

PDA Letter

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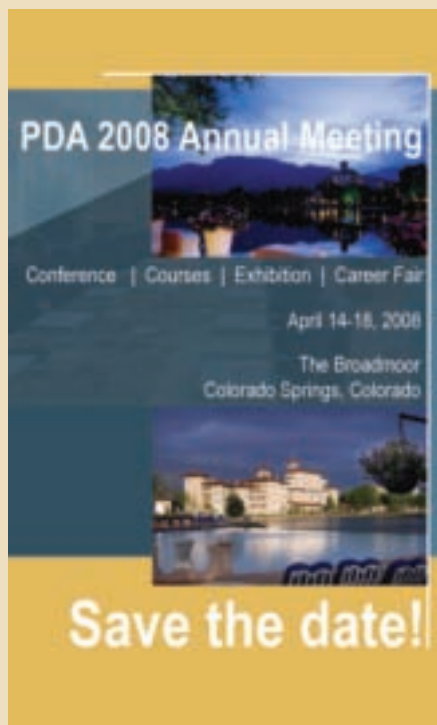
March 2007

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Connecting People, Science and RegulationSM

PIC/S: Why is It Important? What is Its Impact?

A Perspective on the Organization "Of-By-For" Inspectors

James Lyda, PDA

What makes PIC/S important for a PDA member? The following seven paragraphs are my own personal observations based on the view from my PDA staff chair and my U.S. FDA investigator chair before that:

Impact: PIC/S is unique in the world of regulators. It is the only organization which is set-up "of-by-for" inspectors. Inspectors run it, inspectors decide what it will do and not do, and the guidance and training it generates is for inspectors. Those same inspectors will show up sooner or later at your manufacturing site. It was a PIC/S conference in Australia in the 1990s which was the starting point for the API GMP guidance which ultimately became accepted worldwide as ICH Q7A. The PIC/S recommendation on validation was the starting point for what ultimately became Annex 15 of the EU GMP guide. So PIC/S clearly has impact in the development and future of GMP. And PIC/S may provide a forum for the discussion and perhaps attenuation of the increasing and duplicative growth of health authority inspections around the world.

Process: While PIC/S prides itself on the standards required for membership, the daily operations are based on an informal and collegial relationship between the participating inspectorates. Since PIC/S operates outside of the formal administrative and procedural requirements that bind the actual regulatory authorities, decisions can be made much quicker. This was evident at the first PIC/S industry forum, November 23, 2006 (see the *PDA Letter*, Feb. 2007, for details on the forum). The exchange between the inspectors and the industry associations was relaxed and fluid in a way that is simply not possible for the EMEA or FDA who are subject to (necessary) procedures and transparency provisions which can inhibit easy exchange of views. This fluidity allows PIC/S to operate something like a think tank or incubator for ideas which can later take form in official GMP and inspections procedures from the health authorities.

Future: Up until now PIC/S operated without the participation of the largest health authority in the world—The U.S. Food and Drug Administration. Historically FDA could not join the old "PIC," as it was the equivalent of an international treaty and would have obligated FDA to accept inspection results and reports from other PIC members. When PIC transformed into PIC/S in the 1990s, the landscape changed, and there was no legal or institutional reason

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2007



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Cover art: For most PDA members, successful compliance with regulatory expectations—whether about residual solvents or any other issue—boils down to the results of the next site inspection. Artwork by Bruno Budrovic/www.images.com.

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Editor's Message

GMP enforcement and compliance are the themes of this month's issue. Our cover story tackles the topic of enforcement from the angle of GMP inspections, or, more accurately, the need to create an internationally harmonized approach to inspection. PDA's **Jim Lyda's** article, "PIC/S: Why is It Important? What is Its Impact?: A Perspective on the Organization 'Of, By, For' Inspectors," not only provides a comprehensive overview of the organization, it includes the former FDA official's valuable insight into the importance of PIC/S, its value to the authorities and the industry, and its future role.

Our second feature article, "Solvents Training Workshop Drums Up Residual Questions," is my account of the debate that occurred at the PDA/USP Joint Conference on Residual Solvents, Jan. 18-19. By the end of this training workshop, USP officials were stating that many options were "on the table" regarding the status of general chapter <467>.

This issue also contains a report from PDA's conference in Berlin on Technical Report No. 42, updates from the Israel Chapter and Southern California Chapter and an engaging article from Assistant Editor **Lindsay Donofrio** on PDA's newest board members, **Louise Johnson** and **Martin Van Trieste**.

We are sure you will enjoy these and all the articles included in this month's issue. And whether you do, or don't, we want to know! I announced we will start publishing reader feedback. So let us know what you think about the Letter, about specific articles or PDA in general. Contact me at morris@pda.org or Lindsay at donofrio@pda.org. Also, go to www.pda.org/pdaletter to see the current issue and to find links to contact Lindsay and me.

Next month, we will report on PDA's joint activities with the International Society of Pharmaceutical Engineers to help inform industry on the ICH Q8, Q9 and Q10 documents. 🍷

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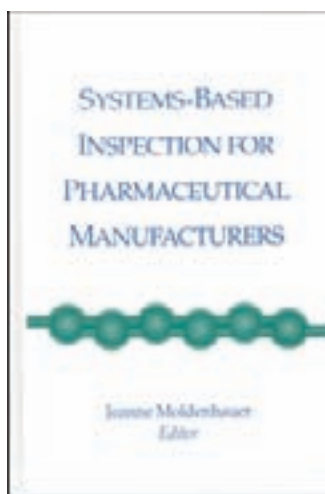
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Top 10 Bestsellers

From the PDA Bookstore



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Edited by Jeanne Moldenhauer, PhD

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By Mark Gibson

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Strong Showing of Support Strengthens New Facility

Bob Myers, PDA

PRESIDENT'S MESSAGE

As the ground breaking of TRI's new Bethesda, Md., facility approaches, PDA would like to thank our members who have already graciously donated equipment and other supplies to this project. Without our members' support, this training facility would not be possible.

Recently I met with **Wenzel Novak, PhD**, Groninger, who on behalf of his company has donated a semi-automatic stopper, filler and insertion machine for syringes. This new machine will allow TRI to offer courses in the basic science of syringe filling. It will be a hands-on course as well as a lecture. Groninger will also provide the syringes to demonstrate the problems associated with poor siliconization of the syringe barrel, including too much silicon and not enough silicon. They have promised their technical expertise in designing the course as well.

Other companies have committed to donating as well, including Vectech Pharmaceutical Consultants, facility design; Sartorius, bioreactors; Millipore, Steritest Equinox pump for sterility testing; Fedegari Autoclavi, autoclave; Stonhard, flooring; and Kewaunee/Glover, lab benches. Donations for the new facility currently total \$700,000 (U.S.).

We look forward to the continued support of our members and encourage you to consider making a donation to the new TRI facility. Please see page 9 for a list of needed laboratory equipment, supplies and services, which will ensure that we can provide optimum training experiences for our students. 🌐



(From left to right) Wenzel Novak, PhD, Groninger, shares details of his company's recent donation of a semi-automatic stopper, filler and insertion machine to the new TRI facility with Bob Myers, PDA, and Gail Sherman, PDA.

Participate in PDA:

Write and/or Review Technical Reports

Authors: PDA is seeking content experts globally to participate on three new Task Forces will begin meeting in March 2007 to draft Technical Reports on the following subjects:

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

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

- Reprocessing of Biopharmaceuticals
- Aseptic Processing Risk Management
- Validation of Column-based Separations
- Sterilizing Filtration of Liquids

For more information on how to participate, contact Genevieve Lovitt-Wood at gilovitt@mindspring.com.

Participate on the Biotechnology Advisory Board

The Biotechnology Advisory Board (BioAB) is looking for volunteers to address the following topics of interest to the PDA community:

1) Cell line characterization phase 1 to license application; 2) Analytical validation: toxicology to license application; 3) GMPs from phase 1 to licensure.

If you are interested, please contact Iris Rice, Executive Coordinator, Scientific and Regulatory Affairs, PDA, at rice@pda.org or call +1-301-656-5900, ext. 129.



INVEST IN THE FUTURE OF PHARMACEUTICAL SCIENCES

Support the Rebuilding of PDA's Training and Research Institute

The PDA Training and Research Institute will move to Bethesda in June 2007. We are pleased to report that Vectech Pharmaceutical Consultants, Inc. has designed this space. And, we are looking to our friends in PDA to help us meet our build-out goals. Having been in our Baltimore facility for the past 10 years, much of the support equipment will be left behind. Some laboratory equipment has become dated or obsolete and should ideally be replaced to provide the optimum training experience.

We plan to dedicate our labs and classrooms to supporters, and will acknowledge any donation with recognition in the facility, be it a plaque on the wall, a plaque on a piece of equipment, or a mention in our Annual Report or PDA Letter. We value all of the support we have received over the years, and hope this support continues in the future. Our grand opening is scheduled for May 2007 to coincide with the 10th Anniversary of TRI. For information, contact Gail Sherman: sherman@pda.org, (410) 455-5800.

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Lyophilizer	1	_____
Isolator Hardwall	1	_____
Laboratory Flooring	4 labs	_____
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Classroom furnishing and equipment		_____
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* Note: All donations may be made to the Foundation for Pharmaceutical Education, Training, and Research, a 501(c)(3) nonprofit foundation.

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Berlin Workshop on PDA's Technical Report No. 42, Biopharmaceutical Process Validation

Workshop Co-chairs: **Norbert Hentschel, PhD**, Boehringer Ingelheim, and **Chris Bussineau, PhD**, Cambrex Biosciences

On December 5 and 6, 2007, PDA held a two-day workshop on biopharmaceutical process validation in Berlin, Germany. The scope of the workshop was to provide an overview of the utility and value of PDA Technical Report No. 42, *Process Validation of Protein Manufacturing*.

On the first day, speakers from industry and the U.S. FDA provided an overview of process validation practices, expectations and the importance of process development and characterization for process validation.

In session 1, **Norbert Hentschel**, PhD, Director of Compliance and Validation, Boehringer Ingelheim, reviewed the changing environment for process validation in the past 20 years. According to Hentschel, industry appreciates the paradigm change to a more science- and risk-based validation approach. A clear pathway for the continuation of the process is desirable, e.g., how to demonstrate process understanding in a regulatory filing. Next **Chris Bussineau**, PhD, VP and General Manager, Cambrex Biosciences, who served as co-chair of the TR-42 task force, provided an overview of the development, purpose and scope of TR-42.

