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PDA Letter

Volume XLIII • Issue #7

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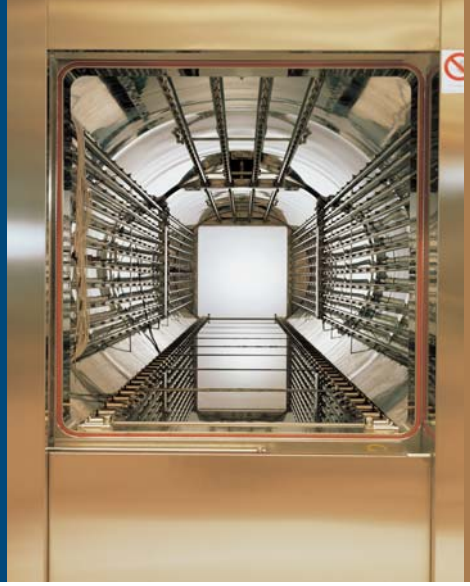

July/August 2007

In This Issue…

What Am I?

If you can successfully identify this issue's cover art (top right of this page) and send us your answer by September 30, 2007 (emails only), you will be entered into a drawing to win a free 1-year membership renewal. Send us your guesses at: lettercontest@pda.org. For more details, turn to page 4.

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New TR-1 Correlates Physical and Bio Principles of Steam Sterilization

Document Revises PDA's Flagship 1978 Technical Monograph

Walter Morris, PDA

For the first time, both the physical and microbiological sciences for steam sterilization cycles are addressed in one reference document for manufacturers and regulators looking to develop or asses a sterilization program—PDA's Technical Report No. 1 (Revised 2007), *Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control.* This document revises PDA's flagship Technical Monograph No. 1, *Validation of Steam Sterilization Cycles* (1978), the first expert pharmaceutical industry reference manual produced by a task force of volunteer PDA members.

There are two general scientific elements to the validation of moist heat sterilization processes, one on the physical characteristics of the steam, temperature and pressure relationships and the other on the biological characteristics of bioburden and bioindicators. While both the physical and biological sciences are essential tools in the development of a moist heat sterilization cycle, the biological aspect has traditionally been the primary focus of many U.S. companies. Companies operating in/for the European marketplace, on the other hand, have placed more emphasis on the physical and steam quality aspects when validating a steam sterilization cycle. The two sciences complement each other and are included in a synergistic fashion in this technical report.

The 2007 edition includes newly added Chapter 3, "Sterilization Science," which describes essential scientific tools used for the design, development and qualification of sterilization cycles. This chapter provides a user-friendly overview of sterilization models, process indicators and thermal science and steam quality. Loaded with this information, the document outlines an approach that is scientifically sound and up-to-date and able to help firms meet the regulatory requirements in all major pharmaceutical markets.

At a June 26-27 workshop in Chicago to publicly introduce the new technical report, task force contributors (see page 24 for a complete list of contributors to TR-1) discussed how the merging of the two sciences broadens the document's usefulness to regions beyond North America and commented on the challenges this effort entailed.

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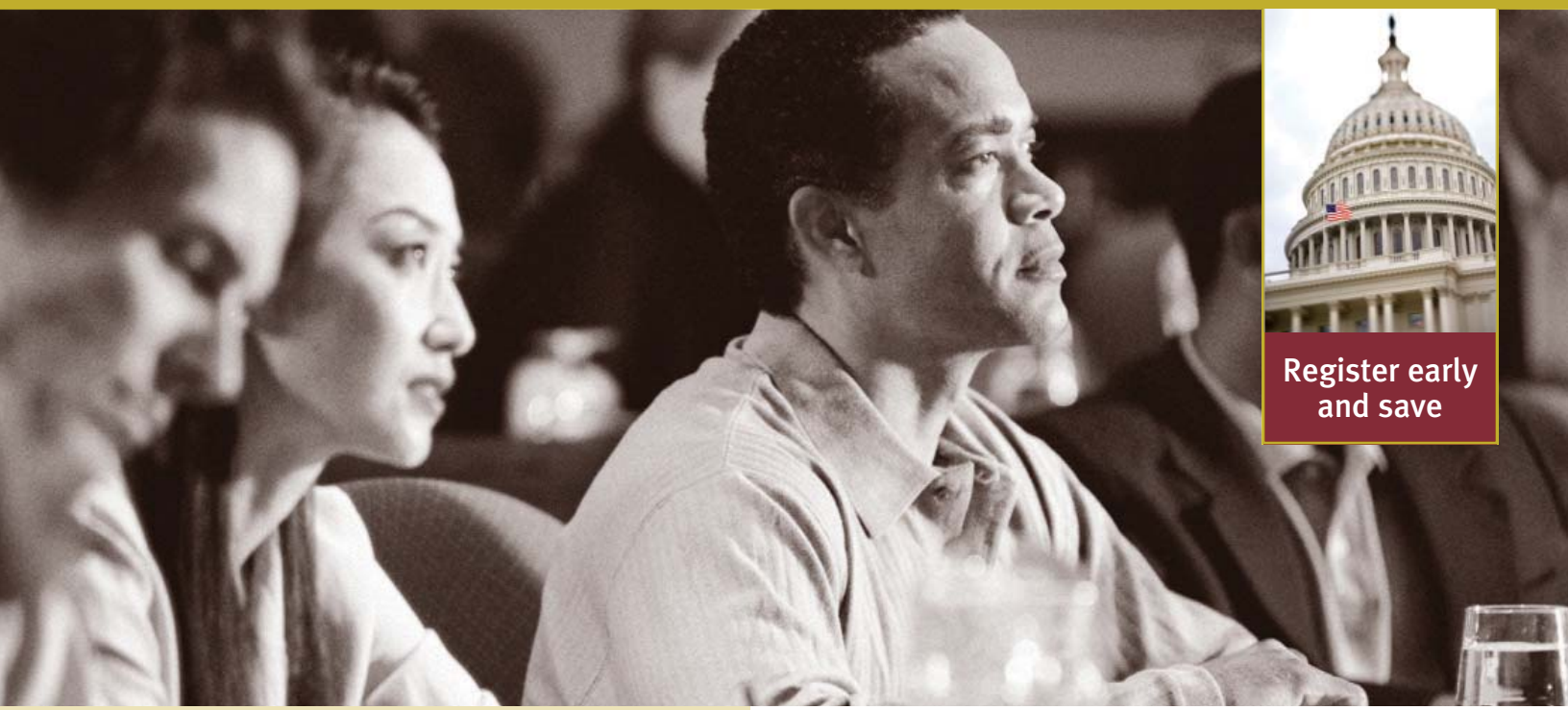
2007

