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PDA Letter

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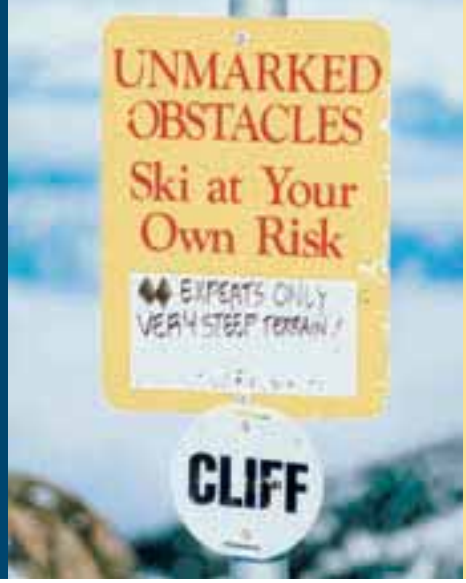

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Managing Quality Risk Management Implementation

With the completion of ICH Q9: *Quality Risk Management* in 2005, many pharmaceutical companies are undertaking the challenge of developing quality risk management (QRM) in their product development/manufacturing and control operations. Although elements of risk management have been employed by firms for years, the major regulatory bodies now are advising companies to formally adopt risk management principles in their quality operations—a task that can be as daunting as it is rewarding.

Many different tacks can be taken to implement QRM within an operation. At the 2006 PDA/FDA Joint Regulatory Conference, several case studies were presented on QRM implementation. The following is a report by PDA on one such case study. It was provided by a large multinational consumer products company that controls a number of pharmaceutical subsidiaries. It is an excellent example of how an organization can move from the conceptual framework of a high-level guidance document to practical implementation across general business practices.

QRM Implementation

Although Q9 is "optional" (regulatory guidances are "recommendations" not "requirements") based on importance to the business and because it is a foundational element for ICH Q8 and Q10, many companies view QRM as mandatory.

In one case study, the company assigned a team of global quality leaders to develop a process to implement QRM for its pharmaceutical subsidiaries. Critical to the success of the project was the selection of appropriate internal project sponsors, which included the Global Quality VPs across the pharmaceutical businesses.

Another critical success factor for the QRM team was to leverage the experience of colleagues who had previously implemented similar concepts of design control and risk management per the U.S. FDA's quality system regulations for medical devices.

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Editor's Message

It is an exciting time to work on the *PDA Letter* as the publication continues to evolve. All good publications periodically reinvent themselves, and that has been the case for the *PDA Letter* over the last three years. First, the *Letter* received a timely facelift at the end of 2004. Building on earlier redesign efforts, the latest style continues the publication's evolution from literally a two-paged letter to a membership magazine. In 2005, we formed the *PDA Letter* Editorial Committee (PLEC) of volunteer PDA members to help generate broader membership participation. The creation of an editorial calendar of topics with the PLEC's input helps us solicit and publish feature articles written by the membership. In 2006, we published more member submissions than in any year prior.

We plan to do even better in 2007. Not only will we continue expanding the membership submission program by working with the PLEC, we will be actively seeking reader feedback about the content in the *Letter.* We intend to use various mediums to encourage participation. First, we have created this "Editor's Page," which will appear in each issue, and, we hope, will include a letters to the editor section. Also, the *PDA Letter* has a new website, www.pda.org/pdaletter, which will contain new and more detailed information for readers on various subjects and will allow readers to provide feedback on every issue.

Involving the members in the *PDA Letter* reflects the Association's renewed commitment to better serving the membership. A new and larger team of membership professionals has recently been formed here at PDA (see page 22), and this enhanced department—lead by 13-year PDA veteran **Nahid Kiani**—is planning vast improvements to the content included in the Membership Resources section of each issue.

More changes will be apparent as the result of the recent addition of a new writer/editor to the *PDA Letter* staff. **Lindsay Donofrio** assumed the role of Assistant Editor to the PDA Letter in October. Not only is Lindsay working closely with the new membership and chapters team, she is working with the Training and Research Institute to mine interesting and useful stories for our readers.

As always, the *PDA Letter* will remain focused on providing scientific, regulatory and technical articles of interest to the membership. To ensure the quality of the publication continues to improve, the *Letter's* editorial staff now reports directly to PDA Sr. VP of Scientific and Regulatory Affairs **Rich Levy**, and we continue to enjoy and benefit from the contributions and support of other expert PDA staff, including **Bob Dana**, VP, Regulatory Affairs, **Jim Lyda,** Director, Regulatory Affairs Europe, and **Volker Eck.** Sr. Director, Science and Technology Europe.

Together, PDA's member volunteers, staff and editorial team can ensure that the *PDA Letter* remains one of the best sources of useful information for the busy professionals in the pharmaceutical and biopharmaceutical industries. I hope you keep reading—and enjoying—the *PDA Letter*!

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

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Louise Johnson and Martin Van Trieste Join PDA Board

The PDA Board of Directors welcomes two new members in 2007: **Louise Johnson,** Vertex Pharmaceuticals, and **Martin Van Trieste,** Amgen, Inc.

Johnson is a devoted supporter of PDA, having served on the Regulatory Affairs & Quality Committee (RAQC), the Program Advisory Board, the Strategic Planning Committee and numerous program planning committees. In 2005, she was the chair of the PDA/FDA Joint Regulatory Conference, which drew record attendance. She received the PDA Distinguished Service Award in 2006 in recognition of her special acts, contributions and service that have contributed to the success and strength of PDA.

Van Trieste is a long-time participant in PDA. He most recently served as co-chair of the Science Advisory Board (SAB). He played a central role in PDA's effort to help the U.S. FDA create a scientifically sound guidance for aseptic processing by participating in the Task Force that interacted with FDA and the Product Quality Research Institute. Following publication of the guidance in 2004, Van Trieste helped devise the curriculum for PDA's training workshops on the new FDA document, which were held in numerous locations in the United States and Europe. In addition, he developed a computerized compliance tool to help companies implement the final aseptic guidance, which he donated to PDA.

Rebecca Devine, PhD, an independent regulatory consultant, and **Anders Vinther,** PhD, CMC Pharmaceuticals A/S, were re-elected as directors.

"PDA is privileged that Ms. Johnson and Mr. Van Trieste have joined our Board of Directors," said **Robert Myers**, PDA President. "Their extensive accomplishments and expertise will enhance the leadership of PDA as we strive to serve pharmaceutical and biopharmaceutical professionals around the globe. Under the guidance of the 2007 officers and directors, PDA's mission to advance science and regulation through the expertise of our global membership will be strengthened."

Outgoing members include **Jennie Allewell**, Wyeth Research, and **Stephen Bellis**, IVAX Pharmaceuticals UK. Allewell was a member of the board from 1996 to 2006. During four of those years (2000-2003), she served as an officer (Secretary). During that time she also chaired the planning committees for two Asia-Pacific conferences, and headed-up the Awards Committee.

"I would like to thank the outgoing members for the contributions and leadership they have provided during their tenure on the board," said Chair of the Board **Vincent Anicetti** (Genentech). "Jennie's balanced perspective and clear direction will be missed."

"I would also like to welcome our newest board members," added Anicetti. "PDA looks forward in 2007 to continued growth and service to our members, the pharmaceutical and biopharmaceutical industry and regulatory agencies worldwide by promoting scientifically sound and practical technical information and education."

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Recent Sci-Tech Discussions: Pharmaceutical Development Reports and Sterile Filtration vs. Terminal Sterilization

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

Pharmaceutical Development Reports

Does anyone know of an FDA guidance on the Format and Content of pharmaceutical development reports? I have searched and cannot find such a thing, but perhaps I have missed the document, or the information might be buried in another document. Any leads will be appreciated.

Respondent 1: The closest I know of is the common technical document proposed by FDA some time ago. Here is the link: www.fda.gov/cder/regulatory/ersr/ectd.htm. This is the format preferred for electronic submissions. Overall, report formats with a table of contents, table of tables, table of figures, then summary, experimental, discussion, conclusion and exceptions and deviations. It is also good to include a method summary with the report if it is not covered under experimental. Titles can be different and based on the type of report; additional sections may be appropriate.

Respondent 2: I don't believe there are any FDA guidances on development reports. There are articles and presentations from consultants and, I believe, some from ISPE and PDA.

Respondent 3: There is an EU guidance for development pharmaceutics reports to be included in license applications. My understanding is that this is largely the basis for the ICH guideline (ICH Q8), which has also been adopted by the FDA.

Respondent 4: For regulatory submissions I would use the ICH Q8 document that others have mentioned. This guidance lays out all the headers and sections with general guidance on the content. You aren't required to use this format internally, but it does make writing your NDA or MAA easier since you can cut and paste more of the information directly from the report.

Respondent 5: There is an excellent model presented by [CDER's Office of Generic Drugs] for a quality summary for a submission, which I feel reflects the thinking in the scope of development activities and the manner by which data should be presented. I don't know if this is of any value, but have a look. www.fda.gov/cder/ogd/OGD_Model_Quality_Overall_Summary.pdf

Respondent 6: You should follow the guidelines in ICH Q8 for your development report.…It has been adopted by the EMEA. It was also adopted by FDA as of May 2006.

Respondent 7: Just one thought to consider when talking about internal documentation. Since I was responsible for R&D and the production side, my experience told me:

1) Require monthly project reports from everyone in R&D

2) For ease of use, it makes sense to use double documentation. Each researcher wants to have [his/her] own work at hand. Since they often work on different projects, the second copy should go in a project library. Patent regulations are very stringent in continuous documentation from a researcher. It is one of the reasons why [a project-only] oriented documentation system might cause problems. The product might be still on the market 50 years from now. Try to find the original experimental data [based on] some remark in the development report, in a documentation system based of personal books. Nobody will know where to look for it!