In session 2, **Anita Derks**, Global Quality Manager (Biotechnology), F. Hoffmann La Roche, explained strategies for successful implementation of manufacturing processes at Hoffmann La Roche. In her talk she stressed the importance of good process understanding for successful process validation and post validation process monitoring. In the following case study, **Mike Lennick**, PhD, Associate Director, Global Biologics Supply Chain, Centocor, shared his experience on how to implement a process validation plan to meet expectations. Next,

Bussineau returned to the podium and continued to explain the TR-42 approach on validation prerequisites such as process description, analytical methods used in different phases of development and what studies need to be performed at which stage of development.

The last speakers of the first day, **Kurt Brorson**, PhD, Staff Scientist, CDER, FDA, and **Jim Lyda**, PDA, gave

“The current paradigm of multiple products with similar biochemical attributes and manufacturing schemes will lead to standardized methods and unit operations.”

updates on current regulatory perspectives on process validation for biotech products. Brorson shared his view as an FDA CMC reviewer on quality by design for biotech products and the increasing standardization of the manufacturing of monoclonal antibody products. In particular he pointed out that there is an extensive and growing cross-industry experience with monoclonal antibody manufacturing processes. The current paradigm of multiple products with very similar biochemical attributes, made with similar manufacturing schemes, will ultimately lead to standardized methods and unit operations. He discussed potential examples for virus removal validation and provided an overview about current developments in adoption of consensus standards in the United States.

The second day of the workshop continued to follow the format of

TR-42 with a presentation by **Tony Christensen**, Director, Scantago, about facility and equipment aspects for process validation. The next case study presentation was prepared by **Wendy Lambert**, Senior Manager, Pfizer, and was presented on her behalf by **Torsten Addicks**, PhD, Senior Manager, Boehringer Ingelheim. The presentation provided Pfizer's approach on how to define critical and key process parameters. **Morten Munk**, VP, CMC Biopharmaceuticals, then explained the different types of process validation, prospective, concurrent and retrospective as well as the application of unit operation, family and matrix approaches in a validation project. Next, Hentschel returned to the podium to address the use of small-scale models in process validation. These models are particularly important for resin lifetime studies and evaluating new raw materials.

The final session concluded with two talks about viral clearance and safety. The first speaker, **Qi Chen**, PhD, Scientist, Genentech, presented Genentech's bracketing approach for modular virus clearance studies applied for clinical products. Chen shared Genentech's view on how to apply previous clearance studies to current processes. The last speaker of the day, **Hannelore Willkommen**, PhD, Regulatory Affairs, NewLab BioQuality, provided a comprehensive overview of current considerations and developments in the field of viral validation. The workshop was concluded with a lively 45 minute panel discussion.

It can be said that PDA TR-42 provides a systematic state-of-the-art approach for validation of protein manufacturing processes addressing developments such as the application

continued on page 22

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.

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Solvents Training Workshop Drums Up Residual Questions

A Report from the PDA/USP Joint Conference on Residual Solvents, January 18-19 • Bethesda, Md.

Walter Morris, PDA

The well-planned PDA/USP training effort on revised General Chapter <467> “Residual Solvents” included a balanced mix of training and some unanticipated yet insightful debate about the language in the chapter itself and the ramifications of applying it retroactively to existing products.

Since 2002, the U.S. Pharmacopeia has worked to revise <467>, currently titled “Organic Volatile Impurities,” to incorporate the concepts for the control of residual solvents set out in the International Conference on Harmonisation (ICH) guideline Q3C *Residual Solvents*. Q3C was finalized by ICH in 1997 and adopted by the U.S. FDA that same year. New USP General Chapter <467> goes into effect July 1, 2007.

The comprehensive training was well received by participants. The majority of the PDA/USP conference was dedicated to discussion of how firms (both manufacturers and suppliers) are implementing the chapter retroactively, application of the analytical methodology and the use of alternative methods. The presentations on the methodology were a highlight of this training conference (see box below for more on these talks).

Following the meeting, USP posted all slide presentations on its website: www.usp.org/eventsEducation/residual-SolventsConference/.

USP intends to continue with an extensive training effort for <467>, hoping to set the table for a smooth transition as the July 1 implementation date nears.

Industry representatives at the conference—both speakers and audience attendees—did raise a number of residual questions regarding the new chapter that went beyond simple implementation issues. Such questions

remain despite the fact that USP reissued a draft of the chapter in 2006 and delayed the implementation date from January 1, 2007 to the now planned July 1 date in order to address issues raised previously by industry.

USP officials on hand were receptive to the unexpected questioning and were open to possible further revisions, even going as far as suggesting that an additional delay in implementation was “on the table”—though highly unlikely. Only a strong demonstration of support from industry would spur USP to enact an additional delay to implementation.

No participant appeared to take issue with the concepts contained in the ICH document. Summarizing its utility for new products, USP CEO **Roger Williams**, PhD, called Q3C “a real advance” and said it establishes a “preregulatory allowance for the limit” on the residual solvents covered. This, in turn, “saves people a lot of time so you don’t have to go through a complicated review time and time again.”

Despite the good sentiments for Q3C, three first-day speakers representing large pharma, generics and consumer product manufacturers pointed to the magnitude of effort required to retroactively apply the guidance to marketed products. In addition, they expressed uncertainty over the differences between USP’s chapter and Q3C. By contrast, they pointed out, the European Pharmacopoeia (EP) “cut and pasted” Q3C language into General Chapter 5.4.

History of <467>

Debate over the USP chapter commenced following USP’s presentation on the history of revised <467>. USP VP of Standards Development **Todd Cecil**, PhD, noted that five years transpired before USP began the process of incorporating the ICH document into the pharmacopeia—not that USP took issue with the harmonized approach to solvent control. Quite the contrary, Cecil called Q3C “revolutionary” and a “wonderful way of setting limits” in that it applies a risk-based approach to setting ➤

Presentations on <467> Methodology from PDA/USP Workshop

The following is a list of the presentations on the methodology included in <467> and alternative methods.

“Residual Solvents, The Final Frontier?—Water Soluble and Water Insoluble Methodologies”
Jennifer Belsky, PhD, USP

“Methodologies Development of a General Solvents Method for DMSO Soluble Compounds”
Ann M. Warner, PhD, Eli Lilly

“A Guide to Residual Solvents Analysis in Pharmaceuticals”
Sky Countryman, Phenominix

“Novel Calibration Strategy for Residual Solvents Analysis by Headspace GC”
Keith Freebarin, PhD, GSK

“USP <467> Residual Solvent Alternative Methodologies”
Curtis Tinker, BMS

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acceptance criteria, it establishes testing options and it pushes compliance (testing) to the finished product. “All of these are revolutionary concepts compared to the OVI [organic volatile impurities] test.”

Cecil said that USP sees opportunities to apply risk management to other standards. It is “one we would like to use more often at USP, and it is something we are trying to use for heavy metals in particular.”

While impressed with Q3C, USP took a conservative approach before acting on it. “There was a lot of discussion at USP as to whether we should be adopting that standard, [but] at the time, we were concerned about a number of items,” said Cecil.

Primarily, he further explained, USP recognized that ICH documents are geared to submissions of new products; USP chapters apply to both new and existing products. Because of this and other issues, the pharmacopeia “decided to wait for a while and see if industry was ready to embrace this new revolutionary approach. Within a few short years it was clear that industry was ready to embrace it and was embracing it in a meaningful way.”

By 2002, USP was not the first standards-setting body applying Q3C to existing products. When Q3C went into effect in Europe in 1998, the European Medicines Agency guideline (CPMP/ICH/283/95) required the use of the ICH standards to all existing marketing products.

Next, the EP adopted the ICH guideline. The language in Q3C was transposed to EP General Chapter 5.4. The pharmacopoeia also added a methodology for testing “class 1” solvents (most toxic/harmful “to be avoided”) and “class 2” solvents (“to be limited”), contained in General Chapter 2.4.24.

The methodology is three-pronged.

The first two methods are intended to be orthogonal to allow identification of a range of solvents. Both are limit tests. USP refers to these tests as “A” and “B,” and they apply to class 1 and class 2 solvents. The third test (method C in <467>) provides a quantitative assay of class 2 solvents when levels are greater than 0.1% and for class 3 solvents when required. The methodol-

Industry representatives expressed concerns over the mandatory status of the methods in <467>.

ogy specifies the use of head space gas chromatography using two column phase systems, A or B.

EP general chapters are only mandatory when referenced in a monograph. EP General Chapter 5.4 is mandatory to all products and substances because it is cited in General Monograph (2034) “Substances for Pharmaceutical Use.” The methodology in General Chapter 2.4.24 is referenced in General Chapter 5.4, although other validated methods are specifically allowed.

In 2002, USP launched its own program to incorporate the ICH residual solvents concepts into the pharmacopeia. “The idea was we would create a general approach for the general chapter and a requirement in the general notices,” explained Cecil. “The text of the USP, the EP and the ICH, for that matter, state that you only test for those solvents that you know to exist or to be created through the manufacturing process. That is the expectation.”

Significant differences between Q3C and the chapters in the EP and the USP are the inclusion of the testing standards in the pharmacopeias and

their applicability to older products. While providing “an excellent risk-based approach” and “innovative and insightful calculations,” Q3C “didn’t include any procedures” and “didn’t apply to older products,” said Cecil.

Residual Concerns

Industry representatives expressed concerns over the mandatory status of the methods in <467>. Eli Lilly Global Compendial Consultant **Neil Schwarzwald** noted that the methods in the chapter are valuable for screening a large number of solvents, but are not suitable for routine control. Since Q3C was finalized, companies have established methods to test for known solvents in their drug products.

The concern is that companies will be required to provide data showing that their current validated methods compare with the USP methods. Schwarzwald, speaking for the Pharmaceutical Research and Manufacturers of America, emphasized that there “is no value added” by generating comparison data, especially since the manufacturer’s methods are validated for specific solvents and materials, while the methods in <467> are not.

USP chapters with numbers less than 1000 are considered mandatory. While manufacturers are allowed under the USP general notices and U.S. FDA regulations to use other validated methods, they are expected to generate comparison data showing that their alternative methods give equivalent results to the official methods in the USP. That expectation might not be as strong today. In response to a question on this issue, CDER Compliance Officer **Rosa Motta** stated, “I know for years and years investigators have said, ‘equal or better.’ In [the Office of] Compliance, we think that it makes sense that if you have demonstrated that your method is properly validated—you would have to have some evidence and you will have to convince your auditor that that is the case—but

we are willing to accept appropriately validated methods, yes.”

