/S will host their first industry forum in late November. FDA recently applied for PIC/S membership. The application is pending before the organization.

(clockwise from front left) Anders Vinther, CMC Biopharmaceuticals/PDA board; Amy Giertych, Baxter Healthcare; Bob Dana, PDA; Steve Bellis, IVAX Pharmaceuticals/PDA board; Michihisa Inokuma, PDA Japan; Tim Marten, AstraZeneca/PDA board; Jacques Morenas, AFSSAPS; Georg Roessling, PDA; Stephan Roenninger, F. Hoffmann-la Roche; Zena Kaufman, Abbott Laboratories/ RAQC chair; Gail Sherman, PDA; Barbara Zink, Cambrex Biosciences; Steve Mendivil, Amgen.

Impact of Drug Preapproval Inspections on Drug Product Review Times

Brenda Wang, CDER, Office of Compliance, and Florence Houn, MD, CBER Office of Vaccines

The preapproval inspection (PAI) is an important component of the evaluation of a new drug application (NDA). This descriptive study was conducted to determine factors that may predict an acceptable PAI recommendation from CDER's Office of Compliance (OC) and the impact on an NDA approval decision when that office recommends approval of an application be withheld. The findings of this study may help industry to improve PAI results and to obtain a satisfactory recommendation from CDER's compliance office. This, in turn, may increase the likelihood of getting approval for applications in the first review cycle.

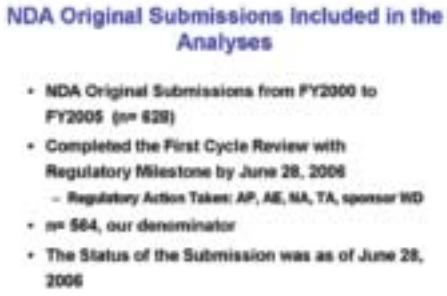


Chart 1

Chart 1 contains the parameters of the study. The analyses included only original NDAs from FY'00 to FY'05 that completed the first cycle review (first decision) by June 28, 2006, and that were subject to FDA action (i.e., approval, nonapproval or approvable). NDAs that were withdrawn by the sponsor after a PAI were also included. Information using automated data systems about the NDAs and inspection outcomes were used. In all, there were 564 NDAs that met the criteria.

Chart 2 displays the median review time for Cycle 1 and Cycle 2 priority and standard reviews. The median time it took industry to respond to deficiencies in priority and standard NDAs

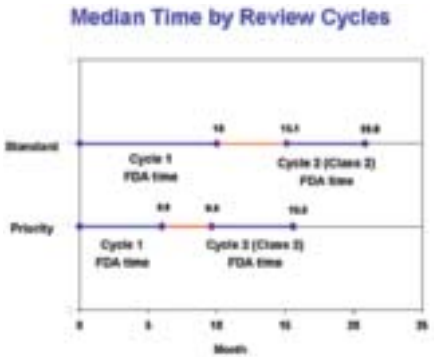


Chart 2

between Cycle 1 and Cycle 2 was also calculated. For priority NDAs, the median first cycle time was 6 months at FDA and 3.6 months for industry to resubmit. For standard NDAs, the median first cycle time was 10 months with FDA and 5.1 months for industry to respond to deficiencies.

[**Authors' Note:** Cycle 2 reviews are prompted during the first cycle, and are designated either Class 1 (minor deficiency) or Class 2 (major deficiency). Class 1 resubmissions are not included in this analysis.]

The right bar graph in Chart 3 represents outcomes for each type of NDA review as of June 2006—priority versus standard and new chemical entity (NCE) versus non-NCE. About 80% priority NDA submissions received approval decisions, with 60% approval for standard NDA submissions. The overall approval rate was 75%.

The left bar graph displays the status of applications from their first review cycle. For all priority applications, about 50% received approval in the first cycle, while about 25% of the standard NCEs and 40% of the standard non-NCEs were approved in the first cycle.

Chart 4 shows the distributions of the number of cycles needed to receive an approval decision. In this study,

Chart 4

422 out of 564 (75%) NDAs received approval. 222 (53%) out of 422 NDAs were approved in their first review cycle. ➤