3) Absolutely require to include everything which did not work in the monthly reports. A) It will help to substantiate production ranges. B) When problems arise from very, very, very small changes, which will happen over the years, you will not have to start from scratch. It makes no sense to reinvent the wheel. Knowing what does not work can help in problem situations. And this is done nearly nowhere. It is not a very pleasurable task to document failures.

4) Use a unique numbering system for every experiment and reference it in the monthly report.

It took me some time to get the researchers to agree to my wishes. But R&D does cost a lot of money. And what you should get out off it should be usable paperwork!

The development report is important for submission and investigations. But always remember that your production has to produce the product on a large scale over an extended period of time.

Development data might be important when no [one is around] who can help you with…information.

Example: An FDA investigator asked me for the rational of drying temperatures for an API which [has been] on the market now for 52 years. Nobody had the slightest idea. But documentation at that time was of a very high standard (they had lots of time then). I found it in the chemical development report. And a very, very old chemist knew who did the work then. The handwritten report books from that person where on some pallets in our warehouse, and it took only 150 man hours to find the right book and show very convincing original data.

It would have been impossible to find the data without the very lucky circumstance that we still had a chemist at hand who was there 50 years ago and could remember who did the work.

Respondent 8: The [FDA] guide to inspection of solid dosage forms (1994) discusses development reports and development documentation: www.fda.gov/ora/inspect_ref/igs/solid.html

Respondent 9: Dear [Respondent 7], Your recommendations are excellent and the story is very interesting. However, I cannot help but be appalled at an inspector insisting on original R&D data for a drying step in a 52-year-old product! That is absurd! Also, while I am impressed that you were able to locate this old notebook, I cannot help but feel that 150 person-hours were expended for no valuable reason. Did finding the original basis for drying temperatures make anyone feel more assured regarding the quality of this product?!? Isn't 50+ years of stable product data enough evidence of sufficient quality? I submit that had the original data not been found, or worse—had it contradicted the current drying process temperatures—that the 52-year history of successful batches would *far* outweigh any small quantities of contradictory (or missing) process development data.

Sterile Filtration vs. Terminal Sterilization

We are the manufacturers of sterile water for injection and normal saline (0.9%). After manufacturing we are filtering the bulk with 0.22 micron filter before its transfer to a sterilized holding tank. From there we transfer the bulk to a blow-fill-seal machine, where again it is filtered through two presterile 0.22 micron filters in series. After this the filled vials are subjected to terminal sterilization.

As per the suggestion of certain experts, terminal sterilization is the preferred method of sterilization as per the guidelines for these products.

My question is why terminal sterilization is required if already we are using sterile .22 micron thrice in our process? Whether we should sterile filter the product or go for terminal sterilization? Can anybody put some light over this problem with a supportive regulatory backup?

Respondent 1: 0.22 micron filtration of any solution can be called as sterile if the container in which it is being filtered is sterile and the representative sample taken from it passes the sterility. In terminal sterilization the container along with the product is made sterile and thereby achieving the greatest possible sterility assurance level. Hence, even though your product is filtered sterile through three 0.22 micron filter, it makes sense to terminally sterilize the final container with product (if the product can be terminally sterilized) to assure the sterility level.

Respondent 2: Three stages for preparation of sterile products are very crucial and critical: sterilization of primary packing materials, sterilization of solution by filtration and filling of sterile solution.

If we individualized each process, only the first two processes can be established with sterility assurance level (SAL). Moreover, there could be many chances of contamination of product during handling of above three processes, and hence no SAL.

While for terminally sterilized product, you can establish SAL for your entire batch with 95% confidence limit, provided stability of such products are justified.

Respondent 3: Terminal sterilization is the preferred method unless the product/package will not tolerate terminal sterilization processing (see [EMEA CPMP/QWP/054/98, *Decision Trees for the Selection of Sterilisation Methods,* www.emea.europa.eu/pdfs/human/qwp/005498en.pdf]). Since WFI and saline will tolerate terminal sterilization, and apparently so does the container/closure, that is the step in your process that "sterilizes" your product.

Filtrations prior to terminal sterilization become steps to simply reduce bioburden and cannot be claimed to be the sterilizing step. You cannot eliminate terminal sterilization, but you could potentially eliminate one of the two filters on the BFS machine. The first bulk filtration is useful to ensure "low bioburden" in case you have a bulk-hold in the process or you have a machine down.

Respondent 4: Besides normal saline infusion/injection, your company may also be manufacturing other products like 5% dextrose, ringers solution, etc. Filtration is good and even necessary for complying with the visual particles limits.

I mentioned the other products because some of them cannot withstand 121°C sterilization temperature and therefore SAL is achieved through calculated sterilization time other than the absolute sterilization temperature, i.e., 121.1°C.

continued on page 14

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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Spring 2007

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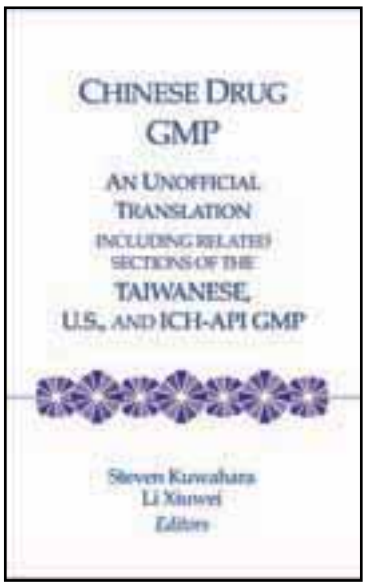

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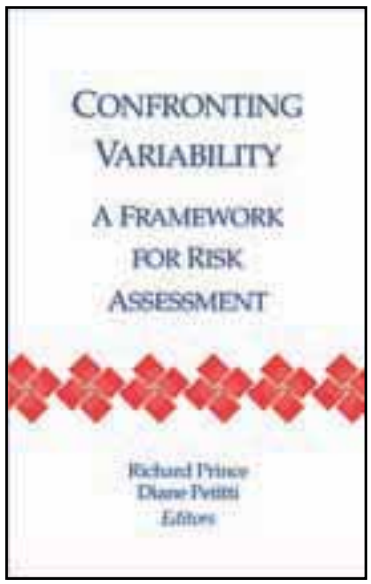

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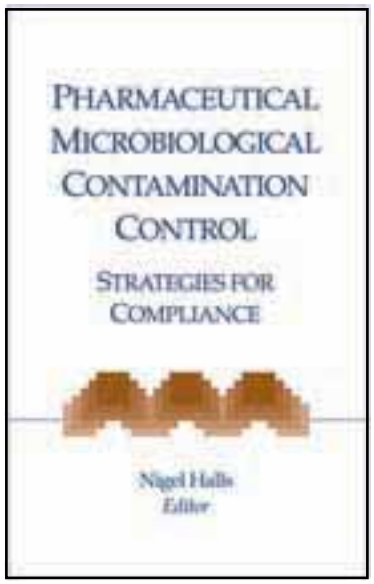

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Managing Quality Risk Management Implementation, continued from cover

The QRM team's first task was to define the business case. They identified three justifications:

1) QRM gives greater assurance of patient safety
2) QRM adds value to the business
3) QRM fosters quality by design

Regarding the first justification, the team reasoned that QRM helps augment patient safety efforts by facilitating more informed decision making and by reducing risks via mitigation strategies.

QRM helps the business (justifications 2) because: resources and priorities can be better focused; the level of product defects, complaints and recalls should drop; and the company can focus on managing risk as opposed to avoiding risk.

Finally, QRM is an important interface with Quality by Design (justification 3), which can help the company reduce the uncertainty typically associated with product development and may help the firm achieve regulatory flexibility.

Development of Internal QRM Guidelines

To fulfill the mission of establishing a successful QRM process, three "strategic imperatives" were defined:

1) Drive accountability of leaders to use QRM
2) Provide clear guidance on managing and communicating risk
3) Embed QRM into business processes

To drive accountability, internal QRM workshops were held in three different regions in order to engage key stakeholders and customers and to elicit feedback. Dialogue at these workshops permitted the team to create a common language and purpose. Creating a common understanding of QRM was critically important because products may move across different functions and companies throughout development and during the product life cycle.

In soliciting thoughts on the second strategic imperative—provide guidance—a common theme heard was that Q9 is a high-level conceptual document, and for many people it takes more than one reading to get comfortable with the content. As such, workshop attendees endorsed the development of an internal guideline which would:

- Provide more detail and more practical application of Q9
- Be easy to use and interpret
- Provide clear direction on where and how QRM should be used

Once again, the internal guideline was more detailed than Q9

Similar to ICH Q9, the internal guideline focuses on QRM in GMP systems. However, stakeholders showed interest in applying the internal guideline to GLP and GCP systems as well. As such, the internal guideline may be updated for those uses at a later date once more experience is gained.

Another strong piece of feedback was a desire for practical advise on how to embed QRM into existing quality systems. Once again, the internal guideline was more detailed than Q9 and included recommended tools that can be applied to specific risk-based activities in each of the different systems.

Embedding QRM into Business Practice

The third aspect of the strategic imperative was to embed QRM into existing business processes. This was accomplished by developing broad-based training programs and implementation tools. Other key elements included identification of QRM champions, deployment of cross-functional teams and ensuring that QRM experience is shared and maintained through proactive knowledge management.

The QRM champions play a key role in the implementation of QRM at individual manufacturing sites. Each champion leads a site-level QRM team tasked with local implementation. They are accomplishing this by following a process similar to that used by the company-wide QRM team.