Schwarzwalder credited USP for previously responding to debate over the proposed revised chapter. He noted that the revised proposal for <467>, published in the September-October 2006 *Pharmacopeia Forum* addressed many industry concerns. At that time, USP announced the delay in the chapter's implementation from January 1, 2007 to July 1.

The way in which firms approach the three-pronged analytical methodology is not clear. During one Q&A period at the conference, an industry participant asked USP's Cecil if companies need to conduct method B (if they “find something at A”) when they already know the solvents involved. “Why not go to C directly?”

Cecil replied: “I don't think there is necessarily a prohibition for doing so. I think the test is written in such a way that a third-party user who didn't know what the solvent is could have the ability to look at it and ensure that it is the right solvent. [The questioner's approach] is an alternative method....If you know, there is no reason not to go to C right at the beginning.”

Conference participants, including the three industry speakers, were concerned with the possibility of filing supplements both in the United States and in the European Union when implementing Q3C to existing products.

Schwarzwalder explained that if tests, limits and suppliers are unchanged and there are no additional registration

changes resulting, no filings should be expected. “A lot of documents will be internal. That's an important distinction. That might be why there are a lot of questions.” However, he added, “It is not straightforward and there are some interpretations involved.”

Irish Medicines Board Sr. Scientific Advisor **John Morris**, PhD, who was on hand to present the activities in Europe regarding Q3C (see box below for more on Dr. Morris' presentation), addressed the issue of post-approval changes filings. “No one is going out with a magnifying glass and checking every single dossier in every company. We don't have the resources for that.... Silence is considered to be assent. If companies don't tell that us there is a problem, we assume there is no problem.”

FDA's Motta suggested that firms making changes to comply with <467> over the next few months should use the annual report mechanism for reporting the changes.

Industry representatives also were uncertain about different language used in the USP compared with the Q3C document. USP intends to address this issue.

“There are some deviations we put into this text from the ICH,” explained Cecil. “Those deviations are extremely minor...and the number of words is very minimal. We have begun a stimuli article to actually identify those differences. They center around the ICH assumption that you are working with a regulatory agency at the time of the submission, and we cannot compel that of a user. So we had to find wording to

get around that concept. By the time you are looking at a USP monograph, you've already got approval from the regulatory agency for the appropriate level of impurity.”

Conference participants also raised the issue of the applicability of the residual solvent limits to dosage forms where the risk of exposure is extremely low, such as topicals.

The discussion wended back to the issue of the methodology. Conference participants suggested that USP consider revising <467> to remove the analytical methodology completely. This is a “nice, interesting and challenging” idea, stated Cecil. In essence, USP would set the expectations and industry would select the methodology—an approach USP “will consider moving forward.”

Finally, a questioner asked Cecil if they would consider delaying the implementation date of July 1 in light of all the issues raised at the 1½-day conference. Cecil replied: “Everything is possible. [We] are not opposed to moving the date....It is not outside the realm of possibility.”

In the final analysis, USP recognized the multitude of questions and concerns industry still harbors with respect to <467>. Officials on hand, particularly Cecil, fielded all questions. It was also clear that concern over the chapter exists not only because of the work involved with implementation, but also because of uncertainty over FDA's yet-to-be-seen expectations regarding the comparison of validated “alternative” methods against the USP tests and application filings.

Regulation of Residual Solvents in Medicinal Products in the European Union

At the PDA/USP conference on General Chapter <467>, John Michael Morris, PhD, Irish Medicines Board, discussed actions taken in the European Union to implement ICH Q3C. Below is the abstract for his talk.

The European Union adopted the ICH guideline on residual solvents into its regulatory process in 1997 following the completion of the Step 4 of the ICH guideline (Q3C), together with the additional changes through the maintenance program. Given that the basis for the controls applied and the acceptance criteria defined was rooted in safety concerns,

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PIC/S: Why is It Important? What is Its Impact? continued from cover

that FDA could not participate. FDA still hesitated, in my judgment due to inertia and a learning curve, to recognize what the PIC/S had to offer. Recently, as part of the 21st Century GMP initiatives, FDA announced its intention to apply for PIC/S membership.

What will FDA membership in PIC/S mean?

First, both organizations will be affected dramatically. FDA will participate in collaborative GMP interpretation and development, rather than the traditional “go it alone” of the past. Both organizations will have much to gain and little to lose. Most important, the “new PIC/S” will allow, for the first time in the modern GMP era, global discussions on GMP requirements with all the key players involved. The fractured GMP world of the past should be no more. The effects on industry could be improved GMP interpretation and harmonization, i.e., clear and appropriate GMP rules and inspections. Approval of an application to join PIC/S can take up to six years. For the benefit of our business, and for the patients we serve, let’s hope for an expedited review process by PIC/S appropriately supported by FDA. It is in everyone’s interest that FDA sit at the PIC/S table as a full member, sooner rather than later!

PIC/S Primer

[**Note:** The following information has been drawn from public information released by PIC/S and edited for clarity and brevity. PIC/S will focus on the Pharmaceutical Inspection Co-operation Scheme, which is the organization with today’s growing impact. PIC will refer to the original Pharmaceutical Inspection Convention, which was the basis for mutual recognition and acceptance of inspection reports by the member countries. PIC/S is the focus of this article.]

PIC/S is the acronym for both the “Pharmaceutical Inspection Convention” and the “Pharmaceutical

Inspection Co-operation Scheme.” Both are international instruments involving many countries and pharmaceutical inspection authorities. Together they provide constructive cooperation in the field of GMP.

“It is in everyone’s interest that FDA sit at the PIC/S table as a full member—sooner rather than later!”

PIC/S was a new transformation of the PIC and became operational in November 1995. There are currently 30 participating authorities in PIC/S. While not a European organization, many EU member states are members. As such, there is a strong relationship between PIC/S and the European GMP environment. The EMEA, the World Health Organization and the United Nations Children’s Fund are observers to PIC/S. Formation of PIC/S became necessary when evolving EU law prohibited individual EU member states to sign agreements with other countries seeking to join PIC. Therefore, a less formal and more flexible cooperation scheme was developed. Instead of being a legal treaty between countries, like PIC, the PIC/S is a cooperative arrangement between competent authorities in the field of inspections.

Mission and Purpose

PIC/S’ mission is “to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products.” This is achieved by developing and promoting harmonized GMP standards and guidance documents, training of inspectors, assessing inspectorates and facilitating the co-operation and networking for health authority inspectorates and international organizations.

The purpose of PIC/S is to facilitate the networking, information exchange and training between participating authorities and inspectorates, through:

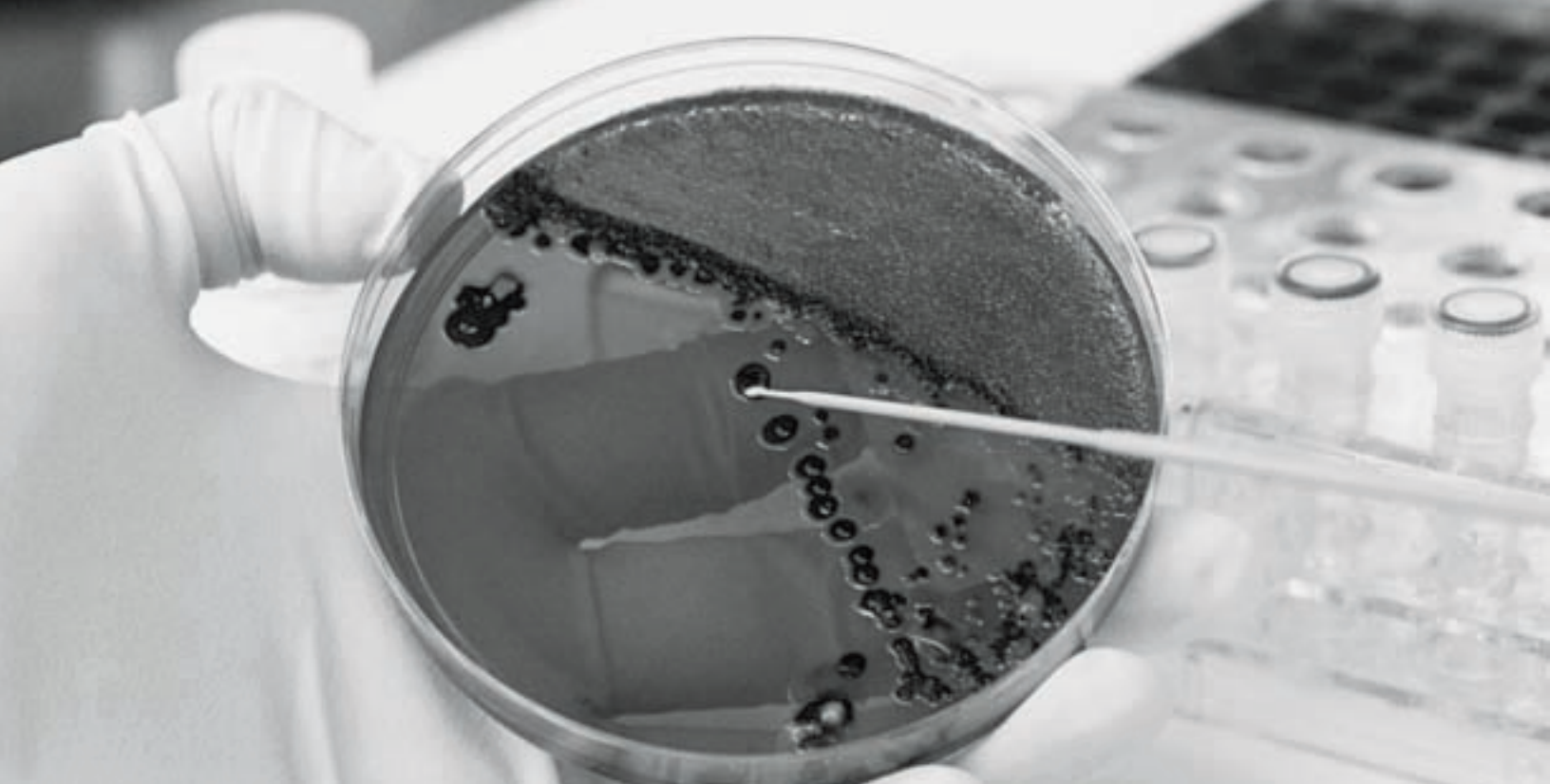
- Cooperation in the field of inspections with a view to maintaining the mutual confidence and quality assurance of inspections
- A framework for exchange of information and experience
- Training for inspectors and other technical experts
- Efforts to improve and harmonize technical standards and procedures regarding the inspection of medicinal product manufacturing.
- Efforts for the development, harmonization and maintenance of Good Manufacturing Practice (GMP), and
- Inclusion of other (non-PIC/S member) health authorities to apply equivalent standards and procedures contributing to global harmonization

Administration and Management

PIC/S leadership is comprised of officials from member regulatory authorities. For 2006-07, the chairman of PIC/S is **Jacques Morénas**, Associate Director, AFSSAPS, France. The secretariat of PIC/S consists of **Daniel Brunner** and **André Kovacs**.