PDA/FDA Joint Regulatory Conference



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Editor's Message

Both PDA and the industry have evolved since we published our technical monograph on steam sterilization; yet, one thing remains the same: the need for sound scientific principles to operate in this industry and to meet the regulations. TR-1 (Revised 2007) updates the original technical monograph with an infusion of the scientific information manufacturers need to design, develop, control and operate steam sterilization cycles. The cover story of this edition of the *PDA Letter* provides a preview of some of the new science contained in this recently published document.

The need for strong guidance in the area of steam sterilization is evident by the number of Sci-Tech Discussions threads on this issue over the last half year. We happily present three of these discussions to you in this issue (page 15).

The Quality and Regulatory Affairs section includes an article on PDA's view of the EMEA Guideline on Residues of Metal Catalysts (page 26)—we thank Sue Schniepp for the contribution. Jim Lyda's series on European regulatory authorities continues with "Know Your Regulators: EMEA Inspections Sector" (page 31).

In Membership Resources, Assistant Editor Lindsay Donofrio shares her "Tales of the Trail"—a recap of her visits to chapter events in the first half of 2007 (page 34). Lindsay also contributes a review of the TRI course "Preparing for and Managing FDA Inspections" from the March Annual Meeting (page 54). Programs and Meetings includes a "Faces and Places" for our spring meetings (page 53).

Finally, this edition is the PDA/FDA Joint Regulatory Conference show issue; see the front cover for a listing of articles about the event. In addition, you can reference the table-top numbers of those advertisers who will be exhibiting at the conference; be sure to visit them as a "thank you" for supporting PDA and the *PDA Letter*.

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

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June Top 10 Bestsellers

From the PDA Publications Store:

Environmental Monitoring:

A Comprehensive Handbook, Volume I, Volume II, and Protocol CD
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Describes methods for developing and operating an appropriate, sustainable microbiological program both in the lab and during production. Numerous useful protocols are included on CD. Published 2005.

Item No. 17239 PDA Member $530 Nonmember $659

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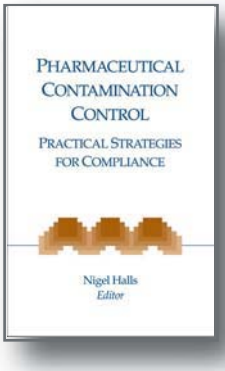

Pharmaceutical Contamination Control
Edited by Nigel Halls
Item: No.17246
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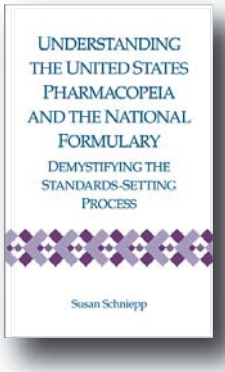
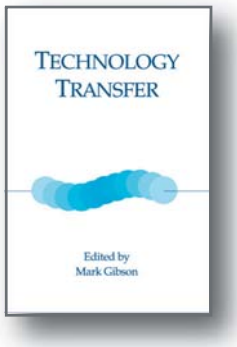
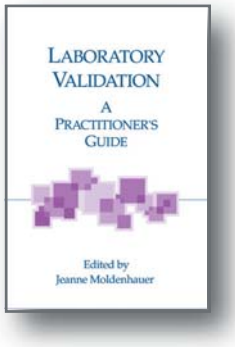


Understanding the United States Pharmacopeia and National Formulary
By Susan Schniepp
Item: No.17250
PDA Member:$240
Nonmember:$299



Technology Transfer
By Mark Gibson
Item: No.17218
PDA Member:$240
Nonmember:$299



Laboratory Validation
Edited by Jeanne Moldenhauer
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1. Environmental Monitoring: A Comprehensive Handbook, Volume 1, II, Protocol CD
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   Item No. 17239, PDA Member $530, Nonmember $659
2. Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
   By James L. Vesper
   Item No. 17219, PDA Member $235, Nonmember $289
3. PDA Archive on CD-ROM – PDA Archive Retrieval Index
   Item No. 01101, PDA Member $395, Nonmember $590
4. Encyclopedia of Rapid Microbiological Methods, Volume I, II and III
   Edited by Michael J. Miller, PhD
   Item No. 17252, PDA Member $730, Nonmember $899
5. Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies
   By Stephan O. Krause, PhD
   Item No. 17264, PDA Member $255, Nonmember $315
6. Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing
   By Destin A. LeBlanc
   Item No. 17253, PDA Member $240, Nonmember $299
7. Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 "The Orange Guide"- Book & CD-ROM Package
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8. Confronting Variability: A Framework for Risk Assessment
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   Item No. 17244, PDA Member, $255, Nonmember $319
9. Systems Based Inspection for Pharmaceutical Manufacturers
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17243, PDA Member $255, Nonmember $319
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    By Siegfried Schmitt, PhD
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New TRI Facility Debuts First Course

Beginning on Monday, July 2, the PDA Training and Research Institute (TRI) will be at a new location in downtown Bethesda, Md. The new location will feature a state-of-the-art facility with an aseptic processing suite, two microbiology laboratories, a biotechnology laboratory, classrooms and student areas.