The site teams are working with plant-level stakeholders to educate and gain feedback. They are analyzing current processes in order to identify opportunities for QRM. This involves cataloguing risk-based approaches already in use and determining where QRM would be beneficial.

One of site teams established pilot programs for risk management to gain early experience and identify "quick wins." Overall 13 QRM pilot projects were established and covered a number of critical manufacturing areas:

- Audit program
- Batch record review
- Change control
- Equipment changeover
- Raw material testing
- Raw material changes
- Validation of laboratory equipment
- Non-conformance handling
- Environmental monitoring
- Animal-derived raw materials

The pilot projects demonstrated that QRM contributed to more streamlined processes, more informed decision making and better prioritization and utilization of resources.

The use of cross-function teams was critical to ensure that diverse perspectives and experience are incorporated during the risk assessment process. In

addition, as more and more people gain facility with risk management tools, it becomes easier to apply QRM. Once a critical mass of knowledge is achieved, QRM begins to sell itself and has great utility across all quality systems and business processes.

Conclusion

Success in implementing QRM relies on a two pronged approach. First there is the important top-down approach, which works to achieve high-level and broad-based management buy-in. Success at this level requires the development of an appropriate business case and selecting sponsors who can drive QRM into the business.

Equally important is the bottom-up approach of cataloguing the numerous risk-based activities that are already ongoing and identifying gaps.

Ultimately, the two approaches must meet in the middle in the form of using more formal RM tools and developing more formal QRM documentation.

Finally, it is necessary to build a critical mass of knowledge and understanding of the tools. As this part progresses, QRM begins to sell itself and gets used throughout all quality systems.

Recent Sci-Tech Discussions: Pharmaceutical Development Reports and Sterile Filtration vs. Terminal Sterilization, continued from page 9

So, filtration is a must for low or even zero bioburden in order to calculate the LRV (log reduction value).

What your company *can* do is that for 0.9% N/S, they can study its retrospective presterilization bioburden data and reduce the time for its terminal sterilization by Fo calculations. This way they can save time.

Respondent 5: A couple of points:

1) Filtration thro 0.22 micron filter does *not* yield an SAL. SAL can only be derived from terminal sterilization.

2) Terminal sterilization is *not* the *preferred* method of sterilization. It is the *mandated* method of sterilization. The three filtrations make sense for the following reasons:

1st filtration: Reduces bioburden and thus minimizes endotoxin build up and *may* allow a longer hold time prior to filling. Also one should have no issues meeting the prefilling bioburden specification.

2nd & 3rd filtration on the BFS: If one of the filters were to fail, the post filling integrity test and the "other" passed you have satisfied the need for filtration at the point of use. If you have one filter and it fails it confuses the decision making process.

Answers from an EU perspective. Hope it helps.

Respondent 6: Have you ever thought on the following:

Any solution that is passed through 0.22 micron filter is supposed to be sterile solution—is it really sterile as the filtration process does not kill any microorganisms but removes them from the filtrate. But what about the endotoxins which may be still present in the filtrate, can it be called a sterile solution?

The filtration process is one of the major measures to reduce the bioburden to very, very low extent. But terminal sterilization, needless to mention, decreases the available bioload to 10^6. Even the utensils used for filtration sometimes may not be adequately devoid of the microorganisms, which may add to contaminate the filtrate. And from every sterilized item, samples are not taken in routine production to check its bioburden. In such a scenario, terminal sterilization is the safest mode to ensure the sterility of the product.

Respondent 7: You mean that a sterile preparation must not have endotoxins, and endotoxins are removed by terminal sterilization, i.e., autoclaving?

Respondent 8: Autoclaving does not remove endotoxins (pyrogens). The purpose of filtration through 0.2µ filters is to get rid of any particulate matter and to reduce the number of bioburden before terminal sterilization by autoclave. The reduction of the bioburden in the final product before autoclaving provides a higher degree of sterility assurance.

Respondent 9: Neither terminal sterilization nor sterile filtration will remove endotoxins from a solution. In fact, a solution can be sterile and still contain endotoxins. Controlling endotoxins is one of the main reasons that bioburden control is critical for terminally sterilized products. Removal of pyrogens from solutions requires a series of specialized treatments such as charged filters, column chromatography, chemical treatment, etc.

Respondent 6: Dear [Respondent 7], I didn't mean it. Moist heat sterilization does not kill or separate endotoxins or pyrogens. It's a question to the forum: If the solution contains endotoxins, can it be called sterile solution?

Respondent 10: Dear [Respondent 6], Yes. You can call it sterile. The solution is sterile but it is not free of endotoxins.

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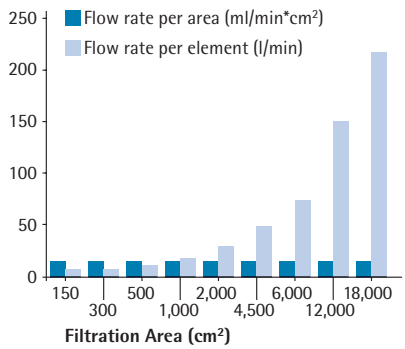

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OOS Final Guidance: What Has Changed?

Eight Years in the Making, the Final Guide is Published

Lynn Torbeck, PhD, Torbeck & Associates

On September 30, 1998, the U.S. FDA announced in the *Federal Register* the availability of a draft guidance, *Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production.* Interested persons were given the opportunity to submit comments by November 30, 1998.

On October 12, 2006, FDA announced the availability of the final guidance in the *Federal Register.* In response to the comments received, the agency made a number of revisions, reorganizations and clarifications in the document. Not many sections of the document were spared revision.

The "Scope" and "Background" are revised to provide more clarity regarding the applicability of the document. The sections "Investigating OOS Test Results—Phase II: Fullscale OOS Investigation" and "Concluding the Investigation" are reorganized. In additions, a number of issues addressed in the guidance are further clarified or include more specific guidance.

This final version provides guidance to the pharmaceutical industry on investigation of laboratory results that fall outside of specification limits. The guidance addresses investigations of OOS results in the laboratory phase, including responsibilities of the analyst and supervisor, and when indicated, the expansion of an investigation outside of the laboratory to include production processes and raw materials as appropriate.

This guidance is intended to apply to traditional methods of drug product testing and release, based on testing of discrete samples of in-process materials and finished products.

What's Out?

There are many minor changes and word substitutions. For instance, the use of the term "failure" investigation has been removed and the term "OOS" or "full scale" investigation has been substituted. The use of "supervisor" has been replaced with "laboratory management." In addition the term "the overall quality assurance program" has been replaced with "the laboratory quality assurance program."

FDA elected to replace "statistical errors" with "calculation errors."

The sentence, "A resampling of the batch should be conducted if the investigation shows that the original sample was not representative of the batch" has been removed.

This paragraph has been removed: "Statistical treatment of data should not be used to invalidate a discrete chemical test result. In very rare occasions and only after a full investigation has failed to reveal the cause of the OOS result, a statistical analysis may be valuable as one assessment of the probability of the OOS result as discordant, and for providing perspective on the result in the overall evaluation of the quality of the batch."

What's New?

The "Introduction" section contains new language, much of which reflects regulatory developments since the 1998 draft was released, particularly the push for better in-process controls. For example, the following sentence was added: "The term [OOS] also applies to all in-process laboratory tests that are outside of established specifications." A footnote indicates this does not apply to adjustments to prevent process drift. In addition, a large paragraph has been added relative to process analytical technology (PAT). "This guidance is not intended to address PAT approaches, as routine in-process use of these methods might include other considerations."

Additional clarifications in the "Introduction" include the notation that laboratory testing is to be "chemistry-based" and "of drugs regulated by CDER." The regulatory references were expanded to include, "the Federal Food, Drug, and Cosmetic Act (the Act) (section 501(a)(2)(B)." Further, "The principles in this guidance also apply to in-house testing of drug product compounds that are purchased by a firm."

In the "Background" section, FDA added a paragraph noting that API's are to be covered by this guidance as well as finished products, referencing ICH Q7A which was finalized after the publication of the OOS draft guidance.

The agency also stressed the responsiblities of contract laboratories with respect to OOS investigations: "For contract laboratories, the laboratory should convey its data, finding, and supporting documentation to the manufacturing firms' quality control unit (QCU), who should then initiate the full-scale OOS investigation."

The next section, "Identifying and Assessing OSS Test Results—Phase I: Laboratory investigation," FDA added an additional step to the supervisor's assessment: "Verify that the calculations use to convert raw data values into a final test result are scientifically sound, appropriate, and correct; also determine if unauthorized or unvalidated changes have been made to automated calculation methods."

In the following section on the full-scale investigation, FDA clarified that all relevant sites must be included: "In cases where manufacturing occurs off-site (i.e., performed by a contract manufacturer or at multiple manufacturing sites) all sites potentially involved should be included in the investigation."

The potential culpability of product or process redesign is addressed in this section in the new paragraph: "OOS results may indicate a flaw in product or process design…In such cases, it is essential that redesign of the product or process be undertaken to ensure reproducible product quality."

The "full-scale investigation" section covers "additional laboratory testing" either through retesting or resampling. Under "retesting," FDA clarified in the final document that, should a second analyst perform the restest, he/she "should be at least as experienced and qualified in the method as the original analyst." Retesting has an additional requirement. "The maximum number of retests to be performed on a sample should be specified in advance in a written standard operating procedure (SOP)…Any deviation from this SOP should be rare…In such cases, before starting additional retesting, a protocol should be prepared that describes the additional testing to be performed and specifies the scientific and/or technical handling of the data."

New statements are included under "resampling": "The original sample from a batch should be sufficiently large to accommodate additional testing in the event an OOS result is obtained. In some situations, however, it may be appropriate to collect a new sample from the batch."