The key decisions by PIC/S are made by the Executive Bureau, which, besides Morénas, consists of: ➤

This is the first in a series of occasional articles to help PDA members understand more fully the regulatory and GMP compliance environment in today’s Europe. This issue covers the PIC/S based in Geneva, Switzerland.



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PIC/S is directed by a permanent committee composed of representatives of the participating authorities meeting at least twice a year to:

- Recommend amending, updating and improving of GMP standards
- Exchange information to achieve uniform and effective inspections
- Promote quality assurance of inspections and quality systems for inspectorates
- Advance the training for inspectors
- Consider special GMP issues for certain medicinal products (e.g., blood products, radio-pharmaceuticals, biotechnologically manufactured medicinal products)
- Decide on membership of authorities of other countries
- Develop new guidance documents to address production and quality control issues
- Support global harmonization of GMP

Training

The PIC/S training seminar is held each year focusing on a particular aspect of GMP. The proceedings of these seminars are published in booklet form and are available for purchase from the PIC/S Secretariat. A list of seminar topics is shown in "Publications" on the PIC/S website. The annual PIC/S Seminar usually results in the formation of a working group to develop draft guidance or recommendations for inspectors. For example, the 1994 Seminar on validation resulted in the preparation of PIC/S *Recommendations on Validation* (available for purchase from the PIC/S Secretariat).

Before a country's regulatory authority can become a member of the PIC/S, a detailed assessment is undertaken to determine whether the authority has the infrastructure and competence necessary to apply an inspection system comparable to that of current PIC/S members.

Another avenue for the training of inspectors is the joint visits program. Under this program three inspectors from different countries are teamed up to observe typical inspections in each country with a view to comparing inspection procedures and techniques. Any differences in inspection are reported to the PIC/S Working Group on Training for appropriate action.

PIC/S has formed several "Expert Circles" to enable inspectors to discuss and exchange information on specific technical areas of GMP. Expert Circles are currently active for Human Blood and Tissues, Active Pharmaceutical Ingredients, Computerized Systems and Hospital Pharmacy. The aim of the Expert Circles is to develop draft guidance, recommendations or Aide Memoir or new Annexes to the PIC/S GMP Guide.

Membership in PIC/S & Benefit to Inspectorates

Before a country's regulatory authority can become a member of the PIC/S, a detailed assessment is undertaken to determine whether the authority has the infrastructure and competence necessary to apply an inspection system

comparable to that of current PIC/S members. This assessment involves an examination of the authority's documentation related to inspection and licensing system (for manufacturing sites), quality system, legislative requirements, recalls, inspector training, etc. The assessment is followed by a visit by a PIC/S delegation to verify the on-site implementation of the above documentation and to observe inspectors carrying out actual GMP inspections.

The following is extracted from the PIC/S Blueprint (PS/W 8/2005) on the benefits to the inspectorates deriving from PIC/S membership:

Training: PIC/S is unique. There is no other international training forum run jointly by regulatory authorities.

GMP harmonization: PIC/S participating authorities are involved in the development, harmonization and interpretation of international GMP guidelines and quality systems

Networking: PIC/S is one of the few international networking and confidence building forums for GMP inspectors and chief inspectors. This networking simplifies contacts and the exchange of GMP related information.

High standards: PIC/S ensures that all members comply with PIC/S standards (assessment of new applicants and reassessment of existing member inspectorates). The application to join PIC/S frequently forces improvements in the GMP inspection system and procedures. This is particularly true for Quality System requirements and for GMP training.

Sharing of information: PIC/S supports effective use of inspection resources through the voluntary sharing of GMP inspections reports. Membership is also a cost-saving measure for inspection authorities confronted with an increase of inspections, notably in the field of active pharmaceutical ingredients (APIs).

continued on page 22

PDA Calendar of Events for North America

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

Conferences

March 19-23, 2007

PDA 2007 Annual Meeting

(Conference, Courses, Exhibition and Career Fair)
Las Vegas, Nevada

March 22, 2007

Workshop on the Universe of Pre-Filled Syringes

Las Vegas, Nevada

May 21-22, 2007

Quality by Design for Biopharmaceuticals: Concepts and Implementation - A PDA Workshop

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 15, 2007

PDA Visual Inspections Workshop

Bethesda, Maryland

October 29, 2007

PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology

Bethesda, Maryland

Training

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

Laboratory Courses

March 28-30

Cleaning Validation

May 1-4, 2007

Pharmaceutical and Biopharmaceutical Microbiology 101

May 8-11, 2007

Downstream Processing: Separations, Purifications and Virus Removal

May 16-18, 2007

Developing a Moist Heat Sterilization Program within FDA Requirements

May 21-22, 2007

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

May 21-23, 2007

Operator Qualification

August 2-3, 2007

Environmental Mycology Identification Workshop (Session 2)

Bethesda, Maryland

August 20-24 and September 17-21, 2007

Aseptic Processing Training Program (Session 3)

Bethesda, Maryland

October 1-5, 2007

Rapid Microbiological Methods

Bethesda, Maryland

October 15-19 and November 5-9, 2007

Aseptic Processing Training Program (Session 4)

Bethesda, Maryland

October 31-November 2, 2007

Advanced Environmental Mycology Identification Workshop

Bethesda, Maryland

Lecture Courses

March 5-7, 2007

Fundamentals of Pharmaceutical Filtrations and Filters

March 22-23, 2007

PDA 2007 Annual Meeting Training Courses

Las Vegas, Nevada

October 8-10, 2007

Advanced Pharmaceutical Filtrations and Filters

Bethesda, Maryland

Course Series

May 7-9, 2007

Indianapolis Training Course Series

Indianapolis, Indiana

June 11-13, 2007

Baltimore Maryland Training Course Series

Baltimore, Maryland

Chapters

April 11, 2007

PDA New England Chapter

Shipping Qualification - From Bulk Drug Substance to Finished Drug Kits

Burlington, Massachusetts

Europe/Asia-Pacific

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

Europe

March 26-27, 2007

Continuous Improvement in Pharma Industry and its Impact on cGMPs Conference and Exhibition

Verona, Italy

May 3-4, 2007

Good Practices for Investigational Medicinal Products

Lyon, France

May 8-9, 2007

Best Practices in Aseptic Manufacturing

Milan, Italy

June 11, 2007

Supplier Quality

Bologna, Italy

June 19-20, 2007

Current Facility Issues in Pharma Manufacturing

Monitoring of Non-Sterile Facilities (June 19)

Dedicated Facilities (June 20)

Langen (Frankfurt), Germany

June 20-21, 2007

From Biopharmaceutical Development to Manufacturing — Challenges in the European Environment

Berlin, Germany

September 11-12, 2007

Industrial Freeze Drying and Spray Drying

Cologne, Germany

September 13, 2007

Technology Transfer

Basel, Switzerland

October 9-10, 2007

Cleanrooms/Isolators/RABS

Co-sponsored by PDA and R3 Nordic

Berlin, Germany

October 17-18, 2007

Pharmaceutical Cold Chain

Berlin, Germany

Online Learning

Please visit www.pda.org for the most up-to-date registration information.

Web Seminars

March 8, 2007

FDA Final Guidance: Investigating Out of Specification Test Results

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PIC/S: Why is It Important? What is Its Impact? continued from page 19

Rapid Alert System: Member authorities automatically benefit from the PIC/S Rapid Alert and Recall System arising from quality defects in medicinal products. The PIC/S alert and recall system is part of a wider system, which includes the alert and recall system of EU/EEA/MRA partners.


Facilitating Other Agreements:

Membership in PIC/S may also facilitate other agreements, e.g., Mutual Recognition Agreements (MRA), between members (e.g., Australia-Canada MRA, EU-Switzerland MRA). During the recently concluded initial negotiation on Association of Southeast Asian Nations MRA on GMP Inspection, PIC/S membership was accepted as an essential criterion for the MRA.

Industry Benefit: There is indirect benefit to industry when their regulatory


authority joins PIC/S. These benefits may include the following: reduced duplication of inspections, cost savings, export facilitation, enhanced market access (some non-PIC/S authorities in countries such as Colombia and South Africa accept GMP certificates from PIC/S participating authorities).

Publications

Most PIC/S publications can be downloaded for free from the website, www.picscheme.org. All PIC/S publications, in particular those which are not electronically available (e.g., annual training seminar booklets), can also be purchased from the PIC/S Secretariat. 

Berlin Workshop on PDA's Technical Report No. 42, Biopharmaceutical Process Validation, continued from page 10


of a risk-based approach. It provides an integrated life-cycle approach for process validation, which takes into account use of process development data as a basis for process validation, confirmation at manufacturing scale during production of conformance batches and maintenance of the validated state throughout the product's life cycle.

PDA thanks the program planning committee for developing the agenda for the Biopharmaceutical Process Validation workshop and for collectively writing this summary of the event. The committee members are: **Chris Bussineau**, PhD, Cambrex (co-chair); **Norbert Hentschel**, PhD, Boehringer Ingelheim (co-chair); **Kurt Brorson**, PhD, FDA; **Morten Munk**, CMC Biopharmaceuticals; **Anurag Rathore**, PhD, Amgen; **Gail Sofer**, GE Healthcare; and **James Lyda**, PDA. 

Solvents Training Workshop Drums Up Residual Questions, continued from page 16

it was considered illogical to apply this only to new products containing new active substances as is the general aim of ICH guidance. Therefore, the European Medicines Agency and its Quality Working Party took the decision to extend the provisions within a two-year timeframe to all new applications containing new and established active substances as well as to products already on the market so that the same residual solvent controls would apply to all medicinal products in Europe.