On August 2, TRI will host its first course at the new facility—"Environmental Mycology Identification Workshop." Pictured to the right is one of the micro labs in the final weeks of preparation for the class.

Come visit TRI at its new location!

The microbiology lab on July 2 (to left) and on July 16 (above).

PDA Member News: Joerg Neuhaus, Kris Evans Join Private Sector

After more than 14 years as an inspector at the Regierungsbehörde Cologne in Germany, longtime PDA member **Joerg Neuhaus,** PhD, is leaving to join a well-known European consulting firm.

Neuhaus has been a strong contributor to PDA conferences both in the United States and Europe for many years. He has served as a speaker or trainer at many PDA meetings.

Neuhaus has experience in aseptic production, medical devices and blood products. His sense of humor, expertise and practical approach to auditing and assessing GMPs make him an interesting partner for discussions.

In response to our congratulations on his new career, Neuhaus said, "I am committed to continuing my contributions to PDA activities as I have in the past."

Kris Evans has joined Amgen after a 20-year career with the U.S. Public Health Service, much of which was with the U.S. FDA.

During that time, he has spoken at numerous PDA conferences. In recent years, he participated in PDA training on the 2004 FDA Aseptic Processing guidance.

Over the last 18 months, Evans spent a great deal of time volunteering to help PDA complete TR-1. He traveled to feedback sessions in Europe and the United States, and participated on several teleconferences. He reviewed and commented extensively on the document's content. About the experience, Evans commented: "I thoroughly enjoyed working on the task force. As I look back on my public health career, which was principally focused on sterile drug policy and compliance, I would say completing the report was one of the accomplishments I am most proud of."

We wish Joerg and Kris all the very best in their new roles.

Joerg Neuhaus, PhD

Kris Evans

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October 17, 2007

Contact Jessica Petree, Manager, Lecture Education, +1 (301) 656-5900 x151

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November 13, 2007

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November 13-15, 2007

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November, 14-15 2007

Development of Qualification and Validation Protocols - A Risk Management Approach
November 15, 2007

Contact Jessica Petree, Manager, Lecture Education, +1 (301) 656-5900 x151.

Science & Technology *Snapshot*

TR-1 Model Adopted for All PDA Tech Reports

Rich Levy, PhD, PDA

In order to resolve some of the most challenging issues in completing Technical Report No. 1, task force members and I returned to the philosophy that soliciting comments from our membership is a very important element of the process of generating consensus documents.

Even though PDA forms task forces of 10-20 individuals, sometimes more, to develop and draft our technical reports, the group working on TR-1 over the last 14 months saw the value of much broader participation. So, we developed a number of tools to solicit comments from PDA members, and each proved very valuable and successful in its own way.

The feedback and review process on TR-1 was extensive. It included four face-to-face feedback sessions with members and an online reviewing tool. Regarding the former, certain members of the task force met with members and other stakeholders three separate times in Europe during 2006. Last summer, we sponsored one in Ireland, one in the United Kingdom and one in Italy. We also had two in North America. We were very, very diligent in going back and reviewing comments. We either recorded or carefully noted all of the feedback from the live sessions.

We also developed a brand new online review tool for this technical report. Stakeholders were able to actually download the draft of the document and then, either online or offline, make comments and propose edits. This tool, like the live feedback sessions, generated a healthy dialogue about the document.

The success of this new feedback model is evident by the fact that regulators from Europe and North America contributed to the document. So successful was this process, that we are continuing it with all of our future technical reports. In the "Technical Report Watch" below, you will see which TRs are

continued on page 12

Technical Report *Watch*

In Global Review: *Drafts of the following TRs are under review by the global PDA membership. To learn how to comment on any one of the drafts, contact Genevieve Lovitt-Wood at glovitt@mindspring.com.*

- **TR-14 (Revised 2007),** ***Validation of Column-Based Separation Processes***
- **TR-15 (Revised 2007),** ***Validation of Tangential Flow Filtration in a Biopharmaceutical Application***
- ***Reprocessing of Biopharmaceuticals***
- ***Aseptic Processing Risk Management***

In Edit: *After global review, task forces responsible for the TRs consider the feedback received. TRs then undergo final technical editing.*

- **TR-26 (Revised 2007),** ***Sterilizing Filtration of Liquids***
- ***Biological Indicators for Sporicidal Gassing Processes: Specification, Manufacture, Control and Use***

In Board Review: *Following technical editing, TRs are reviewed by PDA's advisory boards (SAB, BioAB). If/when approved, the PDA Board of Directors (BoD) makes the final decision to publish or not publish the document as an official PDA TR.*

- ***Filtration of Liquids Using Cellulose-Based Depth Filters*** (BoD ballot)

In Production: *Once approval is achieved, TRs are formatted, printed and sent to members, typically packaged with the PDA Journal.*

- **TR-39 (Revised 2007),** ***Guidance for Temperature-Controlled Medicinal Products***
- **TR-43,** ***Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing***

Journal *Preview*

The July/August PDA Journal has a great line-up of research articles delving into the following areas:

- Materials of construction suitability for aseptic processing environments
- pH- and temperature-sensitive hydrogel nanoparticles
- Leachable accumulation from in-process plastic containers
- Microemulsion for transdermal delivery of terbinafine
- Formulation of procationic liposomes-protamine-DNA (non-viral) complexes
- Parenteral packaging leak testing
- Computational fluid dynamics modeling of isolators
- Sterile filter membrane performance

We also are pleased to announce in this "Journal Preview" the winners of the 2007 Journal Fellowships:

- **Eunjung Jeon,** University of Illinois, for "Parenteral Delivery of Peptides Using Micelle"
- **Hari Desu,** University of Tennessee, for "Development and Stabilization of Methylprednisolone

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Task Force *Corner*

TR-1 Companion Task Forces

The following Task Forces are working on companion documents to TR-1 (Revised 2007) and are holding face-to-face meetings at the 2007 PDA/FDA Joint Regulatory Conference. Each is internationally diverse, with representation from Europe and North America and, in some cases, Asia and South America.