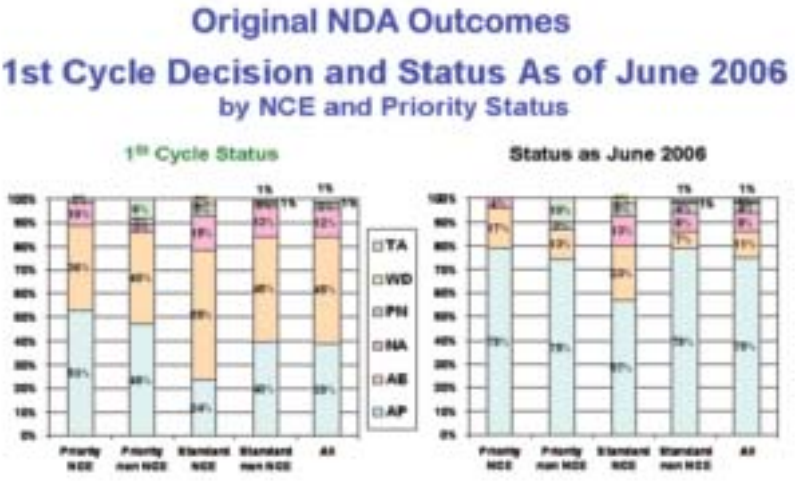
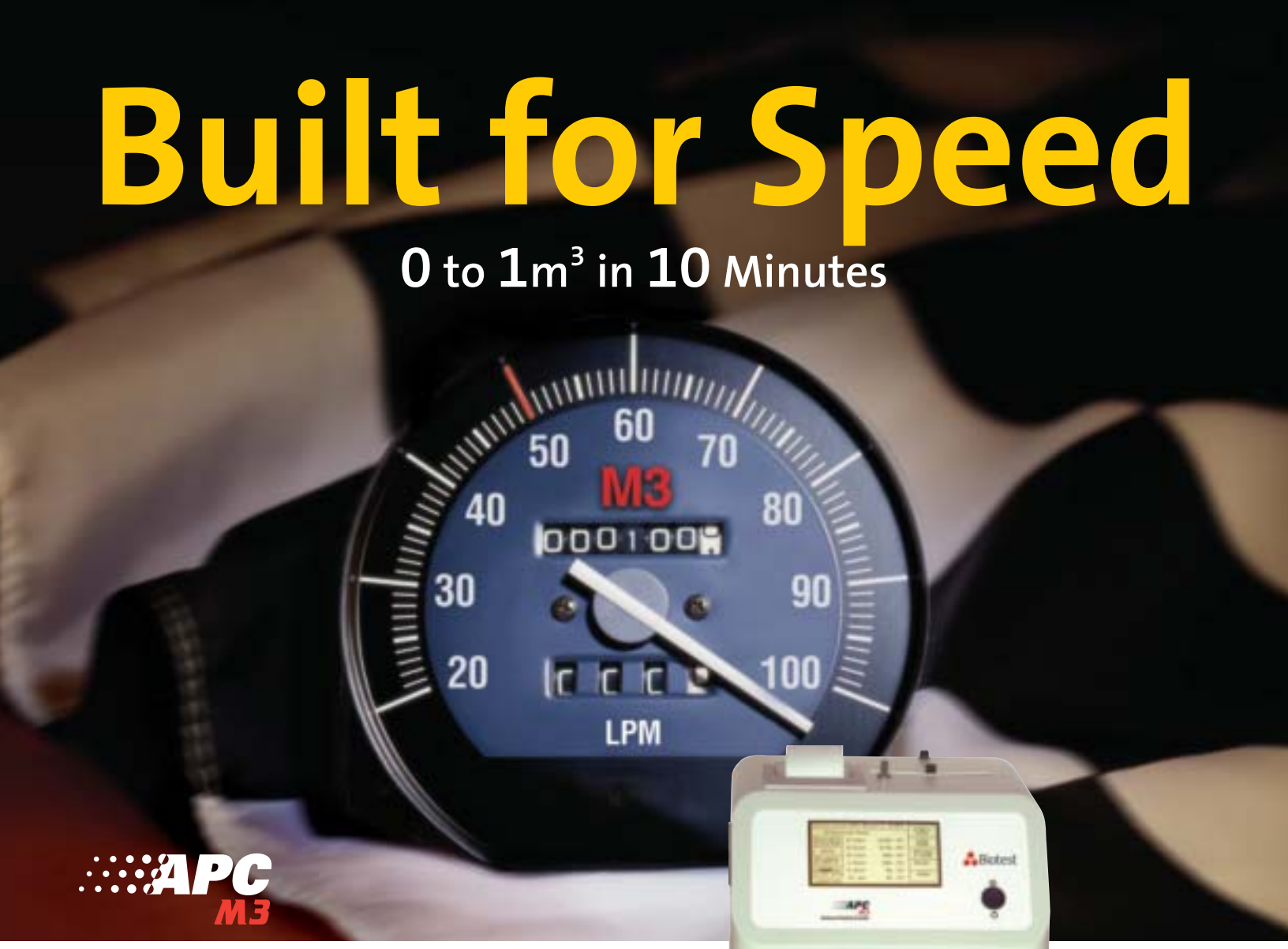


Chart 3

Built for Speed

0 to 1m³ in 10 Minutes



World's Fastest Airborne Particle Counter at 100 LPM

The new APC M3 measures one cubic meter (m³) of air in just 10 minutes. For over 10 years, Biotest has been a global leader in the development of airborne particle counters. Now, Biotest introduces the world's first portable airborne particle counter to sample at a rate of 100 LPM. The APC M3, built for speed and reliability, can reduce the time it takes to monitor your cleanroom by as much as 70%.

- Download utility software supports 21 CFR Part 11
- Custom size channels from 0.3 µm to 100 µm
- Rechargeable lithium-ion battery
- Extended laser life
- 75 and 50 LPM units also available

So get in the fast lane. Start saving time and money today.

Biotest

From Nature for Life

66 Ford Road, Denville, NJ 07834 USA
Tel: 800.522.0090 Fax: 973.625.5882 www.BiotestUSA.com

For priority and standard submissions, the majority of applications take between one and two review cycles to receive approval, with some applications requiring three or more cycles.

The factors that may lead to a predictable first cycle approval include:

- Complete application by the time of submission
- Inspection-ready company
- Strong communication and agreement between FDA and the company

For a PAI to be conducted, CDER's NDA review division consults the Office of Compliance (OC) on the acceptability of every site referenced in the NDA submission. OC makes a recommendation (either as acceptable or to withhold approval) about an application's compliance with GMP requirements. The recommendation is based on review of the sites' profile and inspection history.

If the profile review shows that prior inspection found the process referred to in the application to be unacceptable or if there is no appropriate inspectional history, then a preapproval inspection request is sent to the FDA district office where the site is located. The district then conducts a file review, which may result in the district scheduling an inspection to check the readiness of the company to manufacture the new drug. The file review consists of evaluating all field alerts, complaints, sampling results, recalls, previous history of compliance and other information like adverse drug experience reports.

The inspection evaluates the manufacturing process used for the new drug and the overall systems at the site to ensure acceptable quality controls and processes are in place.