In parallel, the European Pharmacopoeia, which is the official pharmacopoeia named in the European Union, decided to adopt the ICH criteria for controlling residual solvents into its general chapters and monographs. Notwithstanding that the European Pharmacopoeia is an institution of the Council of Europe and has a wider audience than the twenty-five Member States of the European Union, there was unanimous agreement amongst the Member States signatories to the European Pharmacopoeia Convention that ICH based residual solvent control limits were appropriate for all medicinal products covered by the European Pharmacopoeia. Consequently, a General Chapter was developed which implemented the ICH Q3C residual solvent guideline verbatim and a reference was made in the general monograph on Substances for Pharmaceutical Use to apply the residual solvent standards to all substances, active and excipients, described in the European Pharmacopoeia. Furthermore, in 2005 it has been agreed that acceptance criteria for class II solvents would not be mentioned in the European Pharmacopoeia monographs and that class I solvents would be included only where it was known that their use was unavoidable in the manufacturing process for the drug substance using the acceptance criteria laid down in the ICH guidelines.

Finally, it is also recognized that some specific substances produce solvated forms for which there are frequently higher levels of solvents, for example, class III solvents co-crystallizing with the active substances for which higher limits than the normal general 0.5% limit may have to be applied. These higher-level class III solvents would then be named individually on a case-by-case basis where their presence at such levels is considered to be unavoidable. It should be stressed that there is no safety issue relating to such levels since they are low toxicity solvents and the 0.5% threshold is merely a nominal limit. It should also be stressed that this does not bind the regulatory authorities in the European Union to adopt wider limits than the ICH limits of such low toxicity solvents if they feel the need from a safety point of view in insisting that a higher limit in line with the ICH guidance is more appropriate for a given source of an active substance. 

Regulatory Briefs

Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at <http://www.pda.org/regulatorynews>.

Europe

Closer Ties on Medicines Safety between European Union and Japan

The European Union and Japan will from now on be able to exchange confidential information about the authorization and safety of medicines. Confidentiality arrangements were agreed between the European Commission and the European Medicines Agency (EMA) on the one side and the Japanese Ministry of Health, Labor and Welfare (MHLW) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) on the other at a bilateral meeting in Tokyo. The partners will be able to exchange confidential information, for instance on safety issues with marketed medicines and products being developed or considered for authorization.

Commission Vice President Günter Verheugen responsible for enterprise and industry policy said: "This closer cooperation with the Japanese authorities will provide earlier access to information and thus make it easier and quicker to take action to protect public health. Our close relationship will also allow us to tackle technical barriers to trade in medicines and help prevent new barriers occurring."

EMA Executive Director Thomas Lönngren said: "We have been working closely with our Japanese counterparts for many years, and I see these new confidentiality arrangements as an important step forward. Sharing information and expertise will help both the Japanese and European Union to further strengthen public health protection."

The European Commission's Directorate-General Enterprise and Industry, the EMA, the MHLW and the

Pharmaceuticals and Medical Devices Agency (PMDA) have concluded confidentiality arrangements in the area of human medicine regulation during their bilateral meeting of February 2, 2007 in Tokyo.

The European Union and Japan have been working collaboratively for many years in the area of human medicines regulation. This has included a mutual recognition agreement on manufacturing of medicines, through the International Conference on Harmonization (ICH) and through bilateral meetings.

The new confidentiality arrangements build on the previous cooperation and will allow exchange of information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved. The types of information covered include:


- Advance drafts of legislation and/or regulatory guidance documents
- Scientific advice on product development given to companies to promote innovation
- Assessments of applications for marketing authorizations
- Information about the safety of marketed medicines to better protect public health

The potential benefits of this exercise are expected to include:

- Accelerated access of patients to new and innovative medicines
- Resource savings due to reduced duplication of assessment and
- Improved performance and safety as a result of the involvement of the best available regulatory expertise from both the European Union and Japan

North America

Availability of a Draft Guidance for Industry and FDA Staff: Radiofrequency Wireless Technology in Medical Devices

This draft guidance addresses issues relevant to the safe and effective use of radio frequency wireless technology in medical devices, including wireless coexistence, performance, data integrity, security and electromagnetic compatibility. These issues affect all stages of the product life cycle and should be considered in preparing premarket submissions, identifying, documenting and implementing product design requirements, as well as design verification and validation and risk management processes and procedures, according to the *Federal Register* announcement. Comments are invited by April 2, 2007. View the complete draft guidance at <http://www.fda.gov/cdrh/osel/guidance/1618.pdf>. 

New Directors Take Familiar Path to Board

Lindsay Donofrio, PDA

Two longtime PDA members, **Louise Johnson**, VP, Quality, Vertex Pharmaceuticals, and **Martin Van Trieste**, VP, Quality Commercial Operations, Amgen, Inc., were recently elected to the PDA Board of Directors. The evolution of their PDA involvement closely mirrors that of many board members, who typically have been involved in the gamut of PDA activities. The members of the board have been speakers and moderators at PDA meetings; active on task forces, advisory boards, committees and interest groups; and influential in the development of PDA technical reports and other tools and resources. Naturally, having recognized leadership qualities and a passion for PDA are intangible characteristics of many board members.

In Johnson's case, her involvement with PDA began about seven years ago. While giving a plenary presentation at an industry GMP conference, she was asked by PDA member **Kathleen Greene**, Executive Director, Technical R&D, Novartis, and current board member, to give a similar presentation at the upcoming PDA/FDA meeting. Shortly thereafter, Johnson joined the PDA/FDA Program Planning Committee. It was during this time that she began to understand how PDA worked and the value of her membership. "With PDA it was a two-way street. I was benefiting from PDA, and hopefully they were benefiting from me," said Johnson.

Eventually, Johnson served as chair of the 2005 PDA/FDA Joint Regulatory Conference, which drew record attendance. "We were pretty proud of that," said Johnson. "These conferences don't work without a lot of dedicated volunteers giving up their *spare* time."

In addition to her involvement on the PDA/FDA Program Planning Committee, Johnson served on the

Regulatory Affairs & Quality Committee (RAQC), the Program Advisory Board and the Strategic Planning Committee. Most recently, Johnson was asked to serve as chair of the PDA Comment Committee for ICH Q10. In recognition of her contributions and service to PDA, Johnson received the PDA Distinguished Service Award in 2006.



Louise Johnson, Vertex Pharmaceuticals

Van Trieste also received the PDA Distinguished Service Award in 2006 for playing a key role in PDA's efforts to help the U.S. FDA create a scientifically sound guidance for aseptic processing. He served on both the PDA Task Force which drafted the 2002 PDA "Points to Consider on Aseptic Processing" and the Product Quality Research Institute Working Group which produced a lengthy commentary to the FDA aseptic processing concept paper. Following the publication of the guidance, Van Trieste and the task force developed a one-day training program. The program was offered in multiple cities around the world including, San Francisco, Calif.; Philadelphia, Pa.; Washington, D.C.; London and Frankfurt, Germany, and featured Van Trieste and a number of FDA speakers.

Van Trieste also developed a computerized compliance tool to help companies implement the final aseptic guidance, which he donated to PDA.

"While working on the FDA's aseptic guidance document required a lot of sweat and toil and got me involved with PDA on a day-to-day basis, serving as co-chair of the Science Advisory Board [SAB] has been the epitome of my efforts at PDA," said Van Trieste. Van Trieste has served as SAB co-chair since 2004.

Early in his career, Van Trieste joined PDA at the recommendation of a supervisor who told him it was the leading professional organization focusing on sterile products, the area in which he was working at the time. While Van Trieste actually became a member in the 1980s, he has been most heavily involved with PDA since the early 1990s, presenting at PDA meetings, participating on task forces and contributing to technical reports.

Van Trieste attributes his nomination for the PDA Board of Directors to his work as co-chair of the SAB. "It's not something I strived for. It's not why I did the work I did at PDA," said Van Trieste. "My efforts at PDA were to help our industry move forward with continuous improvement and to foster and promote the best possible science related to our industry."

As a board member, Van Trieste would like to implement more computerized compliance tools. Currently, the SAB is undertaking the development of a resource to help aseptic manufacturers with risk management and the risk management process. Soon, PDA will be releasing a risk management technical report. It is Van Trieste's hope that shortly thereafter PDA will release a computerized tool to help people and to facilitate how people do risk management related to aseptic

processing. “That’s one of my goals as a board member—to get the rest of the organization to see the value in these kinds of tools and to have PDA support, develop and promote more of these activities,” said Van Trieste.

Additionally, Van Trieste would like to see the board widen membership across PDA. Much of PDA’s membership is heavily concentrated among regulatory/quality professionals. “I’d like to see if we can extend the olive branch to our manufacturing colleagues and provide value for them to come be part of PDA and bring their experiences to PDA on a much larger scale,” said Van Trieste.

Like Van Trieste, Johnson was also surprised and honored to be nominated for a position on the PDA board. “It wasn’t until I became chair of the PDA/FDA Program Planning Committee and began to understand the potential for influence that a PDA board position could offer that I even thought about it,” said Johnson on her board nomination. “But even then, we’re all so busy doing our day job that it wasn’t something I actively campaigned for. It was just sort of a natural occurrence, I suppose, after a history of being involved.”

Johnson, a member of PDA’s Strategic Planning Committee, hopes to continue emphasizing the importance of staying focused on PDA’s strategic plan as she begins her term as board director. “Because there is so much competition among groups like PDA, the ones that are going to win and survive and add real value are the ones that are going to be agile and move as the industry and FDA move,” said Johnson. “I’m all about ‘what’s the strategy and let’s get aligned around it.’”

Johnson, too, is committed to broadening the scope of the PDA membership. By strategically focusing on PDA’s goals and objectives, Johnson believes PDA can potentially evolve its membership and eventually its programs and

services to meet the needs of current members and attract new members. “Predetermining your focus and your direction will drive the kinds of people who attend your meetings,” said Johnson.

“My efforts at PDA were to help our industry move forward with continuous improvement and to foster and promote the best possible science related to our industry.”



Martin Van Trieste, Amgen, Inc.

Serving on the board is not only the pinnacle of PDA volunteerism, it also requires the greatest commitment of time and effort of all PDA’s leadership and networking opportunities. While PDA greatly appreciates the tremendous contributions from members such as Johnson and Van Trieste, their efforts are not unique. Many of PDA’s members are actively involved at various levels. A member who participates on a task force or an advisory board are usually the most active, working with other PDA members on technical reports, regulatory comments and the establishment of objectives for

the organization in specific areas (i.e., science and technology, regulatory affairs, biotech). Opportunities requiring a lesser commitment also exist, including speaking or moderating at a PDA conference, volunteering with a chapter and serving as a leader of an interest group. Whatever the commitment may be, the generous efforts of PDA’s members continue to make it the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical communities. In turn, PDA volunteers can develop their leadership skills, impact the regulatory and scientific environment in which they work and develop reliable networks.