- **Moist Heat Sterilizer Systems Technical Report Task Force** held its first teleconference on June 28. The technical report will cover IQ and OQ activities that precede PQ in the life cycle of moist heat sterilization. **Christopher Smalley,** PhD, Wyeth, will chair this global group, with participants from North America, Europe, South America and Southeast Asia.
- **Steam in Place Technical Report Task Force** will hold its first face-to-face meeting at the PDA/FDA conference with the intent of developing the scope of the technical report. The Task Force is chaired by **Kevin Trupp,** Hospira.
- **TR-30 (Revision), Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat Task Force** commenced via teleconference on May 21. The team leaders will use the PDA/FDA

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Leadership *Opportunities*

The PDA Analytical Method Validation for Biotechnology Products Task Force, chaired by **Nadine Ritter,** PhD, Biologics Consulting Group, and **Gautam Maitra,** Head of Regulatory Affairs, AC Immune, Switzerland, seeks biotechnology product analytical test method experts to actively participate in the implementation of a technical report affiliated with this new and developing task force. The emphasis will be on method prequalification work, method specificity and method robustness. Examples used in the technical report could include gel electrophoresis, size exclusion chromatography and immunoassay methods.

The leaders are seeking EU and U.S. representation as they develop the task force to address the components of adequate and appropriate test method development and documentation for biotech products.

For more information or to volunteer, please contact **Iris D. Rice,** Executive Coordinator, Scientific and Regulatory Affairs, at rice@pda.org.

Sci-Tech *Trends*

Combining Aseptic Fill with Terminal Autoclave Moist Heat Sterilization

The following dialogue is about using moist heat sterilization in conjunction with aseptic processing for heat sensitive products. The questions were raised at PDA's Technical Report No. 1 (Revised 2007) workshop. Technical Report No. 1 task force members, **Rich Levy,** PhD, PDA, and **Michael Sadowski,** Baxter Healthcare, moderated the dialogue from the podium. Only Levy's and Sadowski's comments are attributed below.

Sadowski: I think the question is, 'If you have an aseptic process that has been qualified and then you are going to follow that up with a terminal sterilization process at the end, what is the purpose of that?' I see that as potentially reducing the risk of contamination versus using aseptic processing alone. Obviously you have a certain probability [of contamination] that is associated with the aseptic process, and then if you apply

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TR-1 Model Adopted for All PDA Tech Reports, continued from page 10

currently undergoing review. We will also announce that a review period has opened at www.pda.org, where interested participants can link to the online review tool. Live feedback sessions will be announced in the "Task Force Corner" (page 11) and on the PDA website. These sessions might be stand-alone meetings or part of a larger PDA or PDA Chapter event.

To help engage interested reviewers, we encourage you to send PDA your name and your areas of interest/expertise. In "Leadership Opportunities" (page 11), we will periodically announce which documents we are seeking reviewers for in the near future. If you want to sign up to review one or more of the documents, you can follow the instructions and join our list.

We are trying to make sure we have broad-based participation in the development of our technical reports. These tools will help us achieve this goal and improve the quality and applicability of our technical reports.

Sci-Tech Trends, continued from page 11

a terminal process to that, typically to a 10^{-6} SAL, you now have put a significant safety factor onto that to where you have much greater control over the risk of that product.

Audience Member 1: A lot of people are not doing the full 10^{-6} autoclaving, so it is like an adjunct. They start with zero and then add on an autoclave cycle. So sometimes I can reduce the amount of heat that I have to input to a product that may be marginally heat sensitive.

Sadowski: What SAL are they going for then?

Audience Member 1: Either three or four in the autoclave…just log reduction.

Sadowski: Typically, what I've seen there is by performing the aseptic process up front, that allows you to make some less conservative assumptions around your product bioburden. So in the end, rather than assuming the bioburden *D*-value is one minute, like you might do with the overkill approach, you might be able to say that the product bioburden population is going be 10^{0}, with a *D*-value that is less than 1.0 minute, provided you characterize your bioburden, and that allows you to use indicators other than *Geobacillus stearothermophilus* or potentially a reduced challenge to demonstrate that SAL.

Audience Member 1: It just allows you to use products that have some heat sensitivity in an autoclave to get the sterility assurance greater than what you can get with the aseptic alone.

Levy: Sounds like the discussion has continued for a long time now, hasn't really changed. I think to your point that is something we should talk about. Another technical forum or maybe even a technical brief on that would be a good idea.

Audience Member 2: Isn't it a requirement to demonstrate an SAL of at least 10^{-6} in final container sterilization?

Sadowski: It is if you are going to utilize a terminal sterilization approach. Obviously, if you are going to use aseptic, the rules are different.

Audience Member 2: Aseptic processing, you use the media fills, you are only qualifying basically an SAL of 10^{-3}. You cannot have any more than one positive in a media fill in 5,000 units, I believe. So same situation on top of our aseptic processing requalification twice a year, which is really our environment, our gown recertification, our techniques under the class 100 hood, all that combined show an SAL of 10^{-3}. But on top of that we assume we have to show 10^{-6}, and you cannot add them together if you have to say 10^{-9}, you separate the two.