Guidance on "averaging" under the subheading "Reporting Testing Results," was reorganized into two subsections: "Appropriate uses" and "Inappropriate uses."

In "Appropriate uses," FDA includes a reference to a new definition for "reportable results": "The term reportable result as used in this document means a final analytical result. This result is appropriately defined in the written approved test method and derived from one full execution of that method, starting from the original sample." This is in accord with industry literature and the United States Pharmacopeia definition. Two additional paragraphs expand on the concept. Included is the new expectation that the variability of the replicates will have acceptance criteria and that "If acceptance limits for replicate variability are not met, the test results should not be used."

Under "Inappropriate uses," the misuse of averaging is expanded in two new paragraphs.

The section on "Interpretation of Investigation Results" has been expanded considerably with five new paragraphs. Interestingly, while the guidance does not give recommendations for the sample size for retesting, the example scenario given uses seven retests. Seven was the suggestion in a footnote in the Barr Case judgment. The sample size question is still unresolved.

A new section titled "Cautions" has been added. The first paragraph continues a discussion of reportable results stating that "…a firm should err on the side of caution…" The second paragraph adds a new issue to the guidance, noting that a low assay result should raise concern and that "One cause of the result could be that the batch was not formulated properly. Batches must be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient." While this is an old GMP concept, it is interesting that it is expressed here in this context.

Conclusion

The final guidance is welcomed by the industry for addressing several issues that had not been resolved. However, there are still issues that need to be the subject of ongoing dialog between FDA and the industry. The final guidance provides a firm platform on which to build those discussions.

Regulatory Briefs

Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at http://www.pda.org/regulatory/RegNewsArchive-2006.html.

North America

Moving In, Up and Out at FDA

On December 7, 2006, the U.S. Senate confirmed **Andrew von Eschenbach,** MD, as Commissioner of FDA by an 80-11 vote. Von Eschenbach had served as acting Commissioner since September 26, 2005. Prior to joining FDA, he was the 12th director of the National Cancer Institute.

Mike Leavitt, Secretary of the U.S. Department of Health and Human Services, made the following comments on von Eschenbach's recent appointment: "Andy has the energy, vision and expertise that will help the agency to improve product safety, spur innovation and help life-saving therapies reach patients faster. He is a superb choice to lead [the Agency]."

CDER Office of Compliance (OC) staffers **Joe Famulare** and **Rick Friedman** were promoted in November. Famulare formally assumed the role of Deputy Director of the Office of Compliance after serving as the "acting deputy" for several months. Concurrently, OC tagged Friedman to fill Famulare's former post of Director of OC's Division of Manufacturing and Product Quality, a position Friedman temporarily filled earlier in the year.

Famulare joined the U.S. FDA as an Investigator in 1977 and has been with CDER since 1996. Since August 2005, he has alternated as Acting Deputy Director and Acting Director of the CDER Office of Compliance. As Deputy Director, Famulare will be involved in a wide range of administrative, technical, scientific and policy issues for the Office, with particular emphasis on manufacturing quality and bioresearch monitoring.

Friedman joined FDA in 1990 as a drug investigator in the New Jersey District Office. In June 1995, he joined CDER's Division of Manufacturing and Product Quality. Friedman participates on many FDA committees, including the Council on Pharmaceutical Quality. He is a member of PDA.

Scott Gottlieb, MD, Deputy FDA Commissioner for Medical and Scientific Affairs announced on Dec. 11, 2006 that he will leave the Agency effective January 16, 2007, to return to the American Enterprise Institute, a Washington-based think tank.

Gottlieb joined FDA as Deputy Commissioner in July 2005. Since that time, he has worked on a number of significant policy initiatives including efforts to improve the advisory committee process and to make the Agency's approaches regarding communication of risk information to the public more effective.

"Throughout Scott's tenure at both FDA and the Centers for Medicare and Medicaid Services, he has served the public health with tireless dedication," said newly confirmed FDA Commissioner Andrew von Eschenbach, MD.

FDA Seeks to Expand Availability of Experimental Drugs

FDA is proposing to amend its regulations on access to investigational new drugs for the treatment of patients. The proposed rule would clarify existing regulations and add new types of expanded access for treatment use.

Under the proposal, expanded access to investigational drugs for treatment use would be available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application (IND). The proposed rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other therapeutic options and who may benefit from such therapies. The proposal also addresses the fees patients are charged for continued access to experimental drugs.

The proposal appeared in the Dec. 14, 2006 *Federal Register.* FDA is accepting public comment until March 14, 2007.

U.S. Court Grants Wholesalers' Request to Hold a Pending FDA Drug-Tracking Rule

On November 30, 2006, the U.S. District Court for the Eastern District of New York granted injunctive relief to prevent a pending FDA drug-tracking rule from taking effect on December 1, 2006.

According to the Report and Recommendation issued by A. Kathleen Tomlinson, U.S. Magistrate Judge, the rule required "each person who is engaged in the wholesale distribution of drugs…and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors."

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PDA Calendar of Events for North America

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

Conferences

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

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

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

May 21-22, 2007
Quality by Design for Biopharmaceuticqals: 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.

Training

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

Laboratory Courses

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

February 27-28, 2007
Computer Products Supplier Auditing Process Model - Auditor Training

March 1-2, 2007
Environmental Mycology Identification Workshop

March 12-16 and April 16-20, 2007
Aseptic Processing Training Program (Session 2)

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 16-17, 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 Annual Meeting Training Courses
Las Vegas, Nevada

October 8-10, 2007
Advanced Pharmaceutical Filtrations and Filters
Bethesda, Maryland

Course Series

February 12-14, 2007
Houston Course Series
Houston, Texas

May 7-9, 2007
Indianapolis Training Course Series
Indianapolis, Indiana

June 11-13, 2007
2007 Baltimore Maryland Training Course Series
Baltimore, Maryland

Europe/Asia-Pacific

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

Europe

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

February 5-6, 2007
Rapid Microbiology Methods: Make It Work, Get It Approved
(Conference and Courses)
Verona, Italy

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

February 12-13, 2007
2006 ISPE/PDA Joint Workshop: Challenges of Implementing Q8 and Q9 — Practical Applications
Brussels, Belgium

March 26-27, 2007
Continuous Improvement in Pharma Industry and Its Impact on cGMPs Conference and Exhibition
Verona, Italy

Online Learning

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

Web Seminars

January 10, 2007
Applications and Advantages of Online Vacuum Filling and Stoppering in Pre-filled Syringes

January 18, 2007
Parametric Release of Drug Products Terminally Sterilized by Moist Heat

February 1, 2007
Quality in Healthcare - Anticipation and Management

February 15, 2007
Online Liquid Chromatography as a PAT in Biotech Process Development and Manufacturing

Did you miss The Universe of Pre-filled Syringes and Injection Devices Forum?

If you missed The Universe of Pre-filled Syringes and Injection Devices Conference on October 23-25, 2006, or would like a re-cap of the presentations, PDA is now providing FIVE of the best recorded sessions of the conference via On-Demand for the price of just ONE recording. Offer ends January 31, 2007.

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A Reinvigorated Membership Department

Lindsay Donofrio, PDA

To better serve its members, PDA recently enhanced the structure of the membership department under **Nahid Kiani**, who is a 13-year veteran of the PDA staff. Since September, the department has grown significantly with the additions of Senior Membership Coordinator **Hassana Howe** (see Nov./Dec. 2006 *PDA Letter*), Chapters Coordinator **Ta-Méla Jeffries** and Membership Coordinator **Emily Alesantrino**.

In her position as Chapters Coordinator, Ta-Méla acts as a resource for PDA members who are interested in becoming more involved in their local chapters. Her role includes promotion of chapter events and maintenance of the chapters' calendar and chapters' pages of the PDA website. Ta-Méla also works with **Henry Kwan**, Senior Chapter Liaison, to facilitate communication between PDA and its chapters. Henry joined PDA in this capacity in early 2006 (see July/Aug. 2006 *PDA Letter*). In addition to her chapter responsibilities, Ta-Méla manages the Career Center, which is PDA's online career resource (www.pda.org/careers/index.html).

Ta-Méla is an ideal fit for the PDA membership department. She graduated from North Carolina Central University in Durham, N.C., with a BA in English. After graduation, she worked as a customer service representative for Chevy Chase Bank, where she was very successful at addressing customer needs.

As Membership Coordinator, Emily serves as a key contact for both prospective and current members. She is an excellent source of information for members with questions or concerns regarding their PDA membership status. Emily's roles include processing membership payments, applications and renewals.

Emily (left) and Ta-Méla recently joined PDA's Membership Department

Emily earned a BS in Business Administration from Colorado Technical University. She gained valuable customer service experience and became skilled with various databases while working as the Office Assistant for Animal Nannies of Mclean following graduation. Emily also has gained valuable insight to the important role regulatory investigators play. She served as an undercover liquor control agent ensuring businesses were not selling alcoholic products to underage consumers during a high school internship with local police.

In efforts to continuously improve our membership services, PDA needs your input. Member feedback enables PDA to offer new services and further develop current services based on your needs. Please send all comments and suggestions to the respective coordinator of the membership team—Hassana, Ta-Méla or Emily.

Questions?

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An Update on North American Chapter Events

Henry Kwan, PhD, Consultant to PDA

Continuing with my Chapter updates, which I started with the July/August 2006 *PDA Letter,* I want to inform the PDA membership about what has transpired at some of the chapter events that I attended during the second half of 2006. This update is not meant to be a comprehensive summary of all the Chapter events that took place, but is intended to provide a flavor of how PDA chapters are bringing exciting topics and expert speakers to their local membership. As you shall see, the scope of the topics is very broad indeed and represents some of the pertinent issues facing the pharmaceutical industry.