“Not to mention,” Johnson said, “it’s a barrel of fun. I have the most wonderful friends from this involvement.” 🍷

To learn more about volunteering with PDA, visit www.pda.org. Also, be sure to check out the *PDA Letter* in the coming months for more on the variety of PDA volunteer opportunities.

Israel Chapter Annual Meeting Draws Fascinating Speakers

December 24, 2006 • Tel Aviv, Israel

Karen Ginsbury, PCI, Pharmaceutical Consulting Israel

Over 250 members of the PDA Israel Chapter met at the Dan Panorama hotel, Haifa, Israel, for the popular chapter annual meeting. Updates on chapter activities were followed by a series of fascinating lectures, which are summarized below. Organization of the event was handled by **Amir Malka**, BioForum Applied Knowledge Center.

Sigalit Portnoy, PhD, Taro Pharmaceutical Industries and outgoing chapter President, presented a summary of activities and addressed the large number of new members who have joined the chapter during the past two years. Portnoy particularly emphasized the high quality of presentations, the scope and depth of professional knowledge and the readiness to share that knowledge within the chapter.

Thanks were expressed to the outgoing committee and particularly to **Yaakov Adar**, PhD, Israel Institute for Biological Research, for editing the newsletter.

Karin Baer, PhD, OMRIX Biopharmaceuticals, presented the treasurer's report, including that the chapter has more than 650 members after nearly ten years of activity. Baer also reported a breakdown of the budget.

Regulation from a Global Perspective

Miriam Kaplan, PhD, Israeli Ministry of Health, gave a presentation on regulation from a global perspective, referring to the EU initiative to draw in neighboring countries. Addressing international regulation, Kaplan emphasized that in countries where the pharmaceutical industry is in the early stages of development, different levels of compliance will exist at different companies. Kaplan noted that contract manufacturing usually drives GMP compliance upwards.

Global harmonization is unlikely to be achieved in the near future. Israel is

a small country with a huge pharmaceutical market. Resources are limited and there are no mutual recognition agreements in place; although, Israel has initiated processes both with PIC/S and the European Union. Addressing the philosophy of regulation of a private sector such as the pharmaceutical industry, Kaplan questioned who is ultimately responsible for the results of regulation in the industry. The Ministry has filled seven new positions in the past year, which is a significant rise in resources.

Polymorphism in the Pharmaceutical Industry

Judith Aronhime, PhD, Teva Pharmaceutical Industries, provided a fascinating presentation on polymorphism in the pharmaceutical industry. Aronhime made a complex and much misunderstood topic appear simple and straightforward, using the popular example of chocolate, which turns white and looks moldy when it undergoes transformation on aging to a different polymorphic form. Polymorphism is very common in pharmaceutical solids, and polymorphs may possess different solid state properties: melting point, solubility, hardness, density, thermal stability, etc. Different polymorphs may have different pharmacological activity, which can be disastrous. Identification of polymorphs uses x-ray powder diffraction. For absolute identification of a particular polymorph, a differential scanning calorimeter is used. Fourier transform infrared spectroscopy (FTIR)/Raman spectroscopy and solid state Nuclear Magnetic Resonance (NMR) are also used for research purposes. X-ray single crystal analysis is used to obtain a clear answer as to which hydrate/solvate exists.

Generation of polymorphs occurs when different crystallization methods

are used (solution, cooling regime, stirring, etc). Control of crystallization parameters to consistently produce one polymorphic form is not always simple. Trace impurities, roughness of the vessel wall and seeds of stable forms floating in the atmosphere are but a few factors that may affect polymorphic form.

Polymorphs differ in thermodynamic stability. Spontaneous transformations may occur from one state to another and are favored by exposure to solutions, light and mechanical stress.

Because polymorphs and their properties are unpredictable, there is a need to invest in process knowledge to look for different polymorphic forms in the laboratory. Change of crystalline form may affect bioavailability, e.g., a drug product was withdrawn from the market because it failed a dissolution test after changing its polymorphic form.

Since patents can be registered on different polymorphic forms, generic manufacturers often produce different polymorphs—it is common to work with metastable forms. In this case process control is critical. In conclusion, polymorphs are a case of opportunity versus challenge.

Risk Assessment in Microbiology

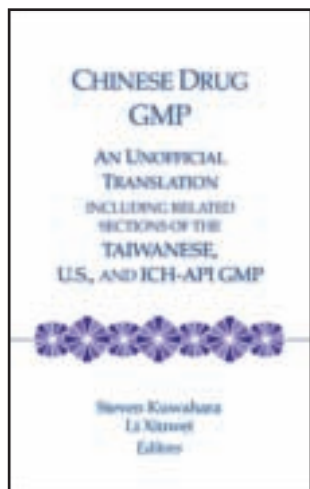
Dudi Meraro, PhD, Taro Pharmaceutical Industries, discussed the use of risk assessment in microbiology.

His presentation focused on risk assessment in the following areas:

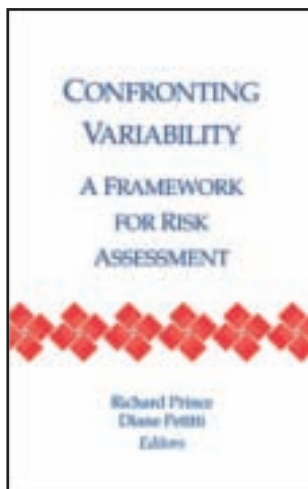
- R&D: quality of raw materials, packaging materials and closure systems
- Formulation: characteristics of products that contribute to growth of microorganisms/preservative efficacy system with case studies

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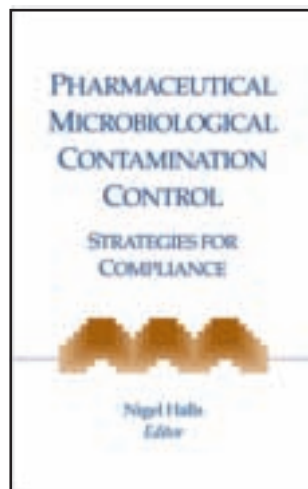
Check out these newly released titles and training CD programs at the PDA Bookstore, your source for pharmaceutical and biopharmaceutical science, technology and regulatory information.



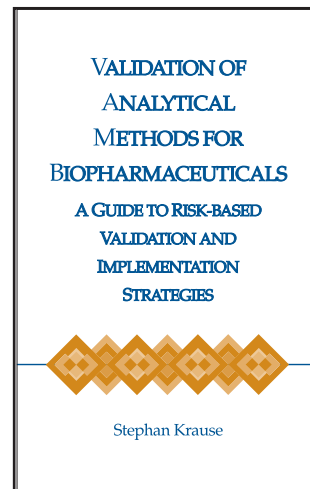
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Item no. 17251



Item no. 17246



Item no. 17264

Multi-media Training Programs

Current Good Tissue Practice Training CD Program - 21 CFR Part 1271, HCT/P Products

- Subpart C, Donor Eligibility, Sections 1271.45 through 1271.90 (**Item no. 11081**)
- Subpart D 1271.320 Complaint Files and subpart E 1271.30 and 1271.350 Adverse Reaction Reports (**Item no. 11082**)
- Subpart. 210 Supplies and Reagents - (Core GTP Requirements) 1271.210 (a) Verification and 1271.210 (b) Reagents (**Item no. 11083**)

****** You can now download demos of our training programs in PDF format at our bookstore.

www.pda.org/bookstore

Southern California Chapter Hosts Consecutive Dinner Events

PDA Southern California Chapter Board

The PDA Southern California Chapter board has been actively looking for practical ways to host quality events for its members, who are located from Ventura County (north of Los Angeles) to San Diego. The newly adopted format of consecutive dinner presentations held in different locations was successfully received on January 17, 2007, in Westlake Village, Calif. (Thousand Oaks), and on January 18 in Newport Beach, Calif. (Orange County). **Scott Sutton**, PhD, Vectech Pharmaceutical Consultants, gave the presentation, entitled "Rapid Microbiology and Contemporary Identification Systems in Support of Manufacturing."

These events were sponsored by Biotest Laboratories and Millipore. The attendees in both locations enjoyed an interactive session covering the latest science, technology and regulatory aspects of microbial identification, environmental monitoring, water testing, biological indicator testing, microbial limits and sterility testing. The U.S. FDA initiatives of interest related to comparability protocols, GMPs for the 21st century and process analytical technology (PAT) were discussed along with available technologies.

The board also presented the chapter initiatives, which are designed to support local events and efficient use



(From left to right) Presenter Scott Sutton, PhD, Vectech Pharmaceutical Consultants, joins Southern California Chapter leaders, Saeed Tafreshi, President; John Holmgren, Membership Chair; and Greg Burnham, Treasurer, along with Senior Chapter Liaison Henry Kwan, PhD, Consultant to PDA.

of time and resources for the members. The chapter's focus is on the following areas:

- Member involvement
- Corporate outreach
- Successful event planning
- Local FDA relationship
- Chapter's geographical coverage
- Local training courses
- PDA/ISPE joint events

The chapter plans to improve these focus areas with the help of the local members. The chapter's corporate outreach program is designed to organize member support through employers who have historically supported PDA and benefited from association and membership. This

initiative hopes to facilitate partnerships between the chapter and industry and maximize the benefits through efficient communication.

The following list highlights aspects of the corporate outreach program:

- Membership goals
- Members' organizations
- Corporate representation within the chapter
- Communication with PDA
- Member orientation
- Event request
- Event planning
- Training
- Sponsorship
- Board membership

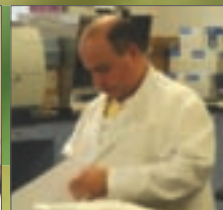
The PDA Southern California Chapter board is presently located in Orange County and plans to expand the board membership to the Los Angeles and San Diego areas. The expanded board coverage will help to better organize and support the chapter initiatives. The board has been pleased with the support of its members in planning and executing the chapter initiatives and will continue to search for the best solutions to maximize membership benefits. Please continue to check the *PDA Letter* for future chapter events. 



Attendees pose after a successful dinner event in Newport Beach, Calif., on January 18, 2007.



Connecting People, Science and RegulationSM



Mark your calendar!

Five laboratory training courses, including two-new programs, will be held this May by the PDA Training and Research Institute. That means five hands-on opportunities to learn from the expert faculty only PDA TRI can deliver!