Task Force Corner, continued from page 11

conference as an opportunity to develop the scope of this revision effort. A full Task Force meeting will take place at PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology in October. The Task Force chair is **Michael Sadowski**, Baxter Healthcare.

- **TR-3 (Revision), *Dry Heat Sterilization and Depyrogenation* Task Force** is busily drafting this technical report following their first meeting on May 9. They will be reviewing a draft during their face-to-face meeting at the PDA/FDA conference in September. The Task Force co-chairs are **Debbie Havlick,** Hospira and **Peter Lee,** Amgen.

Sadowski: That is a great point there. It allows you to make assumptions about the bioburden, but can you really make an assumption that is beyond the technical detection limit for bioburden, is really the question. That brings up a question for the group: Can you start off with a -3 SAL (from aseptic processing) and by adding six log reductions to that achieve a -9 SAL, or can you start off with a -3, add 3 log reductions to that and get to a -6 SAL? ➤

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Audience Member 3: You cannot do that. They are not added. This came up early on, if people remember, FDA put out an aseptic/thermal policy at one time that went nowhere. That was part of that discussion, and that issue was because aseptic processing is a contamination rate and terminal sterilization is a probability of nonsterility of each individual unit, bottle. So you cannot add them because they are not the same thing.

Sadowski: It is two different modes—one of them really is restriction or filtration and the other one is obviously the incorporation of a lethal agent and its associated inactivation.

Audience Member 3: Right, so I think one of the things is, yes, 10^{-6} as you said you were doing terminal sterilization. But the other side of that coin is, if you said that you had a product, while I can give it 10^{-3} terminal on top of aseptic, or the alternative is I can do the whole thing aseptic with no terminal. I think that is where we start to get into that grey zone between those two. And I think from FDA's viewpoint, at least they would like to see the terminal, a better process. It is making those kind of arguments on those products that are falling in between that says we can give them a little bit of heat, but we cannot give them a 6 log reduction amount of heat. But I can give it 10^{-3}, and we'll be okay….I think that is your argument, 'well you have a choice I can do either 10^{-3} terminal or I can do the whole thing aseptic.' And that would be your argument.

Sadowski: There is one other benefit that isn't pointed out very often when you talk about this subject, and that is most folks are performing a sterility test to release that product whether it is aseptic or terminal—for those that aren't doing parametric release. One of the benefits of using terminal sterilization after aseptic is that when you take a look at the types of contaminants you get for false-positive sterility tests, they are normally skin organisms with very low moist heat resistance values. So by taking a look at a sterility test that turned positive and characterizing the resistance of the organism that was present for that positive and you compare its resistance level to the moist heat process that you run in the terminal process, that gives you something additional to consider for your investigation and potentially in dispositioning that lot.

Levy: So do you see this practice primarily in Europe where the EMEA's decision tree pushed the industry towards terminal sterilization? I mean do you see some of that same influence causing industry to consider adding adjunct heat treatments to aseptic processing to improve its SAL?

Audience Member 4: I haven't seen it that much in Europe. They've kind of have a more rigid thing. For them 15 minutes at 121°C it is sterile no matter what.

Sadowski: They require 15 F_0, if you can't do that, go to 8, and if you can't do that go to aseptic. But I haven't seen anything recognized officially in Europe regarding polishing or adjunct processing. But I know there are folks out there doing it.

Audience Member 4: Yeah, I mean there has been a huge reluctance, only a few people have even entered that sort of thing. Just from a regulatory sense everybody is kind of either put in one block or the other as being a rigid type philosophy. But I know discussions have gone on, and I know they are open to discuss it, just as they were for parametric.

Audience Member 3: Really if you were to take a look at it, if there was a candidate for parametric release as far as safety goes, it certainly would be this combination of aseptic followed by terminal.

Audience Member 5: I'm just trying to understand the scenario where you would use both. If you have a heat sensitive product that cannot take the whole 15, you are allowed to make it aseptically. Obviously there would be an advantage if you could heat it a little bit. Would we choose to do that because of the cost? I'm not sure.

Sadowski: There are companies that I'm aware of out there that are using aseptic processing followed but what they call a polishing process which can be as low as 2 or 3 F_0,and again they are running at lower temperatures. I've seen them as low as 108°C. A lot of that has to do with the container that they are filling into. It is the container that is actually sensitive to heat. And I've seen companies who are using aseptic processing followed by terminal overkill, and I'm talking extreme overkill….but there are groups on both ends of the spectrum out there.

Journal Preview, continued from page 11

Sodium Succiante Loaded RGD-Peptide Chjugated Fluorescent Liposomes by Lyophilization"

- **Janjira Intra,** University of Iowa, for "Formulation Studies to Optimize Efficacy of Non-Viral Gene Delivery Vectors"
- **Archana Rawat,** University of Connecticut, for "Effect of Ethanol as a Co-Solvent on the Properties of Parenteral Microspheres"

We thank all applicants for their high-quality submissions.

Recent Sci-Tech Discussions: ASTM vs. HTM 2010, Temp Limit for Sterilization and Sterilization Cycle Times

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.

ASTM vs. HTM 2010

For validation of sterilizer, HTM [High Temperature Material] 2010 is a guidance which covers exhaustive points for the same. Is there any guidance provided by the ASTM [American Standards for Testing Materials] regarding the same? If it is there, can anyone provide the appropriate link/web address for the guidance given? As we are not members of ASTM, the standards/guidance part is not accessible to us. Please send me the same on my ID, if feasible.

Respondent 1: Standards are copyright. You have to pay to access them.