In 2006, a total of 36 events were hosted by nine North American chapters. It is worth noting the revitalization efforts of the Canada and Puerto Rico Chapters in preparation for 2007. If you are interested in contributing to the efforts, please contact **Patrick Bronsard**, Project Manager, SNC-Lavalin Pharma, in Canada (patrick.bronsard@snclavalin.com) and **Manuel Melendez**, Executive Director, Site Quality Head, Amgen Manufacturing Limited, in Puerto Rico (manuelm@amgen.com).

Southeast Chapter Enjoys Record Attendance

On October 10, a record attendance for the Southeast chapter of over 130 people and 36 exhibitors showed support for the fall exhibitor show and meeting. The all-day event included exhibits from 10 a.m. to 4 p.m. and two presentations on the recently-issued ICH quality guidance documents Q8 and Q9 and the U.S. FDA guidance document on quality systems. The featured speakers included:

- **Ron Tetzlaff**, PhD, Vice President, PAREXEL Consulting, whose presentation was entitled, "ICH Q8, Q9 and Q10."
- **Tom Garcia**, PhD, Associate Director, Regulatory CMC, Pfizer Inc., whose presentation was entitled, "The Use of Quality by Design Principles to Define Design Space."

Midwest Chapter Hosts Dinner, Talks Validation and USP

On October 19, the chapter successfully hosted a dinner meeting in Indianapolis, Ind., attended by over 30 people. The event was organized by Midwest Chapter volunteers in the Indianapolis area led by **Scott Hartman**, Division Manager, PCI, who presented, "Maintaining the Validated State of Analytical Laboratory Instrumentation in GMP/GLP Environments."

This was the first event the chapter sponsored outside the Chicago area. It represented the vision of the Midwest Chapter board to diversify the location of its events in an attempt to satisfy the needs of its membership, which currently covers six states including Illinois, Indiana, Iowa, Michigan, Minnesota and Wisconsin.

On November 30 in Northbrook, Ill., the chapter featured **Sue Schniepp**, Manager, Standards and Test Methods, Hospira, Inc., who gave a talk entitled "Demystifying the USP" about the USP and its monograph development process.

Southern California Chapter Back-To-Back Events

With a new board of officers led by **Saeed Tafreshi**, President, Intelitec Corporation, the chapter recently reorganized itself to put on back-to-back events in two different areas of southern California.

On October 25, the chapter kicked off its first event in 2006 in Irvine, Calif.,

TALES of the TRAIL

with the topic of Computer Compliance. Tafreshi delivered the talk, "Requirements and Specifications of Computer Systems," and **Terri Mead**, Founder, Solution2Projects, gave a talk entitled, "Good Business Practices That Satisfy Compliance for Computer Systems in an FDA-Regulated Industry." The event was sponsored by Sparta Systems, Inc.

During the meeting, Tafreshi introduced the new board and the chapter initiatives, which included membership involvement, event planning, local training courses and possible joint events with ISPE. The chapter plans to include a vendor to sponsor each event. The audience was reminded that the chapter is intended for the members; hence, membership feedback is essential for its success.

On November 15, in San Diego, Calif., the chapter hosted another dinner event where **Jaspreet Sidhu**, PhD, Vice President, Business Development, Molecular Epidemiology, Inc., gave the talk "Genetic Identification Techniques as a Means to Understand and Investigate Sources of Microbial Contamination During Drug Manufacturing." The event was sponsored by NOVATEK International.

These two events represent a great start in generating momentum for the rejuvenation of the Southern California Chapter in 2007.

New England Chapter New Board Elected

On November 8, over 70 people attended the New England chapter dinner meeting in Burlington, Mass. The theme of the meeting was "Contract Manufacturing Issues," which featured three speakers and the following diverse agenda:

- **John Dobiecki**, Vice President/ General Manager, MicroTest Laboratories, Inc., "How to Select a Contract Manufacturer"
- **Dr. Shawn Kinney**, President, HCM, "Considerations and Advantages with Prefilled Syringes"
- **Erik Hoglund**, Associate Director, Cell Culture Operations, Lonza Biologics, "Changeover Procedures in a Multiple-Product Facility—Issues to Consider"

At this event, the biannual election for the new chapter board was held. The 2007-2008 slate of chapter officers was unanimously voted in by the PDA members in attendance. Congratulations to the following new board members:

President: **Louis Zaczkiewicz**, Engineering Director, HCM

President-Elect: **Jerry Boudreault**, President, Drug Development Resources, Inc.

Treasurer: **Rusty Morrison**, Validation Engineer, CAI

Secretary: **Melissa Smith**, MJ Quality Solutions

Member-at-Large: **Myron Dittmer, Jr.**, MFD & Associates

Member-at-Large: **Bruce Rotker**, Senior Account Executive, Sparta Systems, Inc.

Thanks!

On behalf of the PDA, I would like to once again acknowledge the volunteer efforts and the contributions made by all the chapter leaders, as well as the guest speakers who took time out of their busy schedules to support the PDA chapters and membership. I encourage all the PDA members to step up their efforts by contributing to the chapters as a volunteer, a sponsor and/or a prospective speaker at chapter events.

Happy New Year!

About the Author

Henry is a long-time PDA member and former member of the Board. In 2006, he signed-on as a consultant to PDA in the capacity of Senior Chapter Liaison. Henry also is an independent consulting to the industry. Look for his "Tales of the Trail" in future issues.

European Chapters Fact

PDA's seven European chapters were very actice in 2006. In total, the chapters sponsored eight events.

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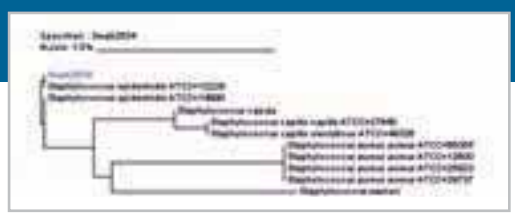

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PDA Welcomes 215 New Members

Dwight Abouhalkah, Vistakon Pharmaceuticals

Ron Adkins, Particle Measuring Systems

Shimon Amselem, Pharmos Ltd.

Yvan Applagnat-Tartet, bioMerieux S.A.

Barbara Armstrong, Fleet Laboratories

Partha Banerjee, Chugai Pharma USA LLC

Brent Bankosky, Steris Corp.

Marilyn Bartha, Wyeth Pharmaceuticals

Lisa Beaudry, DSM Pharmaceuticals, Inc.

Peter Bedingfield, Steritech Ltd

Siddharth Bhargava, Bayer Healthcare LLC

Corinne Blankenship, Durect Corporation

Grant Bomgaars, Baxter Healthcare

Bethann Brescia, Amgen

Jeffrey Brown, West Pharmaceutical Services

Dorthe Bruun, Genmab A/S

Mark Bufkin, Schering-Plough

Sheryl Chalmers, Canadian Blood Services

Alvin Chapital, Kimberly-Clark Corporation

Edward Chin, Genentech

Diane Clarke, Johnson & Johnson

John Coombs, Meadvale International Ltd

Rebecca Cosford, Cosford Consulting

Suzanna Crowe, Lonza Biologics

Vincent Demaiffe, GlaxoSmithKline Biologicals

Sanjay Deshpande, Wockhardt Limited

Ian Dettman, Biological Therapies

Ellen DiPaolo, Advanstar

Heidi Dirga, Althea Technologies

John Donohue, Boston Scientific

Jayne Dovin, Sanofi Pasteur

Shiri Dovrat, Teva Petah-Tikva

Dana Elias, DeveloGen Israel

Bernard Elissondo, Aktehom

Adi Elkeles, Bioline

Zanetti Emmanuelle, bioMerieux

Eric English, AppTec

Monica Escobar, Merial Ltd

Kevin Feezor, Harmony Labs

Scott Ferguson, JM Hyde Consulting

Richard Francis, Protherics

Bruce Frazier, Avid Bioservices

Meir Gal, Clalit Health Services

Asher Gamliel, Nasvax

Manuel Garcia, Bristol Myer Squibb

Inna Gerasenkov, Lycord Bio

Iris Goldenberg, Taro

Dennis Graver, Bayer HealthCare

Kevin Greenstein, Teva Kfar-Saba

Neil Grumbridge, Health Protection Agency

Hector Guadalupe, Amgen Mfg. Ltd.

Gali Guzikevich, Teva Teac

Avichai Hadad, Trima

Leah Hanogoglu, Rekah

Yukari Haramaki, Nihon Waters

Tuval Harel, Bio-Rad Haifa

Nicole Hauptmann, Abbott GmbH & CokG

Shawn Haynes, Allergan

Gabi Hazan, Rafa Laboratories

Carl Hitscherich, Biogen Inc.

Erik Hoglund, Lonza Biologics

SungSang Hong, Berna Biotech Korea

Dennis Huang, Allergan, Inc.

Michael Huang, Merck & Co.

Raffaella Invitto, Janssen Cilag

Elza Iscovitch, Vitamed

Julie Jaillet, University C. Bernard Lyon I, France

Maribeth Janke, Cambrex

Ingry Jaramillo, Gambro

Emur Jensen, Vitrolife, Inc.

Lisa Jewkins, Amgen Australia

Virginia Johnson, Emergent BioSolutions

Tamar Kadar, Trima

Ravi Kadire, Schering-Plough

Kimberly Kainec, Amresco Inc.

Yoshihara Kakuji, Shionogi & Co., LTD.

Dawn Kalnajs, MedImmune Vaccines, Inc.

Jan Karibian, Mallinckrodt Inc.

Ho Keck-Choong, Genentech

Sean Kelly, Amgen, Inc.

Narufumi Kitamura, Sepa-Sigma,Inc.