With the inspection information and the file review, the district office makes a recommendation to OC on the acceptability of the site for manufacture of the new drug.

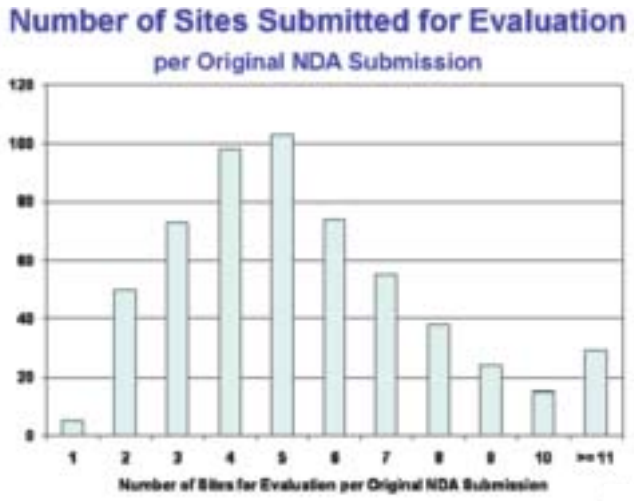


Chart 5

Chart 6

OC then makes its recommendation to the NDA review division.

There were 1,754 domestic sites and 1,340 foreign sites submitted for evaluation in the study. Chart 5 represents the number of sites identified per NDA. The majority of NDAs submitted between three and six sites for evaluation.

Chart 6 traces the first cycle PAI process and shows the results of that process.

Of those 564 applications studied, OC made 77 withhold approval recommendations and 487 acceptable recommendations.

The study showed that, in all but one case, when OC made a withhold recommendation, the relevant review division did not approve the application. However, the results also show that even if an application has an OC acceptable recommendation, other aspects of the application may still affect the NDA decision.

Chart 7 shows preapproval NDA inspection outcomes by the process indication code or the profile inspections. The outcomes are official action indicated (OAI), voluntary action indicated (VAI) and no action indicated (NAI). The data are not limited to the NDA applications in this study.

The average OAI rate is 8% and the VAI rate is 44%. This chart shows that nonsterile ointments, aerosol

Chart 7

dispensed medication, sterile liquids, small volume parenterals, prompt release capsules and soft gelatin capsules received the highest OAI rate. The combined OAI and VAI rates of small volume parenterals reached 60%, which is the highest combined rate for any profile. The major reason for an OAI outcome related to small volume parenterals was deficiencies with the aseptic process.

Chart 8 displays some of the characteristics of the 77 NDAs that got a withhold recommendation compared to the NDAs that got an acceptable recommendation.

The withhold applicants had a greater mean number of sites submitted per application, which were made up of more domestic sites. Also the profile

First Cycle EER Decision of New Drug Applications – Withhold vs. Acceptable

	Withhold	Acceptable
Mean number of sites submitted per application	5.7	5.2
Mean number of Domestic sites submitted per application	3.9	2.9
Mean number of Foreign sites submitted per application	1.9	2.3
Mean number of Profiles submitted per application	3	3
Major Profiles submitted	'CSN' 'CTL' 'SVS' 'TCM'	'CSN' 'CTL' 'TCM'

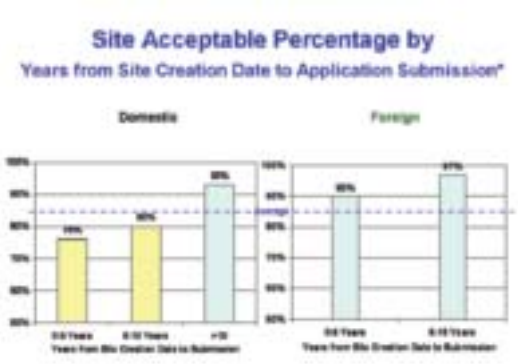


Chart 9

for these NDAs included sterile-filled small volume parenterals.

Chart 9 shows that sites with older creation dates, which means they were in operation longer, had higher acceptable recommendation rates when compared to newer sites. The average acceptable rate is 85%, the dotted line

Conclusion

This study had some interesting findings. We found that the fewer number of sites submitted in the NDA and the submission of sites with longer histories of operation tended to get more recommendations from OC for acceptable than NDAs with larger numbers of sites and newer sites.

This may mean that, as pharmaceutical manufacturing becomes more compartmentalized and there are new sites involved, there is need for attention to organization, quality management and communications to ensure the required level of control. The findings may also suggest that investment in new facilities should be accompanied by commitment to quality control implementation and follow through.

The 2006 Booze Hamilton Report on Prescription Drug User Fee Act first cycle performance showed that roughly one third of applications that were not approved in the first cycle had chemistry, manufacturing, and controls deficiencies. The findings in the present study may produce improvements in these areas, which may in turn increase application approvals.

[**Editor's Note:** PDA thanks Brenda Wang and Florence Houn for preparing this article, which is based on their presentation at the 2006 PDA/FDA Joint Regulatory Conference. The slide presentation can be found in the membership resources section of www.pda.org.]

2006 PDA/FDA Conference: FDA Compliance and Inspection Trends Session Draws Standing Room Only Audience, continued from page 27

clearing the Agency. Other steps will be necessary such as clearance through the U.S. government's Office of Management and Budget. "While I cannot say when exactly it will get done, I certainly can say it will take into next year," said Famulare. Until then, "we want to follow those approaches we espoused in the 2003 guidance."

CDER's API compliance program is being aligned with the risk-based approach in effect for finished products. "The PAI compliance program is next on the agenda for update," Famulare said, and will "take a lot of collaborative thinking from all parts of the Agency" considering the recent inclusion of therapeutic biotech under CDER's review, the creation of the Pharmaceutical Inspectorate and the ongoing integration of review, inspection and compliance. "[This is a] work in progress."