Pharmaceutical and Biopharmaceutical Microbiology 101

PDA #142 | May 1-4, 2007

www.pdatraining.org/pbm101

Instructor: David Matsuhira, President, *Cleanroom Compliance, Inc.*

Downstream Processing: Separations, Purifications and Virus Removal

PDA #176 | May 8-11, 2007

www.pdatraining.org/downstream

Instructors: Michael Dosmar, Jeff Mora, and Mark Trotter, *Sartorius Corporation*
Jennifer Campbell and Paul Genest, *Millipore Corporation*

**NEW
COURSE!**

Developing a Moist Heat Sterilization Program within FDA Requirements

PDA #506 | May 16-18, 2007

www.pdatraining.org/dmhs

Instructors: Jeanne Moldenhauer, PhD, Pharma Consultant, *Vectech Pharmaceutical Consultants, Inc.*,
Margarita Gomez, Manager of Technical Services, *VPCI*

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

PDA #324 | May 21-22, 2007

www.pdatraining.org/DVCD

Instructor: Art Vellutato, Jr., Vice President of Technical Support Operations, *Veltek Associates, Inc.*

Operator Qualification

PDA #337 | May 21-23, 2007

www.pdatraining.org/operator

Instructor: Anne Marie Dixon, Principal, *Cleanroom Management Associates, Inc.*

**NEW
COURSE!**

Location:

PDA Training and Research Institute
UMBC Technology Center
1450 South Rolling Road
Baltimore, Maryland 21227 USA

For more information, please contact:

James Wamsley, Manager, Laboratory Education
Tel: +1 (410) 455-5800
email: wamsley@pda.org
Visit: www.pdatraining.org

PDA Welcomes New Members

Czubak Agnieszka, Grodziskie Zakłady
Farmaceutyczne

Yazmin Alvarez, Amgen
Manufacturing

Mark Ambrose, Wyeth
Pharmaceuticals

Frederick Andersen, Wyeth
BioPharma

Maham Ansari, Johns Hopkins
University

Watanabe Atsushi, Hakuto

Amber Aziz, CIBA Vision Sterile
Manufacturing

Michael Bassett, Confluent Surgical

Amanda Bell, Alkermes

Irina Belyakova, Iomai

Karsten Binder, RCC

Julia Bodnar, sanofi pasteur

Yilma Bonilla, Quality Compliance
Group

William Botha, Baxter International

Tor Boye, Inspectorate of Western
Switzerland

Leah Bredehorst, Lifecore Biomedical

Gary Brennan, Harmony Labs

Matt Britz, Acambis

Winston Brown, Tunnell Consulting

Gerald Brown, TMA

Robert Bryant, Eli Lilly and Company

Michelle Butler, Genentech

Regine Cadet, Bayer

Javier Camposano, Baxter BioScience

Rebecca Cannon, Massachusetts
Biologic Laboratories

Win Cayo, Cardinal Health

John Paul Cerroti, Ahura Scientific

Alison Chan, CIBA Vision Sterile
Manufacturing

Roberto Cintron, Centocor

Leila Cjevanovic, CIBA Vision Sterile
Manufacturing

Bert Claessens, Helvoet Pharma

Katie Connelly, PAREXEL
Consulting

Amy Critcher, Abraxis BioScience

Aimee Davidson, Genentech

Keyla Davila, Amgen

Farrokh Dehbozorgi, Bayer Health-
Care

Bharat Desai, Shire Developments

Patricia Disciascio, Bend Research
Pharmaceutical Process
Development

Raquel Dompenciel, Amgen
Manufacturing

Elizabeth Dunn, Amgen

Joern Felten, Sanofi-Aventis

Lars Gabe, ICE

Gino Gallo, CIBA Vision Sterile
Manufacturing

Rahul Gavankar, United Books and
Periodicals

Luca Ghirotto, Helsinn

Bidisha Ghosh, Wyeth

Amy Githens, Tengion

Edouard Gudin, UNITHER

John Guthy, Medical Instill
Technologies

Renata Hawthorne, Brookwood
Pharmaceuticals

Mette Heller, Novo Nordisk

Tari Helmers, VWR International

Allison Herbert, Merck

Johnny Hilo, Grifols Biologicals

Ludwig Huber, LabCompliance

Abe Ikumi, Mitsubishi
Pharmaceuticals Corporation

Jim Jones, ChemImage

Xu Junjun, GE Healthcare

Vijay Kasireddy, Alexion
Pharmaceuticals

Flavio Kawakami, Doctor Bit
Informatica

James Kenny, Schering-Plough

William Kessler, Physical Sciences

Harinder Khara, Amgen

Musbah Khribah, TABUK

Derrick Kim, Cell Therapeutics

In Seop Kim, Hannam University

Seong Jae Kim, Korean Redcross
Fractionation Center

Susan Klein, Luitpold Pharmaceutical

Patrick Klopchin, Isis Pharmaceuticals

Hagen Koch, Sanofi-Aventis

Deborah Kreider, Amgen

Philip Kuhlman, Sembiosys Genetics

Peter Kulseth, Berlex

Harry Lam, Genentech

Daniel Lanzon, Pfizer (Perth) Pty

William Lichtman, Biogen Idec

Ai Lin, Genentech

Chris Luck, Cook Pharmica

Ryan Ludwig, Boston Scientific

Jennifer Mahilo, Sanofi-Aventis

Almansouri Malika, GlaxoSmithKline
Biologicals

Victor Maqueda

Veronica Martinez, Allergan

Sengul Matay, CIBA Vision Sterile
Manufacturing

Marlene McCallum, Pyramid
Laboratories

Craig Meinhardt, Wyeth

Brian Meyer, Merck

Brandye Michaels, Wyeth Biotech

Anna Mills, Celsis

Koorosh Mirfakhrai, Amgen

Masami Miura, Hakuto

Mark Morgan, Genentech

John Moxley, Camstar Systems

Julie Murrell, Millipore

Raymond Nims, Amgen

Mohammad Nobani, EtQ

Pat O'Driscoll, Eli Lilly and Company

Shannon O'Rourke, Baxter
Healthcare

Wanda Pachink-Konecka, Grodziskie
Zakłady Farmaceutyczne

Rita Peralta, Mediatech

Linda Perez, Boston University
Corporate Education Center

Charles Phiefer, Eli Lilly and
Company

James Pierantozzi, Wyeth

Kevin Pipkins, Centocor GBSC

Tej Poonai, Pharmatech Associates

Merritt Postma, IMA North America

Kip Priesmeyer, Novartis

Hinh Quy, Valdepharm

Suzanne Remy, Hema-Quebec

Mark Roache, Bayer HealthCare

Seth Rodgers, BioProcessors

Warren Roman, IMA North America

Sandy Rubio, MicroWorks

John Ruga, Teva Sicor

Franz Schmitting, Abbott

Denise Schnaufer, Merck

Merete Schneider, Novo Nordisk

Christian Schoch, Novartis

Sean Searfoss, sanofi pasteur

Jessica Serrano, Amgen
Manufacturing

Holly Settles, Elanco Animal Health

Kinnar Shah, Stryker Biotech

Kevin Shandy Shandy, Genentech

Jamie Singh, Amgen

Vasily Skrypin, Pharmapark

Thomas Spear, STERIS

Sandra Stack, Elan

Charles Steiniger, Sparta Systems

Shrinivas Tamaskar, GMP Consulting

Gunner Thorlund, LEO Pharma

John Thorup, Amgen

Kazuo Tozaki, JGC Project Services

Melody Trexler Schmidt, Genentech

Klaus Tschürtz-Lusiardi, Laetus

Bruno Tse, Chemir Analytical Services

Tracey Vogt, ChemImage

Michael Vorwerk, LifeConEx

Laura Warren, Novartis

Terry Wilhide, Wyeth

Caitlin Wilson, Lonza Biologics

Alan Wong, Wyeth Biotech

Yuan Xu, Amgen

Atif Yardimci, Baxter

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

Chapter Contacts

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

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Areas Served: MD, DC, VA, WV

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allen.burgenson@cambrex.com

website: www.pdacapitalchapter.org

Delaware Valley Chapter

Areas Served: DE, NJ, PA

Contact: Art Vellutato, Jr.

Email: artjr@sterile.com

website: www.pdadv.org

Metro Chapter

Areas Served: NJ, NY

Contact: Nate Manco

Email: natemanco@optonline.net

website: www.pdametro.org

Midwest Chapter

Areas Served: IL, IN, OH, WI, IA, MN

Contact: Madhu Ahluwalia

Email: madhu@cgxp.com

Mountain States Chapter

Areas Served: CO, WY, UT, ID, NE, KS, OK, MT

Contact: Sara Hendricks

Email: scarry@att.net

New England Chapter

Areas Served: MA, CT, RI, NH, VT, ME

Contact: Louis Zaczekiewicz

Email: [lzaczekiewicz@hyaluron.com](mailto:lzaczkiewicz@hyaluron.com)

Puerto Rico

Contact: Manuel Melendez

Email: manuelm@amgen.com

Southeast Chapter

Areas Served: NC, SC, TN, VA, FL, GA

Contact: Patrick Sabourin

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Southern California Chapter

Areas Served: Southern California

Contact: Saeed Tafreshi

Email:

saeedtafreshi@intelitecorporation.com

Website: www.pdasc.org

West Coast Chapter

Areas Served: Northern California

Contact: Peter Rauenbuehler

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website: www.wccpda.org



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Colorado Springs to Host 2008 Annual Meeting

Maik Jornitz, Sartorius and 2008 Program Chair



Maik Jornitz

In a world of information and communication, the most valuable means is still the face-to-face discussion and networking with colleagues from the industry and regulatory agencies. PDA's Annual Meeting creates an optimal platform to exchange information, either as a speaker, recipient of highly qualified presentations, participant at an interest group meeting or as an active volunteer. We want to encourage you to take this opportunity to utilize the Annual Meeting in April 2008 at The Broadmoor resort, Colorado Springs. 🌊

Israel Chapter Annual Meeting Draws Fascinating Speakers, continued from page 26

- Production: critical systems, seasonal fluctuations, power outages and loss of pressure
- Cleaning validation
- Risk during product life cycle: failure of preservative efficacy test, customer complaints and distribution chain
- Changing production site
- Quality assurance/quality control investigations of objectionable organisms
- Planning and control
- Purchasing as a separate activity for the laboratory
- Technical and technological contents (IQ, OQ and calibration)

Of particular interest was the use of automated work centers and assessment of average cycle time—metrics as well as a computerized prioritization system.