David Klug, sanofi-aventis U.S. LLC

Dennis Kraus, Centocor

Miri Kupermintz, Albaad

George Laidlaw, NHS

Adi Lavi-Loebl, Teva Petah-Tikva

Jim Lawton, Amgen

Tony Lee Hon Ling, Schering-Plough

Anne Leonard, Baxter BioPharma Solutions

Yeri Ler, Vitamed

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Sveta Mikhcin, Biovac

Eitan Mislish, Orgenics

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Iris Mor, Teva Teck

Malanie Morin, Hema-Quebec

Ilana Nachum, Teva Plantex

Regina Nadborny, Sol-Gel Technologies

Adil Nashed, Government of Canada

Wendy Nelson, Genentech

Joseph Newell, Cardinal Health

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Brian O'Sullivan, Wyeth Biotech

Takehiro Okumura, Japan

Debby Ortal, Meditec

Bhavesh Patel, Marck Biosciences Ltd.

Joel Patlis, Meditec

Bill Paulitzky, Hyaluron

Estella Pelayo, Schering-Plough

Derek Pendlebury, ATMI

Dennis Pierro, Colorado State University

Maya Polishuk, Teva Plantex

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Astar Ram, Gamida Cell

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Shelly Zelznick, Amresco Inc.

Niels Zeuthen, Novo Nordisk A/S

Daniel Ziegler, Sandoz SA

Chapter Contacts

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

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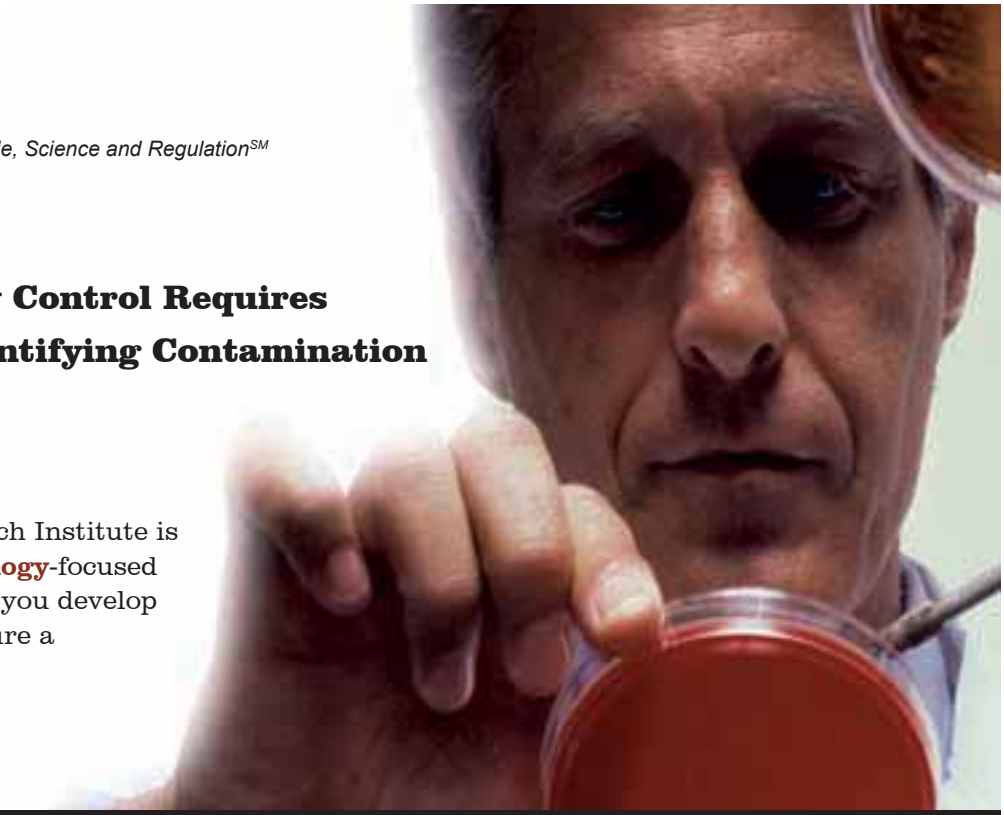


Successful Quality Control Requires a Keen Eye for Identifying Contamination

PDA Training and Research Institute is offering several **Microbiology**-focused courses in 2007—helping you develop the skills required to ensure a quality product

Up Next:

Environmental Mycology Identification Workshop
PDA #230
Session I: March 1-2, 2007
Baltimore, Maryland, USA
www.pdatraining.org/mycology

Identification of fungal contamination is a must for any successful quality control program. This course is designed to offer hands-on experience with both traditional and new fungal identification techniques for QA/QC and Microbiology personnel. Various methods, including fungal detection, identification flow charts and use of camera for documentation will be introduced. By providing participants with the proper tools to perform accurate and reliable fungal identifications in-house, outsourcing costs for fungal identification can be reduced/eliminated.

Upcoming in 2007:

Pharmaceutical and Biopharmaceutical Microbiology 101
PDA #142
May 1-4, 2007
Baltimore, Maryland, USA
www.pdatraining.org/pbm101

One Time Only in 2007!

Environmental Mycology Identification Workshop
PDA #230
Session II: August 2-3, 2007
Bethesda, Maryland, USA
www.pdatraining.org/mycology

Rapid Microbiological Methods / PDA #326
October 1-5, 2007
Bethesda, Maryland, USA
www.pdatraining.org/rapidmicro

One Time Only in 2007!

Fundamentals of D, F and z Value Analysis
PDA #301
October 23-24, 2007
Bethesda, Maryland, USA
www.pdatraining.org/DFZ

One Time Only in 2007!

Advanced Environmental Mycology Identification Workshop
PDA #396
October 31-November 2, 2007
Bethesda, Maryland, USA
www.pdatraining.org/advmycology

One Time Only in 2007!

For a complete listing of training courses from PDA TRI, please visit *www.pdatraining.org.*

TUAA7

People and Places

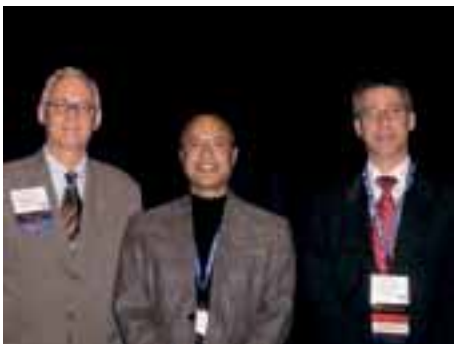
Prefilled Syringes Forum, Bethesda, Md., Oct. 23–25, 2006

Patricia Love, MD, U.S. FDA

Anthony Watson, U.S. FDA

Ravi Harapanhalli, PhD, U.S. FDA

Microbiology Meeting, Bethesda, Md., Oct. 30–Nov. 1, 2006



Richard Levy, PhD, PDA; Anwar Huq, PhD, University of Maryland Biotechnology Institute; Michael Miller, PhD, Eli Lilly and Company

The macro view of the Micro Meeting

Edward Tidswell, PhD, Eli Lilly and Company; James Agalloco, Agalloco & Associates; Rebecca Devine, PhD; Stephen Langille, PhD, FDA

Asia-Pacific Congress, Tokyo, Japan, Nov.13–17, 2006

Yukio Hiyama, PhD, National Institute of Health Sciences

Taiichi Mizuta, PhD, Denka-Seiken Co., Ltd; Jennie Allewell, Wyeth Research; Yoshihito Hashimoto, Chiyoda Corporation; Wanda Neal-Ballard, PDA

Yoshiaki Hara, Sartorius KK, and colleagues take a break to perform"

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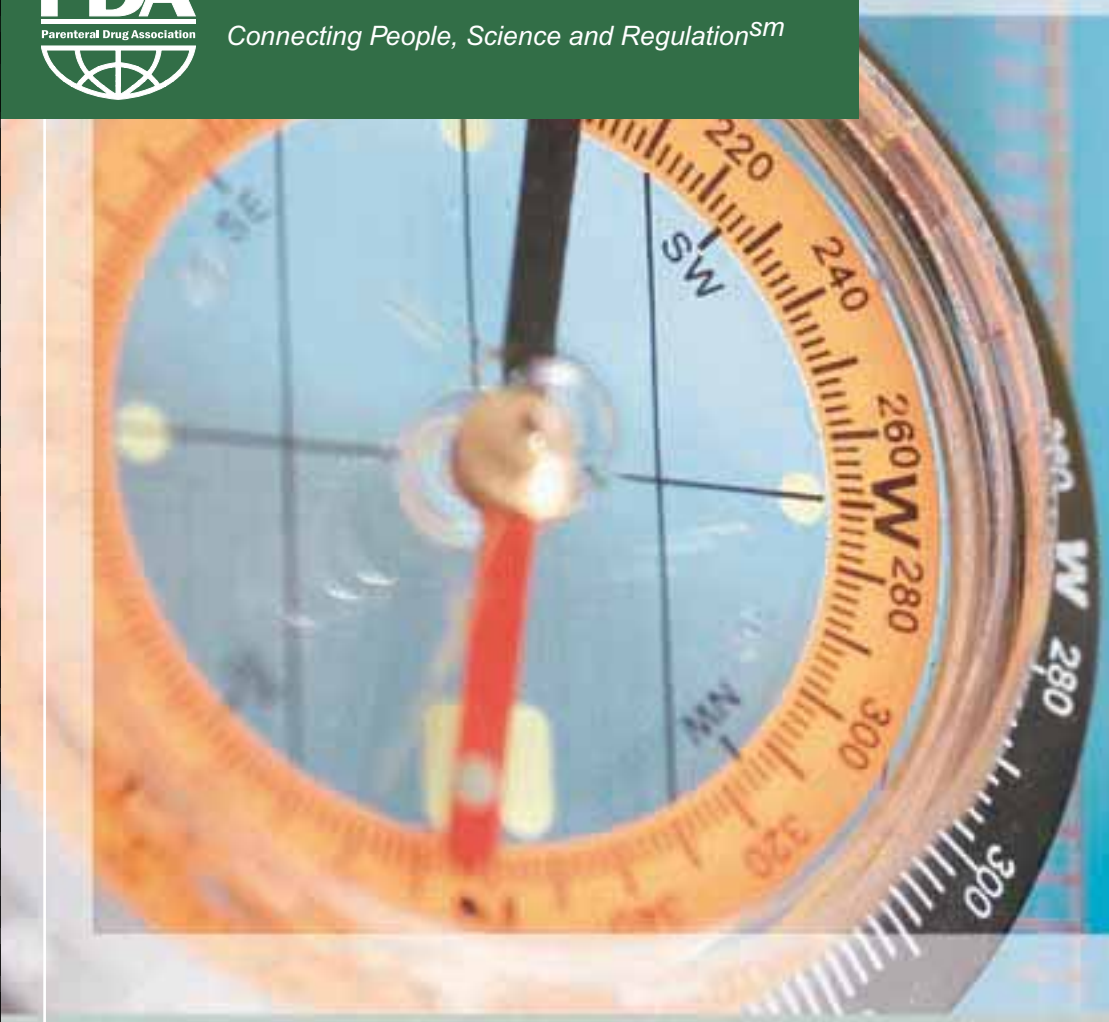