Lastly, Famulare mentioned the process validation guidance: "As we had noted in the 2004 cGMP for the 21st century final report, [the process validation guidance] is in the works to update it in line with the compliance policy guide that we announced in March 2004 to really have a life-cycle approach to validation. So look for that to come."

PDA/FDA "On-Demand"

A number of presentations from the 2006 PDA/FDA conference are available "on-demand." Go to **www.pda.org/webseminars/ondemand.html**for more information.

PDA Comments on ICH Q4B

October 5, 2006

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

Ref: International Conference on Harmonisation; Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Published August 8, 2006 (Docket No. 2006D-0297)

Dear Sir/Madam

PDA is pleased to provide comments to FDA on ICH Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological and device manufacturing and quality.

The draft guidance provides a procedure to facilitate acceptance by regulatory authorities of Pharmacopeial test methods in the three ICH regions. These test methods are referred to in the draft guidance as "analytical procedures and/or acceptance criteria (APAC)". The draft guidance is intended to facilitate regulatory acceptance of these proposed test methods and their interchangeability with test methods contained in the local regional pharmacopeias, thus avoiding redundant testing and different acceptance criteria in favor of a common testing strategy in each ICH regulatory region. PDA wishes to thank the Agency for the opportunity to provide comments on this document.

PDA's comments were developed by a cross functional team of PDA members, working through our Regulatory Affairs and Quality Committee. We support the general concepts presented in this draft and we believe that this document will help to ensure that harmonization efforts remain a high priority across the regulatory regions and among the USP, JP and Ph. Eur. Our detailed comments are provided in the attached table; however the following list presents some of the major conclusions reached by the PDA review team.

1. The document should provide registration guidance on the appropriate reference for the harmonized procedure. This would ensure consistent referencing that is acceptable by the regulatory authorities for the various geographic regions. Detail regarding regulatory filing implementation must be developed in concert with this guidance either as part of this document or a companion document. The individual Q4B annexes should not move forward until this guidance is available.
2. PDA recommends replacing the term "Non-PDG" with the phrase "one or more of the three pharmacopeias that comprise the PDG" through out the document. This would clarify that proposed harmonized text would be proposed from one or more of the PDG members. This phrasing is consistent with the scope and intent of this document.
3. The content of section 2.8 (Pharmacopeial Tests and Acceptance Criteria) of ICH Q6A would need to be updated to agree with the concepts outlined in this draft of Q4B.

If you have any questions regarding our comments, or how we may further assist with the development of the Guidance, please contact me.

Sincerely,

Robert Myers

Robert B. Myers

President, PDA

Attachment: Detailed Comments Table

[For the complete comments, including the "Detailed Comments Table," go to www.pda.org/regulatory/RegComments.html.]

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/regulatory/RegNewsArchive-2006.html.

North America

FDA Publishes Final OOS Guide

In the October 12 *Federal Register,* FDA announced the availability of the final guidance for industry entitled *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production*. This guidance provides information on how to evaluate laboratory test results that fall outside of specification limits. The guidance is intended to provide clear and consistent communication of regulatory expectations and to promote voluntary compliance with current FDA requirements. The guidance addresses investigations of OOS results in the laboratory phase, including responsibilities of the analyst and supervisor, and when indicated, the expansion of an investigation outside of the laboratory to include production processes, and raw materials as appropriate.

FDA Publishes Final Deviations Guide

In the October 19 *Federal Register,* FDA announced the availability of the final guidance for the industry entitled *Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components*. The guidance is intended to provide assistance to licensed manufacturers of biological products other than blood and blood components in the reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling or storage, or with the holding or distribution of a licensed biological product which may affect the safety, purity or potency of a distributed licensed product. The document will assist these licensed manufacturers in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report.

FDA Releases Final Guide on Quality Systems

The FDA has released the final version of their *Quality Systems Approach to Pharmaceutical CGMP Regulations.* This version finalizes the draft which was published in 2004. The October 2nd Federal Register announcement notes that the FDA considered all comments received on the draft as they established the final version; however no substantive changes were made, according to the announcement. The final version does contain a number of clarifying edits. The guidance is intended to encourage the use of modern quality management system principles by the regulated industry and to foster innovation and continuous improvements in pharmaceutical manufacturing.

New Face Brings Enthusiasm to PDA

PDA welcomes **Hassana Howe,** Senior Coordinator of Membership and Chapters, to its global headquarters in Bethesda, Md. In this position, Hassana serves as a liaison between PDA and its members and chapters. Her roles include providing chapter support, responding to member inquiries and fulfilling member needs.

Hassana comes to PDA with a BA in microbiology from North Carolina State University. Also, she has recently taken health communications courses at Johns Hopkins University. Prior to joining PDA, Hassana worked for the Melody Shafie Foundation for Neuroblastoma and the American Institute of Implant Dentistry.

Hassana supports the ever-growing needs of PDA and its members by implementing strategies to increase membership and chapter involvement. A growing membership and strong chapters give PDA the resources to strengthen its valuable career-long learning programs by expanding the breadth of expertise that contributes to technical programs, courses, reports and books.

Hassana and the membership team are working to build a stronger association. For more information on how to get involved with PDA or to become a new member, please contact Hassana at howe@pda.org.

PDA's new Membership Sr. Coordinator, Hassana Howe

PDA Welcomes New President of Central Europe Chapter

PDA Europe welcomes Dr. **Andreas Wenng,** Chemgineering AG, Basel, as the new President of the PDA Central Europe Chapter. Wenng assumes the leadership of the chapter after the long and distinguished service of **Erich Sturzenegger,** Novartis Pharma, who stepped down from the chapter leadership earlier this year.