Respondent 2: I believe certain parts of HTM 2010 got adapted into EN 285 (example, steam quality testing). We refer to that rather than HTM 2010. Check the European Committee for Standardization website, which should direct you to national standards organizations in different European countries. You should be able to purchase it from one of those.
http://www.cenorm.be/cenorm/index.htm

Respondent 3: HTM 2010 is not mandatory in Europe. In fact the Medicines and Healthcare Regulatory Agency (MHRA) stated at a meeting I attended (last summer) that it has no regulatory significance whatsoever. Industry should use appropriate EN or ISO standards.

Respondent 4: While HTM 2010 and its forthcoming replacement HTM 01-01 may have no statutory significance for pharmaceuticals, it is very important for medical devices and other products supplied to the UK National Health Service (NHS), and indeed within the NHS itself. It would be interesting to know which part of the MHRA considers that these documents have no significance.

Respondent 5: I tend to disagree with previous contribution about this topic, as the USP in April 2006 added a monograph for pure steam.

When looking at the new USP monograph for pure steam, this monograph states that: "The level of steam saturation or dryness and the amount of non-condensable gasses are to be determined by the pure steam application."

This means that pharmaceutical manufacturing companies in the United States cannot "avoid" testing of "sterilization" relevant quality attributes related to pure steam quality. No references are given in USP for suitable methods for testing of these attributes. One might assume that the method described in EN 285 currently is the preferred method.

Any comments are highly appreciated.

Respondent 6: HTM 2010 part 3 has given a guidance value (+/-) for temperature recording and measuring devices used during the validation of sterilizer chamber. Shall we use this guidance to carry out validation to observe changes in temperature profiles of sterilizer chamber?

Temp Limit Criteria during Sterilization

I would like to know if it is necessary to set an upper temperature limit for all probes from the target sterilization temperature during sterilization in an autoclave or SIP run.

Respondent 1: It is usually advisable to set an upper temperature limit. This limit should be based on the characteristics of the materials being sterilized and of the materials used to wrap the sterilized materials.

Respondent 2: Talking of autoclaves and from a European perspective, there is EN 285 which sets certain criteria regarding temperature. By memory, the temperature range for sterilization is between sterilization temperature and + 3°C with an overall measurement range of 50-150°C. I don't know what others have done (and look forward to hearing from other participants), but in our case the upper temperature criterion is based on EN 285. We also bear in mind the upper temperature calibration point of the temperature probe and the design specification of the equipment in question. We also used this for our SIP bioreactors where the temperature probe's upper calibration point is 130°C (the system's design temperature is higher than this). For SIP, if I used 123°C, then following EN 285, I would use <126°C as an upper value. Based on the upper calibration point I would use <130°C, so the EN 285-based value would be okay.

Questioner: Thanks for the comments. My company doesn't apply the EN285 and uses min F_0 as the criterion. I was wondering if the upper temperature limit was to control overheated steam (less moist), which may affect the quality of the steam. Thanks.

Sterilization Cycle Times

During the validation of load pattern study (penetration load) in HPHV sterilizers, we have noticed a lag time of about 5.0 minutes for one of the critical load (media load) used for the sterilization. Now my question is, do we have to increase the sterilization time by 5.0 minutes during the normal sterilization cycle, or can we continue with the same time fixed during the cycle development? My concern is that if we increase the time by 5.0 minutes, certain articles may sense more duration of hold time with the set temperature and certain [articles] may not. If we do not increase, certain articles may sense less hold time than the set temperature and set time. Is it acceptable?

Respondent 1: Additional studies are needed on the heat distribution within the chamber of the autoclave to determine where the cold spots are and whether this lag time is actually representative of product heat-up.

Questioner: Thanks for your response. We have carried out the distribution studies and we have identified the drain trap/condensate valve as the cold spot for the selected run. But we are getting the lag time of 5.0 minutes in the penetration load with the probe inserted to the container containing the agar media, and the set temperature of the probe connected to drain trap is achieving earlier to the probe inserted in the agar media. Your suggestion to the above is requested.

Respondent 2: There's no required maximum lag time (equilibration time) from the control to the internal temperature of any liquid filled container. HTM-2010 and its follow-on documents requirements for equilibration do not apply there—[they are] restricted to hard goods.

Respondent 3: During heat distribution, you should check that the cold spot remains the same for all the distribution cycles, which is the objective of distribution study of loaded cycle. While during heat penetration, you should check the cold spot to compensate the lag time according to your required Sterility Assurance Level (SAL).

Ten PDA Interest Groups to Meet at PDA/FDA Conference

As one of PDA's two major recurring meetings, the PDA/FDA Joint Regulatory Conference provides a forum for PDA Interest Groups to gather and discuss issues important to them. Some Interest Groups have a set agenda with speakers; others meet to have a free-flowing dialogue among participants. Interest Group meetings are open to all attendees at the PDA/FDA conference.

We encourage you to attend an Interest Group session. Who knows, you might contribute an idea the results in a future PDA technical report, TRI course or focus meeting!

The following is a list of the Interest Groups meeting with either a brief description of the group's focus to help direct discussion or the planned agenda. The leader of each IG session is also indicated. [Note: To learn when and where each IG is meeting, go to www.pda.org/pdafda2007.]

Facilities and Engineering Interest Group

Chris Smalley, PhD, Director, Compliance Operations, Wyeth Pharmaceuticals

The Facilities and Engineering Interest Group provides a forum for the discussion of topics and interests related to the design, construction, operation and maintenance of the production and research facilities used for GMP and GLP purposes. For the 2007 PDA/FDA Joint Regulatory Conference, the group will be a forum for the presentation of the current draft of a new technical report entitled *Sterilizer Systems.* This technical report will address the design, specification, commissioning and IQ/OQ of sterilizers, complementing Technical Report No. 1. Those attending the Facilities and Engineering Interest Group session will have the opportunity to hear about this draft and submit comments.