Navigate Your Way Through the World of Pharmaceutical Filtrations and Filters

The PDA Training and Research Institute brings you two training courses in 2007 dedicated to pharmaceutical filtrations and filters.

Fundamentals of Pharmaceuticals Filtrations and Filters
PDA #132 | March 5-7, 2007 | *www.pdatraining.org/FPFF*

Filtration is used to separate unwanted particles, both viable and non-viable, from drug preparations. This highly-interactive training course is intended to provide a fundamental understanding of pharmaceutical filtrations and filters. The course will enable the participants to concentrate on the use of filters for the most demanding and critical operations for the manufacture of aseptic products.

Advanced Pharmaceutical Filtrations and Filters
PDA #174 | October 8-10, 2007 | *www.pdatraining.org/APFF*

This course is a follow-up to the Fundamentals of Pharmaceutical Filtrations and Filters and Basics of Biopharmaceutical Sterilizing Filtration. Focusing on more advanced concepts in filtration, this course includes practical experience in the laboratory. The course format will be a combination of lecture and laboratory functions with interactive question and answer sessions. Time will be allotted both during the presentations and following presentations for participants' questions.

For more information, please contact:

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Visit: *www.pdatraining.org*

UMBC Technology Center
1450 South Rolling Road
Baltimore, Maryland 21227
USA

After July 1, all TRI Training courses will be held at the new TRI facility in Bethesda, Maryland.

PDA's Global PAT Conference: Unlocking the Knowledge in Your Process

Bethesda, Maryland · May 22–23, 2007

Michael Miller, Eli Lilly and Company and Program Chair

Development and implementation of Process Analytical Technology (PAT) is progressing rapidly within the pharmaceutical and biopharmaceutical industries. On behalf of the program planning committee, I invite you to join colleagues and industry experts from around the world to learn more from case studies on recent PAT development and implementation projects and to discuss how these advances will affect the industry in the near future.

The PDA Global PAT Conference: *Unlocking the Knowledge in Your Process* will be held in Bethesda, May 22-23, 2007. Special emphasis will be placed on the following topics:

- The resources commitment necessary for developing and implementing PAT
- Impact of PAT on the quality unit
- Tested strategies for moving PAT projects through the regulatory process
- The business case for PAT from the PAT users' point of view
- Practical solutions for scaling PAT projects to the size of your operations
- Challenges facing smaller companies

The PDA Global PAT Conference will be held in conjunction with the PDA Workshop *Quality by Design for Biopharmaceuticals: Concepts and Implementation* on May 21-22, 2007 in Bethesda.

I hope you will join me and the entire committee at the PDA Global PAT Conference to learn about the science and technology behind PAT and its effect on Quality and Regulatory Affairs. For more information on *Unlocking the Knowledge in Your Process* please visit www.pda.org/pat.

Quality by Design for Biopharmaceuticals: Concepts and Implementation

Bethesda, Maryland · May 21–22, 2007

Program Co-chairs: Rebecca A. Devine, PhD, Regulatory Consultant, and Anurag S. Rathore, PhD, Amgen, Inc.

The concepts behind Quality by Design (QbD) have been an emerging focus within the biopharmaceutical community over the past few months. The U.S. FDA is even working on a pilot program to collaborate with the biotech industry towards providing more clarity on the topic.

However, little information has been provided to elucidate the implementation of these concepts towards process development activities in the biopharmaceutical industry. PDA is striving to address important topics in the area of biotechnology and will be presenting a meeting to address QbD for biotechnology products.

Quality by Design for Biopharmaceuticals: Concepts and Implementation, a one-and-a-half day workshop presented by PDA, May 21-22, 2007, Bethesda, Maryland, will bring together industry and regulatory representatives to address the application of QbD concepts as applied to various aspects of biopharmaceutical manufacturing, including process development and design, process characterization, validation, regulatory filing and process monitoring. Topics of discussion include:

- QbD definition and concepts
- QbD impact on process development and design
- Case studies of QbD in the biopharmaceutical world
- Impact of QbD implementation on different departments: process development, quality, manufacturing and regulatory

In addition, industry and regulatory experts will address:

- What is QbD?
- How does QbD apply to biopharmaceutical processes?
- What are the connections between QbD, design space and process validation?
- How would QbD evolve as we move towards PAT?
- How have companies been successful at implementing QbD principles?
- How are global regulatory authorities driving QbD?

For more information about the *Quality by Design for Biopharmaceuticals: Concepts and Implementation* workshop, please visit www.pda.org/qbd.

12-13 FEBRUARY 2007

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BRUSSELS, BELGIUM

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CHALLENGES OF IMPLEMENTING ICH Q8 & Q9

Practical Applications

This is a conference you can not afford to miss! The "Who's Who" of ICH will be presenting their expectations for implementing the Q8 and Q9 Quality Guidances in the USA, EU and Japan... Learn first-hand what these important developments mean for you and your organisation.

Part of a new conference series co-hosted by the International Society for Pharmaceutical Engineering and the Parenteral Drug Association

www.ispe-pda.org/Q8Q9

2007 PDA Annual Meeting: *Putting Science and Technology into Practice*

Michael Eakins, PhD, Eakins and Associates and Program Chair

On March 19-21, the Red Rock Casino, Resort and Spa in Las Vegas will be home to the 2007 PDA Annual Meeting: *Putting Science and Technology into Practice*. TRI training courses will be held from March 22-23. The resort is situated away from the Las Vegas Strip on 70 acres overlooking the Red Rock Canyon.

This year there are more networking events than ever. You'll have the opportunity to hit the links at Arnold Palmer's newest golf course, the Arroyo Golf Club. If visiting the local sights is more your style, be sure to join us for a riverboat cruise on Lake Mead followed by a visit to the famous Hoover Dam. New members are invited to learn more about PDA and its member benefits at the new member breakfast. After relaxing with your friends and colleagues at one of PDA's receptions or gala, be sure to check out two of Las Vegas' signature Cirque de Solei shows: "Love" and "Ka."

This year's program combines case studies, science interest group forums, technical report updates and workshops. Case studies begin on Monday and will be featured throughout the conference. Tuesday morning kicks off with the Student Symposium featuring presentations from rising graduate students in the field. Other sessions include updates on Technical Report No. 1: *Validation of Moist Heat Sterilization Processes, Cycle Design, Development, Qualification and Routine Control*, Technical Report No. 43: *Identification and Classification of Defects in Molded and Tubular Glass Containers in Pharmaceutical Manufacturing* (2007) and Technical Report No. 28: *Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals* (Revised 2006).

For the first time, the PDA Annual Meeting has been extended to three full days. Join PDA after lunch on the third day for one of two exciting workshops, the first of which will showcase updates on Japanese regulatory issues and second will feature process validation.

Keynote speakers will be a part of both the opening and closing plenary sessions. Our opening plenary speaker will be **Dan Denney,** PhD, CEO, Genitope Corporation, with a presentation on the subject of "Individualized Medicine." In the final plenary, **Peter Barton Hutt**, Senior Counsel, Covington & Burling LLP, will continue the discussion with his presentation on how personalized medicine will impact existing regulations.

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

TRI Courses

A Comprehensive Guide to OOS Regulations
March 22, 2007

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

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

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

Process Validation for Biopharmaceuticals
March 22, 2007

Assay Validation Basics
March 23, 2007

Methods of Reducing Costs for Cleanroom Operations
March 23, 2007

Pharmaceutical Cold Chain Distribution Best Practices
March 23, 2007

Risk Estimation in Aseptic Processing
March 23, 2007

PDA
Parenteral Drug Association

2007 ANNUAL MEETING

Putting Science and Technology into Practice

LAS VEGAS, NEVADA | MARCH 19-23

The Parenteral Drug Association extends a very special "thank you" to our sponsors!

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Eisai Machinery U.S.A., Inc.
EMD Chemicals
Fagerdala USA - Tempcell
General Physics Corp.
Genesis Packaging Technologies
Hyaluron Contract Manufacturing
JM Hyde Consulting, Inc.
Kimberly-Clark Professional
Lancaster Laboratories
Lighthouse Instruments
Masy Systems, Inc.
Microbiology International
Midi, Inc.
Millipore Corporation
Mission3
Moda Technologies
Molecular Epidemiology, Inc. (MEI)
Novatek International
Nuova OMPI SRL
Optima Group Pharma
Pall Life Sciences
PAREXEL Consulting
PharmaSys, Inc.
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VETTER

TRI TALK

Happy New Year!