Wenng serves with Chemgineering AG, Pratteln, Switzerland, (near Basel) a full service engineering and consulting company that has supported the pharmaceutical business for many years. Some of the upcoming activities and goals for the chapter include:

- Round tables and chapter meetings to discuss current topics like RFID, risk management, regulatory issues, nanotechnology, etc.
- Improved network for biopharmaceutical "start-ups."
- Technical articles in the *PDA Letter* on relevant subjects
- Growing PDA membership
- International conference in September 2007 on the topic of technology transfer

Andreas Wenng can be reached at: Andreas.Wenng@chemgineering.com.

PDA's new President of Central Europe Chapter, Andreas Wenng, Chemgineering AG

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 e-mail address. Where applicable, the Chapter's Web site is listed. More information on PDA Chapters is available at www.pda.org/chapters/index.html.

Asia-Pacific

Australia Chapter
Contact: Anna Corke
E-mail:
acorke@medicaldev.com

India Chapter
Contact: Darshan Makhey, PhD
E-mail:
dmakhey@hotmail.com

Japan Chapter
Contact: Katsuhide Terada, PhD
E-mail: terada@phar.toho-u.ac.jp
Web site: www.j-pda.jp

Korea Chapter
Contact: Woo-Hyun Paik
E-mail: whpaik@hitel.net

Southeast Asia Chapter
Contact: K. P. P. Prasad, PhD
E-mail: prasad.kpp@pfizer.com

Taiwan Chapter
Contact: Shin-Yi Hsu
E-mail: shinyi.hsu@otsuka.com.tw
Web site: www.pdatc.org.tw

Europe

Central Europe Chapter
Contact: Andreas Wenng, PhD
E-mail:
andreas.wenng@chemgineering.com

France Chapter
Contact: Jean-Louis Saubion, PhD
E-mail: ufch@wanadoo.fr

Ireland Chapter
Contact: Frank Hallinan
E-mail: hallinf@wyeth.com

Israel Chapter
Contact: Sigalit Portnoy
E-mail: sigalit.portnoy@teva.co.il

Italy Chapter
Contact: Gabriele Gori
E-mail: gabriele.gori@bausch.com
Web site: www.pda-it.org

Prague Chapter
Contact: Zdenka Mrvova
E-mail: zdenka.mrvova@zentiva.cz

Spain Chapter
Contact: Jordi Botet, PhD
E-mail: jbotet@stegroup.com

United Kingdom
Contact: Frank W. Talbot
E-mail: ftpharmser@aol.com

North America

Canada Chapter
Contact: Patrick Bronsard
E-mail: patrick.bronsard@snclavalin.com
Web site: www.pdacanada.org

Capital Area Chapter
Areas Served: MD, DC, VA, WV
Contact: Allen Burgenson
E-mail:
allen.burgenson@cambrex.com
Web site: www.pdacapitalchapter.org

Delaware Valley Chapter
Areas Served: DE, NJ, PA
Contact: Art Vellutato, Jr.
E-mail: artjr@sterile.com
Web site: www.pdadv.org

Metro Chapter
Areas Served: NJ, NY
Contact: Nate Manco
E-mail: natemanco@optonline.net
Web site: www.pdametro.org

Midwest Chapter
Areas Served: IL, IN, OH, WI, IA, MN
Contact: Madhu Ahluwalia
E-mail: madhu@cgxp.com

Mountain States Chapter
Areas Served: CO, WY, UT, ID, NE, KS, OK, MT
Contact: Sheri Glaub
E-mail: saglaub@comcast.net
Web site: www.mspda.org

New England Chapter
Areas Served: MA, CT, RI, NH, VT, ME
Contact: Myron Dittmer, Jr.
E-mail: mdittmer@mfdassociates.com

Southeast Chapter
Areas Served: NC, SC, TN, VA, FL, GA
Contact: Lisa Eklund
E-mail: lisa.eklund@pharma.com
Web site: www.pdase.org

Southern California Chapter
Areas Served: Southern California
Contact: Saeed Tafreshi
E-mail:
saeedtafreshi@inteliteccorporation.com
Web site: www.pdasc.org

West Coast Chapter
Areas Served: Northern California
Contact: Peter Rauenbuehler
E-mail: pbr@gene.com
Web site: www.wccpda.org

In Focus: PDA/FDA & PDA/EMEA Plenary Sessions

PDA/EMEA 1st Plenary: (seated l–r) Martin Terberger, European Commission; David Cockburn and Emer Cooke, EMEA Inspections Sector; (standing) Tim Martin, AstraZeneca and conference co-chair

The "sky view" of the packed crowd at the PDA/EMEA Joint Conference

PDA/FDA 1st Plenary: (l-r) Paul Allen, Clarkston Consulting; Daniel Diermeier, Northwestern University; Cindy Rockel, Millipore and conference chair; Scott Gottlieb, FDA

PDA thanks those who planned the PDA/EMEA Joint Conference: (l-r) Tim Martin, AstraZeneca and conference co-chair; Vince Anicetti, Genentech and Chair of the PDA Board of Directors; Emer Cooke, EMEA; Bob Myers, PDA President; David Cockburn, EMEA; Georg Roessling, PDA Europe; Anders Vinther, CMC Biopharmaceuticals and conference co-chair

PDA/FDA 2nd Plenary: (l-r) Daniel Diermeier, Northwestern University; Josh Boger, Vertex Pharmaceuticals; Guy Villax, Hovione