Quality System Guidance

The final presentation of the evening was made by **Karen Ginsbury**, PCI, Pharmaceutical Consulting Israel, on the topic of the U.S. FDA's recently issued quality system guidance. Ginsbury compared the FDA approach with the existing European GMP guidelines which address many of the items that appear in the new guidance. In particular, Ginsbury mentioned quality management, job descriptions for personnel and evaluation activities such as auditing and quality metrics. 🌊

Managing an Efficient Quality Control Laboratory

Dror Wohlfeiler, PhD, Teva Pharmaceutical Industries, gave a presentation on managing an efficient quality control laboratory. Wohlfeiler addressed the following:

- Laboratory in the manufacturing process
- Theory of constraints and analytical compliance
- Quality control technologies and analytical services

PAT Team Delivers PDA's First PAT Conference

Michael Miller, PhD, Eli Lilly & Company and Program Chair

In 2005, PDA initiated a task force team on advancing the science and knowledge of Process Analytical Technology (PAT). Our goal was to develop a shared learning experience for industry, regulatory authorities and the pharmacopoeias on the implementation of PAT platforms within development and manufacturing. Today, we have realized this goal by bringing together industry leaders to discuss case studies in the implementation of PAT within the pharmaceutical and biopharmaceutical industry.

On behalf of the program committee, I am pleased to invite you to join us at the **2007 PDA Global PAT Conference: Unlocking the Knowledge In Your Process**. Our program features case studies on actual PAT implementation programs across the parenteral, biotech and oral dosage form product life cycles. Finally, the conference will focus on implementation strategies for both small and large companies.

This is a tremendous opportunity to benchmark recent successes in PAT implementation across our industry. We look forward to seeing you at PDA's first Global PAT Conference in May!

Elections were held at the end of the evening and a new committee was selected.

2007 Israel Chapter Leadership

President	Raphael Bar , PhD, Pharmos Ltd.	Chapter Liaison	Karen Ginsbury , PCI, Pharmaceutical Consulting Israel
Treasurer	Amir Malka , BioForum Applied Knowledge Center	Committee Members	Einat Frydman , Teva Pharmaceutical Industries
PDA Liaison	Rivka Schmell-Meister , BioForum Applied Knowledge Center		Mordechai Izhar , PhD, Ludan Engineering
Former Presidents	Sigalit Portnoy , PhD, Teva Pharmaceutical Industries		Dudi Meraro , PhD, Taro Pharmaceutical Industries
	Benny Klener , Teva Pharmaceutical Industries		



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Is Your Product Manufacturing All That it Can Be?

PDA TRAINING AND RESEARCH INSTITUTE **Indianapolis Training Course Series**

May 7–9, 2007

Holiday Inn North at the Pyramids
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The Parenteral Drug Association Training and Research Institute presents the Indianapolis Training Course Series—eight training courses to help you get the most out of your product manufacturing:

- Assessing Packaging & Processing Extractables/Leachables
- GxP Priorities: A Systems Thinking Approach — **New Course!**
- Introduction to Competency-Based Training
- Pharmaceutical Data and Analysis — **New Course!**
- Statistical Tools Supporting Quality Risk Management and Analysis (ICH Q9)
- Investigating Microbiological Failures — **New Course!**
- Risk Management
- Risk Management and Design for Six Sigma: Partners in the Drug Development Life Cycle

For more information, please contact:
Jessica Petree, Manager, Lecture Education
petree@pda.org ■ +1 (410) 455-5800

www.pdatraining.org/indianapolis

Faces and Places

USP/PDA Joint Conference: Residual Solvents

Bethesda, Maryland • January 18-19, 2007



Meeting co-chairs, (center left) Thomas Chapman, PhD, BioScreen Testing, Inc., and (center right) John Towns, PhD, Eli Lilly and Company, pose with regulatory experts, (far left) Rosa Motta, FDA, and (far right) J. Michael Morris, PhD, Irish Medicines Board



Thought-provoking presentations kept attendees engaged



Susan Schniepp, Hospira, Inc.



"Excipients –
IPEC Perspective":
David Schoneker,
Colorcon/IPEC

2007 Microbiology Planning Committee Meeting

Bethesda, Maryland • January 24, 2007



Program Committee Chairs: (left) Bryan Riley, FDA, and (right) Jette Christensen, Novo Nordisk A/S



Microbiology Planning Committee Meeting: (sitting l-r) Jette Christensen, Novo Nordisk A/S; Bryan Riley, FDA; Cindy Tabb, PDA; Luis Castro, PDA; (standing l-r) Bob Myers, PDA; Michael "Peyton Manning" Miller, Eli Lilly and Company; Edward Balkovic, PhD, Genzyme Corporation; Wanda Neal-Ballard, PDA; Jennifer Fraser, PDA; Anthony Cundell, PhD, Schering-Plough Research Institute; Gail Sherman, PDA; Richard Levy, PhD, PDA; Paula Pagano, PDA; Carrie Weaver, PDA



2008 PDA Biennial Training Conference

Focus on Performance: Partnering for Business Success

May 19–23, 2008 | Ritz Carlton Hotel | New Orleans, Louisiana

Announcement and Call for Papers

PDA is seeking abstracts for the 2008 PDA Biennial Training Conference. The attendees will include regulatory training professionals training managers, quality professionals, human resource professionals, supervisors, technical trainers, and others who train within the international pharmaceutical, biopharmaceutical and related industries. PDA will consider abstracts of a noncommercial nature that significantly contribute to enhancing the knowledge and skills of regulatory and technical trainers in these industries.

SUBMISSION DEADLINE: MAY 1, 2007

This conference will focus on building successful partnerships between pharmaceutical trainers and their customer groups to develop, sustain and continually improve value-added training programs for their sites. Abstracts outlining problems/solutions, best practices, and the latest trends in training, including but not limited to the following topics are being sought:

- **Technical Training:** Trainer qualification, OJT, effective procedures/SOPs, partnering with e-learning, cross training, measuring training impact, training in aseptic areas
- **Training Theory and Design:** Developing learning objectives, evaluation methods and methodologies; developing e-learning; measuring the impact of training; facilitation techniques; participant-centered training; developing games
- **Training Program for Senior Managers:** How to engage senior management to influence workplace learning, training as a business goal, non-training solutions, from trainer to problem-solver, successful performance consulting, training top management, training vs. performance improvement, learning initiatives
- **Training Professional:** Effective needs assessments, from trainer to problem-solver, influencing workplace learning, business goals and training, diversity on the training floor, training outside North America, internal consultant and performance improvement professional
- **Regulatory Training:** Ways to effectively communicate existing and changing regulations, guidance documents and other compliance related information
- **Technology-based Training:** Using various computer/web-based delivery mechanisms, electronic LMSs and simulators

Visit www.pda.org/Training2008 to submit your abstract today.
Commercial Abstracts Promoting Products and/or Services Will Not Be Considered.

PDA will provide one complimentary meeting registration per presentation.

Additional presenters will be required to pay appropriate conference registration fees.

Submissions must include the following information:

- | | |
|--|---|
| • Presenter | • Proposal title |
| • Title | • Target audience (by job titles, department and specialty areas) |
| • Company | • Session description - Describe format and include methods to ensure participants' involvement (estimate facilitator speaking time and participant interaction time) (Examples - presentation with small group discussions, case studies, demonstration, panel discussion) |
| • Full address | • Presentation Duration (including content and interactive portions) select one: 45 or 75 minutes |
| • Phone, fax and email address of presenter | • Learning objectives for the session |
| • Presenter's biography (<100 words) | • Rationale: Explanation of specific take-home benefits your audience can use immediately on the job |
| • Co-presenter(s) | |
| • Title(s) | |
| • Company | |
| • Full address(es) | |
| • Phone, fax and email address of co-presenter | |
| • Co-presenter's biography (<100 words) | |

Upon review by the program committee, submitters will be advised in writing of the status of their abstracts after October 1, 2007.

If you have any questions, please contact Jason E. Brown, Senior Coordinator, Program & Meetings, PDA at 301-656-5900 ext. 131, or via email at brown@pda.org.

PDA also reaches a broad market with their signature audio conferences. If you are interested in submitting your abstract as a possible audio conference or web seminar 1-2 months after the conference, please contact Jiwan Giri, PDA at 301-656-5900 ext. 132 or giri@pda.org.

First Steps to Going Global

Gail Sherman, PDA

TRI TALK

The success of last year's training program at the PDA/EMEA Joint Conference confirmed our notion that it's time to take TRI across the ocean. At January's end, **James Wamsley**, Manager, Laboratory Education, PDA, and I visited the University College Cork (UCC), Ireland, to meet with Colman Casey, PhD, Director, Pharma/Biopharma Training Unit, about implementing lab based training programs at this facility beginning in 2008. While we don't have any firm commitments, we all agreed to work towards accomplishing this goal. Now we have to figure out which courses would best fit the Cork venue. In the meantime, we will be holding our Practical Aspects of Aseptic Processing in Basel, Switzerland, in December—look for an announcement soon.



(From left to right) Colman Casey, PhD, University College Cork, Ireland, and James Wamsley, PDA, review plans for the UCC aseptic training facility.

On the lecture front, we talked with **Frank Hallinan**, PhD, President, PDA Ireland Chapter, about putting on a course series tailored to the junior staff of Irish pharmaceutical companies. We will be working closely with the Ireland Chapter to find speakers and topics relevant to this audience. We are very excited about the possibility of providing this training in Ireland.

In May, we will be providing a quality course to complement the PDA conference, "Good Practices for Medicinal Products" in Lyon, France. We hope to provide additional training along with focused meetings in Europe as we have started to do in the United States.

Next, we are looking at venues either in Frankfurt or Berlin, Germany, to hold a course series in November of this year. We have started to talk with instructors about the possibility of teaching in this series. Look for a "save the date" and further information on the Germany program.

I hope that by the next issue we will have more of our globe trotting events confirmed and can tell you when, where and what we will be offering!

We still have many courses on our agenda for this year and hope that you and your staff will take full advantage of these offerings. As always, if you have hot topics that you would like to teach, please contact us. And don't forget, we are offering training in Las Vegas, Nev., following the Annual Meeting in March.

Finally, we are looking forward to the swing of the first sledge hammer in the demolition of the space in Bethesda, Md., which TRI will call home in June—maybe some photos in April? 🍷

All donations to support the TRI move to Bethesda may be made to the PDA Foundation for Pharmaceutical Education, Training and Research, incorporated as a 501(c)3 supporting organization of the Parenteral Drug Association.



Global PAT Conference

Unlocking the Knowledge in Your Process

**May 22-23, 2007
Bethesda, Maryland**

www.pda.org/pat



**Quality by Design for
Biopharmaceuticals:
Concepts and
Implementation**

**May 21-22, 2007
Bethesda, Maryland**

www.pda.org/qbd

The Quality by Design for Biopharmaceutical workshop will be held in conjunction with the PDA Global PAT Conference.

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