Gail Sherman, PDA

It is a new year, and we have so much to look forward to in 2007—most specifically the consolidation of TRI to Bethesda. Now that 2006 is over and our preparations for training programs for 2007 are almost complete (we have space on the calendar to add courses both here and in Europe and are looking for your input!), we can turn our attention to the building of the TRI facility in Bethesda Towers.

Gail reviews plans for the new facility.

As I write this, our construction plans are 100% complete. Minor modifications are being addressed for the new Fedegari double door autoclave, which will be installed shortly after our move in date. We are meeting with the building management for permitting and talking to contractors for construction, so I hope that by the time this article reaches you, demolition of the existing space will be in the works—though we all know permitting with the local government could cause a delay.

We have received early donations of equipment from our loyal PDA members, including bioreactors from Sartorius and a Steritest Equinox from Millipore Corporation. We are also working with other PDA sponsors—to be named later—on flooring for our labs, the cleanroom and other necessary equipment and supplies.

In the past, I have alluded to the general need for equipment and other donations and support needed to make this state-of-the-art facility truly that. After careful consideration, I'm now able to announce our specific needs. On the next page, we've included a list of equipment and non-consumables PDA TRI will need in order to continue to provide the one-of-a-kind training programs for which we have become known around the world. If you have questions or would like to help, please feel free to contact me.

We look forward to showing off our facility in June with an open house for our members and supporters. Thank you in advance for your continuing support of PDA TRI.

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.

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.

How Your Organization Can Help

Laboratory Equipment Needed	Number	Investment Amount*
Laboratory Chairs	30	_____
Microscopes	12	_____
Equipment Carts	4	_____
Movable Lab Tables (6')	4	_____
Biosafety Cabinets	2	_____
Laminar Flow Hoods – 6' or 8'	2	_____
Incubators	6	_____
Storage Refrigerator	1	_____
Lyophilizer	1	_____
Isolator Hardwall	1	_____
Laboratory Flooring	4 labs	_____
Cabinets and Storage for Laboratories	Multiple	_____
Labware/Glassware Washer	1	_____
Stainless Steel Storage Racks	Multiple	_____
HEPA Filters	Multiple	_____
Lockers	30	_____
Rigging Service (for move from Baltimore to Bethesda)		_____
Classroom furnishing and equipment		_____
Other laboratory supplies and equipment		_____

* Note: All donations may be made to the Foundation for Pharmaceutical Education, Training, and Research, a 501(c)(3) nonprofit foundation.

CONTACT INFORMATION

Organization Name _____

Contact Name _____

Department/Division _____

Address _____

City _____ State/Province _____

ZIP/Postal Code _____ Country _____

Telephone _____ Fax _____ Email _____

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
- Title
- Company
- Full address
- Phone, fax and email address of presenter
- Presenter's biography (<100 words)
- Co-presenter(s)
- Title(s)
- Company
- Full address(es)
- Phone, fax and email address of co-presenter
- Co-presenter's biography (<100 words)
- Proposal title
- Target audience (by job titles, department and specialty areas)
- 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)
- Presentation Duration (including content and interactive portions) select one: 45 or 75 minutes
- Learning objectives for the session
- Rationale: Explanation of specific take-home benefits your audience can use immediately on the job

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.

2008 "Trainers' Choice" Awards

2008 PDA Biennial Training Conference

New Orleans, Louisiana | May 19-23, 2008

Trainers' Choice Awards are presented to trainers, by their peers, for outstanding achievement, creativity and originality in design, development, and delivery of cGMP and technical training programs or materials. The awards will be presented during the final day of the 2008 PDA Biennial Training Conference (May 21), at the Ritz Carlton, New Orleans.

Categories May Include:

- **Multimedia Presentation** (Videos, slide shows and PowerPoint presentations)
- **Classroom Training Manual** (Course design and materials from classroom training – participant handouts and trainer guides)
- **E-Learning program/web-page design** (Interactive computer-based programs, Web pages, Web programs)
- **Experiential/Interactive Training** (Games, simulations, exercises, magic tricks)
- **Other Creative Approaches**

Eligibility

Consideration for this award will be given to all trainers currently employed in the pharmaceutical, biotechnology, medical device, biologics, or related health-science industries. Consultants or vendors to such industries are not eligible. **Internal training staff must have designed and own the training programs and materials.**

All entries must be received by January 31, 2008

Please visit www.pda.orgTraining2008 for submission information and to complete the application outlining your entry. Submissions without full information will not be considered.

Preliminary Judging

The PDA Training Conference Committee will conduct preliminary judging. (Entries will be judged on how well they meet the stated objective, serve the target audience and incorporate principles of adult learning theory. Finalists will be notified by March 15, 2008. Finalists should be prepared to display their materials and be available to answer questions at the 2008 PDA Biennial Training Conference. Displays should be designed for tabletop demonstration. Exhibits larger than a tabletop will not be permitted, nor will the distribution of premiums promoting the company or the exhibit. A standardized fact sheet with information on the design of the material will be the only item which may be distributed to conference attendees.

Final Selection

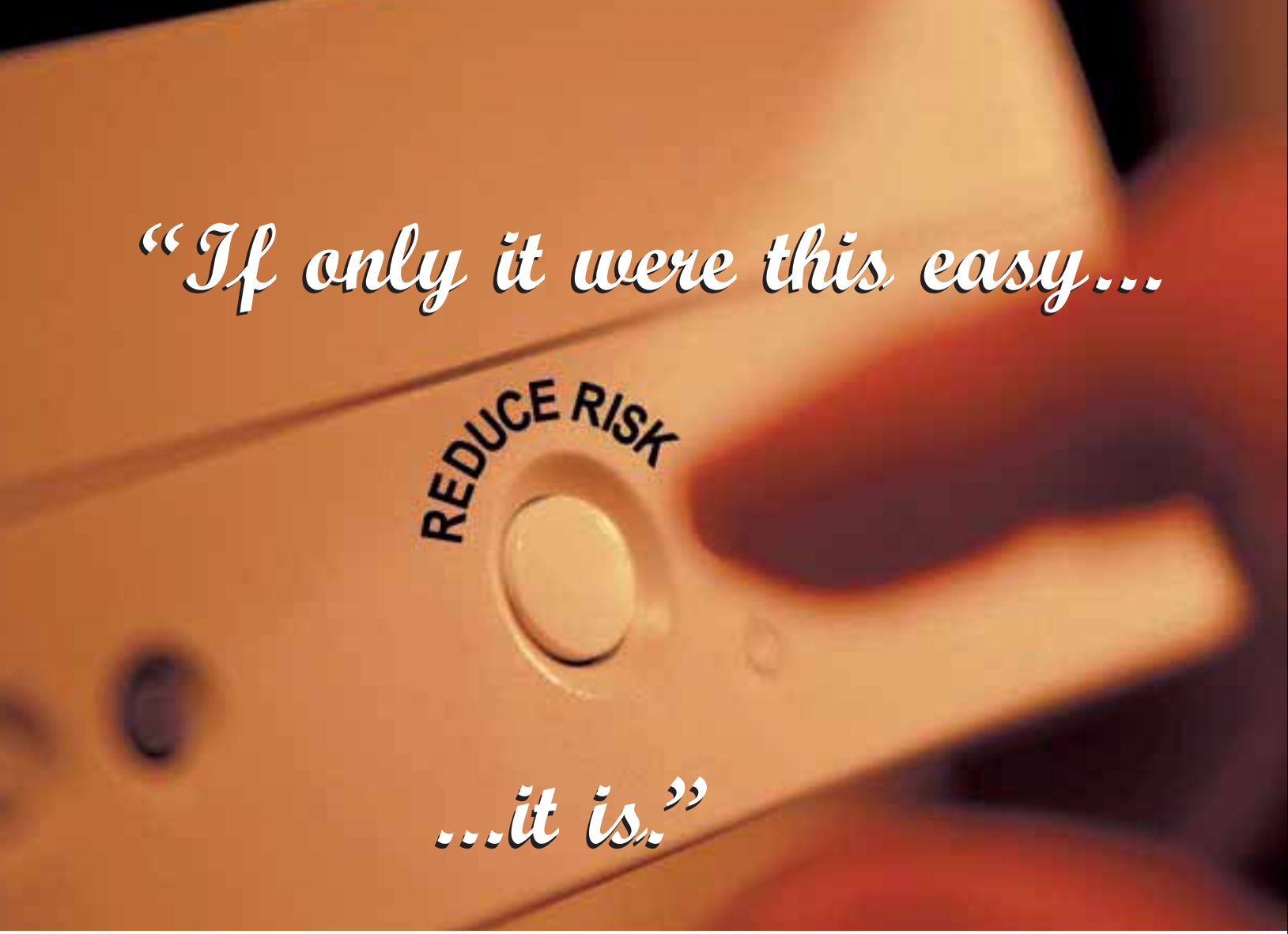
All finalists' programs will be displayed at the conference site, The Ritz Carlton, New Orleans, on May 19-21, 2008. Winners will be chosen by vote of the trainers attending the 2008 PDA Biennial Training Conference. Finalists selected to display at the conference are required to pay the full registration fee.

Recognition Ceremony

Finalists will be recognized and the winners announced on the final day of the Conference, May 21, 2008.

Questions about the Award

Please address all questions to: Jason Brown, Coordinator, Programs and Meetings, PDA
+1 (301) 656-5900, ext. 131 or brown@pda.org.



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