PDA/EMEA 2nd Plenary: (l-r) Milan Smíd, State Institute for Drug Control, Czech Republic; Gerald Heddell, MHRA, UK; Stuart Heir, Novartis Pharmaceuticals; Anders Vinther, CMC Biopharmaceuticals and conference co-chair

Welcoming Remarks: (l-r) David Mackay, EMEA, and Georg Roessling, PDA

FDA's Scott Gottlieb discussing the Critical Path Initiative in the opening session of the PDA/FDA Joint Regulatory Conference

PDA/FDA Closing Session: (l-r) Sue Schneipp, Hospira and Chair of 2007 PDA/FDA Joint Regulatory Conference; Todd Studer, Bose Corporation; Keith Webber, CDER

PDA/FDA 3rd Plenary: (l-r) Louise Johnson, Vertex Pharmaceuticals; Jon Clark, CDER; Chris Joneckis, CBER

PDA/EMEA 3rd Plenary: (seated l-r) Tor Graberg, Medical Products Agency, Sweden; Jacques Morenas, AFSSAPS, France; Thomas Linz, Schering AG; (standing) Stephan Roenninger, F. Hoffmann-La Roche

PDA/EMEA Closing Plenary: (seated l-r) Emer Cooke, EMEA; John O'Sullivan, Pfizer; Jacques Morenas, AFSSAPS, France; (standing) Tor Graberg, Medical Products Agency, Sweden

In Focus: PDA/FDA & PDA/EMEA Breakout Sessions

Session R1: (l-r) Emanuela Lacana, FDA; Charles Demarest, Pfizer Global Biologics; John Finkbohner, MedImmune

Session R2: (l-r) Galen Radebaugh, Black River Pharma Consulting; Asenath M. Rasmussen, Pfizer Global Biologics; Maria Guazzaroni Jacobs, Pfizer

Session R7: (l-r) Patricia Love, FDA; Stephanie Simek, FDA; Mason Diamond, TyRx Pharma

Session R1: (l-r) Elizabeth Leininger, StemCells

Session A2: (l-r) Mike James, GlaxoSmithKline; Susanne Keitel, Bfarm; Richard Funnell, MHRA; Hiltrud Horn, consultant

Session C2: (l-r) Jirí Holý, USKVBL, Czech Republic; Jason Todd, DEFRA, UK; Arthur J. Faulkner, Pfizer; John Lynch, Irish Medicines Board

Session B3: (l-r) Matt Moran, APIC, Ireland; Kevin McGlue, Colorcon; Ian Stewart, MHRA, UK; Steve Bellis, IVAX

Session Q5: (l-r) Marsha Major, Centocor

Session M1: (l-r) Frank Davis, Hospira Worldwide; Ron Kraus, PAREXEL Consulting; Hank Stern, Genentech; Sloan Rausser, Genentech

Session A3: (l-r) Bob Myers, PDA; Stephan Roenninger, F. Hoffmann-La Roche; Li Yan, QILU Pharmaceutical; Steve Fishwick, AstraZeneca; Georg Roessling, PDA

Session Q3: (l-r) Ajaz Hussain, Sandoz; Diane Hagerty, Johnson & Johnson; Sue Schniepp, Hospira; John O' Sullivan, Pfizer Ireland Pharmaceuticals

Session R6: (l-r) Neil Wilkinson, AstraZeneca; Richard Saunders, Wyeth Research; Jackie Schumacher, Pfizer Global Research and Development; Sally Anliker, Eli Lilly and Company; Maria Guazzaroni Jacobs, Pfizer

Session C1: (l-r) Nigel Hodges, AstraZeneca; Lynne Hill, Ih Consultancy; Kathleen Greene, Novartis; Christine Comerci, F. Hoffmann-La Roche; Rudolf Voeller, German Pharmaceutical Inspectorate

Session B2: (l-r) Benno Weber, Bayer Healthcare; Michael Deats, MHRA; Gerald Heddell, MHRA; Dries de Kaste, RIVM

In Focus: PDA/FDA Exhibits and Networking

(l-r) Kathleen Greene, Rich Levy, Nikki Mehringer, Jennie Allewell, Ian Elvins, Suze Fry, and Louise Johnson

"Hey, did you wash your hands?" Rick Friedman checking conference attendees aseptic techniques, here with Valerie Welter (center) and Sue Schniepp

Stephen Bellis and Stephanie Gray strike a deal!

PDA Board Members Tim Martin and Anders Vinther

Bob and…

Art Velutato

Martin Van Trieste

Vince Mathews

PDA Board Members Nikki Mehringer, Tim Martin and Maik Jornitz

PDA Chair Elect John Shabushnig

Zena Kaufman sits next to PDA's Jim Lyda and Volker Eck

In Focus: PDA/FDA Nourishing the Mind, the Body and the Spirit












It is a well known fact, the quality of a conference can be correlated directly to the number of people sitting like this!





After meaty sessions, attendees enjoy a hearty meal!






After learning about risk management for two days, attendees applied their knowledge at the Gala Extravaganza!

PDA Returns to Las Vegas!

PDA Annual Meeting, Exhibition and Courses • Las Vegas, Nev. • March 19-23

Michael Eakins, PhD (Eakins and Associates) Chair of the 2007 Annual Meeting

Some members may recall that PDA held a spring meeting some years ago at the Aladdin Casino and Resort in Las Vegas. In 2007, PDA will return to Las Vegas for its annual meeting and exhibition, which will be held from March 19–21, followed by TRI training courses from March 22–23. The meeting will be held at the Red Rock Casino, Resort and Spa, which was completed at a cost of more than $925 million and opened in April 2006. The hotel's location is away from the Las Vegas Strip near the Red Rock Canyon and has breathtaking views of both the canyon and the Las Vegas valley. The hotel design has been described as "desert modern" and is situated on 70 acres, which include a three-acre pool complex.