Filtration Interest Group

Russ Madsen, President, The Williamsburg Group

At this session, the Filtration Interest Group participants will have an opportunity to review and analyze revisions to PDA Technical Report No. 26, *Sterilizing Filtration of Liquids.* Task Force co-chairs **Maurice Phelan**, Director, Regulatory, Millipore, and **Paul Stinavage**, PhD, Senior Manager, Global Quality Technical Service, Pfizer, will present the draft and answer Interest Group questions.

Biotech Interest Group

Jill Myers, PhD, President, BioPro Consulting

The Biotechnology Interest Group provides a forum for technological, regulatory and educational discussions with the challenges facing the biotechnology sector of the industry, including use of recombinant organisms, novel biochemical, technological and regulatory approaches in bringing biotechnology-based products to the public.

Combination Products Interest Group

Michael Gross, PhD, Vice President, Regulatory Affairs, Cardiome Pharma Corporation

This Interest Group provides a forum for discussion of topical issues concerning submissions and compliance matters related to a variety of combination product types with emphasis on drug delivery devices and functional pharmaceutical packaging. The format of the Combination Products Interest Group meetings includes open discussions of hot topics and formal presentations by industry and government experts on a variety of topical combination product quality and regulatory issues.

Visual Inspection of Parenterals Interest Group

John Shabushnig, PhD, Senior Manager, Global Quality Technology Services, Pfizer

The Visual Inspection of Parenterals Interest Group provides a forum to discuss topics related to the visual inspection of injectable products. Past topics have included selection and qualification of human inspectors, validation of automated inspection systems, recent regulatory activity and country-specific inspection requirements. This group has also initiated activities to survey industry inspection practices, organize special meetings on visual inspection and to provide scientific guidance on compendial requirements for the inspection of injectable products.

Process Validation Interest Group

Hal Baseman, Chief Operating Officer, ValSource

The Process Validation Interest Group provides an ongoing forum for the exchange and dissemination of information and ideas for the purpose of education, innovation and compliance related to the validation of critical processes and those activities that support the validation of critical processes. The Interest Group is a forum for presenting and discussing issues and trends in validation.

Inspection Trends/Regulatory Affairs Interest Group

Robert Dana, Vice President, Quality and Regulatory Affairs, PDA

The Inspection Trends/Regulatory Affairs Interest Group provides a forum for sharing experiences and knowledge in the subject areas. Historically, most interest was in the area of inspection trends. Meeting format varies from

panel discussions featuring industry and FDA participants, podium presentations on inspection-related activities and programs and an open forum for questions and answers relative to company experiences with government inspections. Data on current inspection findings and trends are presented, as well as discussions on new regulatory and compliance initiatives.

Lyophilization Interest Group

Ed Trappler, President, Lyophilization Technology

This Interest Group provides an open forum for discussions on current topics, which are identified at the onset of the meeting by participants. This provides a unique opportunity to learn from a variety of experiences and perspectives and provides an excellent benchmark for current industry practices.

Clinical Trial Materials Interest Group

Vince Mathews, QA Consultant, Eli Lilly

The Clinical Trial Materials Interest Group offers members an opportunity to discuss topics of interest associated with the development and manufacture of clinical supplies. This includes the preclinical phase (involving pharmaceutical development operations), the manufacture of all phases of clinical supplies (including both API and drug product), and the ultimate transfer of the manufacturing process to the commercial manufacturing site.+ This group offers a valuable opportunity to interact with professionals and regulators alike, to share ideas, discuss opinions and offer advice to each other in this very complex area of the pharmaceutical business.

Pharmaceutical Water Systems Interest Group

Ted Meltzer, PhD, Consultant, Capitola Consulting Company

Quality Systems Interest Group

David Mayorga, President, Global Quality Assurance

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/interestgroups for more information.

North American Interest Groups

Section Leader	Frank Kohn, PhD *FSK Associates*	David Hussong, PhD *U.S. FDA*	Don Elinski *Lachman Consultants*	Sandeep Nema, PhD *Pfizer Inc.*	Robert Dana *PDA*
Section Title	**Biopharmaceutical Sciences**	**Laboratory and Microbiological Sciences**	**Manufacturing Sciences**	**Pharmaceutical Development**	**Quality Systems and Regulatory Affairs**
Related IGs and Group Leaders	**Biotechnology** Group Leader: Jill A. Myers, PhD *BioPro Consulting* Email: jmyers@bioproconsulting.com **Lyophilization** Group Leader: Edward H. Trappler *Lyophilization Technology* Email: etrappler@lyo-t.com **Vaccines** Group Leader: Frank S. Kohn, PhD *FSK Associates Inc.* Email: fsk@iowatelecom.net	**Analytical Labs/ Stability** Group Leader: Rafik H. Bishara, PhD Email: rafikbishara2@yahoo.com **Microbiology/ Environmental Monitoring** Group Leader: Jeanne E. Moldenhauer, PhD *Excellent Pharma Consulting* Email: jeannemoldenhauer@yahoo.com **Visual Inspection of Parenterals** Group Leader: John G. Shabushnig, PhD *Pfizer Inc.* Email: john.g.shabushnig@pfizer.com	**Facilities and Engineering** Group Leader: Christopher J. Smalley, PhD *Wyeth Pharma* Email: smallec2@lwyeth.com **Filtration** Group Leader: Russell Madsen *The Williamsburg Group, LLC* Email: madsen@thewilliamsburggroup.com **Pharmaceutical Water Systems** Group Leader Theodore H. Meltzer, PhD *Capitola Consulting Co.* Email: theodorehmeltzer@hotmail.com **Sterile Processing** Group Leader: Richard M. Johnson *Fort Dodge Animal Health* Email: johnsor4@fdah.com	**Clinical Trial Materials** Group Leader: Vince L. Mathews *Eli Lilly & Co.* Email: vlm@lilly.com **Combination Products** Group Leader: Michael A. Gross, PhD *Chimera Consulting* Email: michaelgross@novuscom.net **Packaging Science** Group Leader: Edward J. Smith, PhD *Wyeth Pharmaceuticals* Email: smithej@wyeth.com **Process Validation** Group Leader: Harold S. Baseman *ValSource, LLP* Email: halbaseman@adelphia.net	**Inspection Trends/ Regulatory Affairs** Group Leader: Robert L. Dana *PDA* Email: dana@pda.org **Quality Systems** Group Leader: David A. Mayorga *Global Quality Alliance, LLC* Email: david@gqaconsulting.com