PDA has arranged several events for both meeting attendees and guests. New activities include the first annual golf tournament, which will be held at the Arroyo Golf Club, programs for spouses and guests, and the opportunity to see some of the city's signature shows. Also, on-site there will be a new member orientation, expanded career fair, receptions and a gala.

The theme of the 2007 Annual Meeting is **"Putting Science and Technology Into Practice."** PDA aims to provide high quality presentations from its members on this them, as well as to provide a forum for stimulating discussion within the science interest groups, to present and discuss PDA's latest technical reports and to present the best papers selected from the graduate student abstracts.

Keynote speakers will be a part of both the opening and closing plenary sessions. **Dan Denney,** PhD, CEO, Genitope Corporation, has been invited to speak on the subject of "Individualized Medicine" in the opening plenary session.

Please visit www.pda.org/annual2007 to register for the 2007 PDA Annual Meeting.

I look forward to welcoming you all to Las Vegas!

Company Name	Booth #
Accugenix	100
AES - Chemunxex, Inc.	508
American Stelmi	403
Applied Biosystems	515
BD Medical - Pharmaceutical Systems	301
Biocorp	307
bioMerieux	318
bioMerieux	316
Bioscience International	507
Biotest	513
BOC Edwards Pharmaceutical Systems	319
Celsis, Inc.	501
Compliance Software Solutions, Corp.	306
Drumbeat Dimensions, Inc.	416
Drumbeat Dimensions, Inc.	416

Company Name	Booth #
Duoject Medical Systems, Inc.	419
DuPont Qualicon	201
Eisai Machinery U.S.A., Inc.	510
Genesis Packagin Technologies	512
Lighthouse Instruments	418
Microbiology International	200
Midi, Inc.	408
Millipore Corporation	202
Millipore Corporation	204
Moda Technologies	409
Molecular Epidemiology, Inc. (MEI)	119
Novatek International	521
Nuova OMPI SRL	514
Pall Life Sciences	203
Pall Life Sciences	302

Company Name	Booth #
Pall Life Sciences	302
Pall Life Sciences	205
Pall Life Sciences	304
PAREXEL Consulting	506
PharmaSys, Inc.	423
Remel, Inc.	503
Saint Gobain Desjonqueres	518
Saint Gobain Desjonqueres	516
Sartorius Corporation	502
Sartorius Corporation	504
Steris Corporation	505
Veltek Associates, Inc.	303
Veltek Associates, Inc.	402
Veltek Associates, Inc.	305
Veltek Associates, Inc.	404

TRI Courses

A Comprehensive Guide to OOS Regulations
March 22, 2007

Development of Qualification and Validation Protocols – A Risk Management Approach
March 22, 2007

Essentials of U.S. and EU GMPs for Manufacturers of Active Pharmaceutical Ingredients (APIs)
March 22, 2007

Preparing for and Managing FDA Inspections
March 22-23, 2007

Process Validation for Biopharmaceuticals
March 22, 2007

Assay Validation Basics
March 23, 2007

Methods of Reducing Costs for Cleanroom Operations
March 23, 2007

Pharmaceutical Cold Chain Distribution Best Practices
March 23, 2007

Risk Estimation in Aseptic Processing
March 23, 2007

FDA Initiatives Spark Interest in Emerging Technologies

Emerging Manufacturing and Quality Control Technologies Global Conference • San Diego, Calif. • Jan. 29-31, 2007

The U.S. FDA has recognized the need to facilitate the implementation of new manufacturing and quality control technologies within the pharmaceutical and biopharmaceutical industries. FDA has even gone so far as to sponsor several programs that call for the industry to develop, validate and employ emerging technologies. In turn, FDA has challenged itself to create appropriate regulatory systems for reviewing and assessing these advanced manufacturing techniques.

Taking an in-depth look at new and emerging manufacturing and quality control technologies, the PDA Emerging Manufacturing and Quality Control Technologies Global Conference will provide guidance on how to register, validate and gain regulatory acceptance when employing these technologies to new and existing drug products.

This two-and-a-half day conference offers attendees the opportunity to interact with company representatives during sessions and technology demonstrations and to learn about the science behind their developments. The agenda features technologies and manufacturers for the following disciplines:

- Disposable Processing
- Restricted Access Barrier Isolator Systems
- Microarrays, Microsensors
- Advances in Environmental Monitoring
- High Therapeutic Process Development
- Process Compression
- Alternative Biotech Manufacturing Strategies
- Nanotechnology
- Rapid Microbial Detection

In addition, industry and regulatory experts will address:

- Advantages of these new technologies to overall manufacturing and quality control processes
- Long-term potential of new technologies
- Benefits and risks of implementing these new technologies
- How compendia incorporate new technologies
- How new technologies relate to ongoing efforts in Process Analytical Technology (PAT), quality by design and continuous improvement

For more information about *PDA Emerging Manufacturing and Quality Control Technologies Global Conference*, visit www.pda.org/emerging.

The PDA Letter is published 10 times per year, exclusively for PDA members. Subscriptions are not available. Articles in the PDA Letter may be reproduced with permission—contact the PDA Letter Editor for details.

***PDA Letter* Editor**
Walter Morris
+1 (301) 656-5900, ext. 148
morris@pda.org

Assistant Editor
Lindsay Donofrio
donofrio@pda.org

Advertising
Cindy Tabb, *Sales*
+1 (301) 656-5900, ext. 222
tabb@pda.org

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
E-mail: info@pda.org
Web site: www.pda.org

PDA European Office
Industriestrasse 31
6300 Zug
Switzerland
Tel: + 41 41 720 33 07
Fax: + 41 41 720 33 08
E-mail: info-europe@pda.org

PDA Training and Research Institute
c/o UMBC Technology Center
1450 S. Rolling Road
Baltimore, MD 21227 USA
Tel: +1 (410) 455-5800
Fax: +1 (410) 455-5802
E-mail: info-tri@pda.org

Vice President's Message

Gail Sherman

Goodbye 2006, Hello 2007

I can't believe another year has gone by so quickly, and I am already writing a 2006 retrospective. It seems like I just finished the review of 2005. I'd like to believe we're not getting older; rather, we are so busy that the time just flies by. In any event, 2006 was a very good year!

On the lecture side, we visited Research Triangle Park, N.C.; Lake Tahoe, Nev.; Boston, Mass. and St. Louis, Mo. Our most successful course series this year was in St. Louis in August, thanks primarily to input from the PDA Midwest Chapter on course topics and to strong participation from the companies in the area. Thank you St. Louis!

Additionally, we held courses at the PDA Annual Meeting in Anaheim, Calif.; the PDA Biennial Training Conference in Philadelphia, Pa.; the PDA/FDA Joint Regulatory Conference in D.C.; the PDA/EMEA Joint Conference in London and the PDA Asia-Pacific Congress in Tokyo.

On the laboratory side, we filled our ever-popular Aseptic Processing Training Program four times and continued to have success in our standard short lab courses. We offered a few new lab courses this year, including Environmental Monitoring Database and Trending Technologies, which ran at capacity. To meet the strong demand for this course, we are offering it again in February 2007. Be on the look out for more new courses in 2007.

We also continued our training for staff from the Kazakhstan Ministry of Health, which began in late 2005. The 2006 training included a spring and autumn session. GMP issues and medical devices were among topics covered. In the October session, the trainees had the opportunity to visit a large stent manufacturer—one of the highlights of the training program to date. During the one day visit, the Kazakh regulators visited with personnel in R&D, quality, regulatory and clinical. This unique experience allowed them to witness firsthand the manufacturing processes and design of stents..

As you all may know, our biggest initiative in 2006 was planning the TRI move to Bethesda for mid-2007. We have had the opportunity to work with **Bob Ferer** and **Bill Bennett** from Vectech Pharmaceutical Consultants on the functional and construction designs for the space. This has been a total treat. **Allan Pfitzenmaier,** President, Vectech Pharmaceutical Consultants, told me we are all having entirely too much fun on this project! When our facility opens next year, it will truly be a state-of-the-art training facility for manufacturing processes in the United States—if not the world.

We have many supporters and sponsors who have committed equipment and materials for our facility, and we thank them all. To show our appreciation, we have given many of them hard hats to wear when they visit the construction site. In the next few months, we will post construction updates and photos on the PDA website. Plenty more opportunities still exist to help outfit our new lab space and classrooms with furniture and equipment.

Finally, the May issue of the *PDA Letter* will serve as a tribute to the 10th anniversary of TRI. Soon, we will be contacting some of you for interviews, pictures and articles, and, if we miss you, please contact us.

As we enter 2007, our course catalogue is published and has been mailed. Copies are available online at www.pda.org. We are open to adding additional courses, both laboratory and lecture, so, if you have hot topics on new technologies, regulations and other relevant issues, please feel free to contact us.

The staff at PDA TRI wish a fond farewell to 2006 and welcome 2007. And again: A great big thank you to our sponsors, instructors and students for contributing to our 2006 successes.

Does your facility have **the winning ticket?**

PDA Training and Research Institute

Aseptic Processing Training Program

4 Course is run 4 times a year to accommodate your busy work schedule

5 Two 5-day sessions scheduled weeks apart for minimal impact on your organization

10 10 days of training make this course the most comprehensive aseptic program available

20 Faculty of 20 leading industry, academic and regulatory experts

47 Over 47 hours of hands-on laboratory training

2007 Schedule

Session 1:
January 22-26 and February 12-16

Session 2:
March 12-16 and April 16-20

Session 3:
August 20-24 and September 17-21

Session 4:
October 15-19 and November 5-9

Venue

Sessions 1 and 2 will be held at the PDA Training and Research Institute (PDA TRI) facilities in Baltimore, Maryland, USA

Sessions 3 and 4 will be held at the new PDA TRI facilities in Bethesda, Maryland, USA

PDA℠
Parenteral Drug Association

www.pdatraining.org • +1 (410) 455-5800

Connecting People, Science and Regulation℠

Not *Everything* that happens in Vegas...

Stays in Vegas

SAVE $200
Register by December 29
www.pda.org/annual2007

PDA 2007 ANNUAL MEETING – MARCH 19-23

Putting Science and Technology into Practice

CONFERENCE | EXHIBITION | TRAINING COURSES

Take home the Knowledge, Connections and Experience that will make a difference all year.

What's new this year? The exciting setting of Las Vegas and an expanded schedule of networking activities make it easier than ever to meet colleagues, exchange ideas and have fun!

What has not changed? Our commitment to providing valuable bio/pharmaceutical knowledge, insights and training

Join PDA at the spectacular Red Rock Resort, Casino and Spa

- Develop your practical knowledge of science and technology
- Connect with decision makers and thought leaders
- Strengthen your role in advancing sound science and regulation

Expanded networking activities you can't afford to miss!

- PDA's 1st Annual Golf Tournament at Arroyo Golf Club
- Las Vegas signature shows and live entertainment
- Spouse/guest/child day programs
- Local sightseeing tours

PLUS: New member orientation, receptions, an expanded career fair and a gala event you won't forget!

PDA℠
Parenteral Drug Association