European Interest Groups

Related IGs and Group Leaders	**Biotech** Group Leader: Roland Guenther *Novartis Pharma AG* Email: roland.guenther@pharma.novartis.com	**Visual Inspection of Parenterals** Group Leader: Markus Lankers, PhD *Rap.ID GmbH* Email: markus.lankers@rap-id.com	**Filtration** Group Leader: Roger Seiler *Sartorius SA* Email: roger.seiler@sartorius.com **Production and Engineering** Group Leader: Philippe Gomez *Sartorius SA* Email: Philippe.gomez@sartorius.com **Prefilled Syringes** Group Leader: Thomas Schoenknecht, PhD *Bünder Glas GmbH* Email: t.schoenknecht@gerresheimer.com	**Nanotechnology** Group Leader: D F Chowdhury *Aphton BioPharma* Email: Fazc@aol.com **Technology Transfer** Group Leaders: Volker Eck, PhD *PDA* Email: eck@pda.org Zdenka Mrvova *Zentiva* Email: zdenka.mrvova@zentiva.cz

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New TR-1 Correlates Physical and Bio Principles of Steam Sterilization, continued from cover

"One of the challenges in the entire process of this development was to actually make this document applicable to all regulatory areas of the world as much as possible," stated **Rich Levy,** PhD, Senior VP of Scientific and Regulatory Affairs, PDA. "And this took a degree of negotiation and a significant comment period. We wanted to make sure the scientific principles were generally accepted in those geographies more broadly and that they still were scientifically sound based on a review process."

PDA President **Bob Myers** added, "In this particular case, there was a little bit different focus in Europe versus the United States on moist heat sterilization, and I think we were able to accommodate both points of view. You will see in the list of contributors, well-known scientists from industry (United States and European Union), Medicines and Healthcare products Regulatory Agency (MHRA – United Kingdom) and the U.S. FDA. There were strong views on the importance of the various approaches when we began the process, but by early 2007 they were blended into a consensus document. This should be a technical report that can be used just about anywhere in the world."

The document works to harmonize the two scientific viewpoints, according to **Michael Sadowski,** Manager, Sterility Assurance, Baxter Healthcare. "One of the things this document advocates is establishing agreement between both physical and biological sides of things as far as qualification," he said. "And that is really important because the two really need to go hand in hand. You cannot look at one and not the other. In the case of physical, you can think that you have the right temperature on your heat penetration units inside of a porous/hard goods load, but because the thermocouple cannot understand what the steam quality is in that area, you may have a dry heat situation and have drastically different biological results. From a biological standpoint, the same type of thing is true. You want to be able to show that physically you can predict what is going to happen biologically." The two approaches, he said, "really complement each other."

The document recommends establishing a relationship between the physical and biological results.

The document recommends establishing a relationship between the physical and biological results. "There is going to be some variability," explained Sadowski, "but you want to be able to understand why you have differences, if there are significant differences, because there might be a process problem that you are not aware of."

The inclusion of the thermal science/steam quality section was critical to building the international consensus for the document. As the document explains, *understanding the basics of thermal science (thermodynamics) is essential to the design and control of moist heat sterilization.*

The section specifies important properties of the various heating media used that are critical to ensuring the industrial reproduction of the specific temperature-pressure relationship in a saturated steam cycle established during cycle design. Carrying over these relationships in routine production is vital to ensuring effectiveness of the cycle.

The thermodynamics section includes charts depicting the heat capacity of steam, water and steam-air mixtures. These demonstrate that steam and water possess similar heating capacities (on a volume basis); however, steam does not require forced circulation to transfer heat, whereas superheated water does.

The heat delivery rate of steam-air mixtures depends on the ratio of air to steam and the forced circulation of the medium throughout the sterilizer. Steam-air mixtures have a much lower heat capacity per volume than water or steam but still can be effective when properly applied.

The document describes three types of steam that can be used for moist heat sterilization cycles: plant, process and pure. Regarding the latter type, section 3.3.3 covers steam quality testing. Referencing the European Committee for Standardisation's EN 285, "Sterilization – Steam Sterilizers – Large Sterilizers" (1996), the section states:

For sterilization of porous/hard goods, steam quality characteristics should be evaluated as part of the qualification of the steam supplied to the sterilizer; and should be repeated at regular intervals and documented in internal company policy or in accordance with applicable regulatory requirements.

At the Chicago workshop, **Keith Shuttleworth,** Senior Consultant, Keith Shuttleworth & Associates, discussed the thermal dynamics portion of the document. He underscored the need to monitor the quality of the steam when it is used as a sterilant because its physical properties "can have a profound impact on its performance and the performance of the sterilizer." Extended equilibration times, unexplained biological indicator failures, wet loads and excessive temperatures are some of the measurable effects of poor steam quality, he explained. As a heating agent, on the other hand, the physical properties of steam will have little impact on its performance.

The scientific principles in Chapter 3 set the groundwork for the content

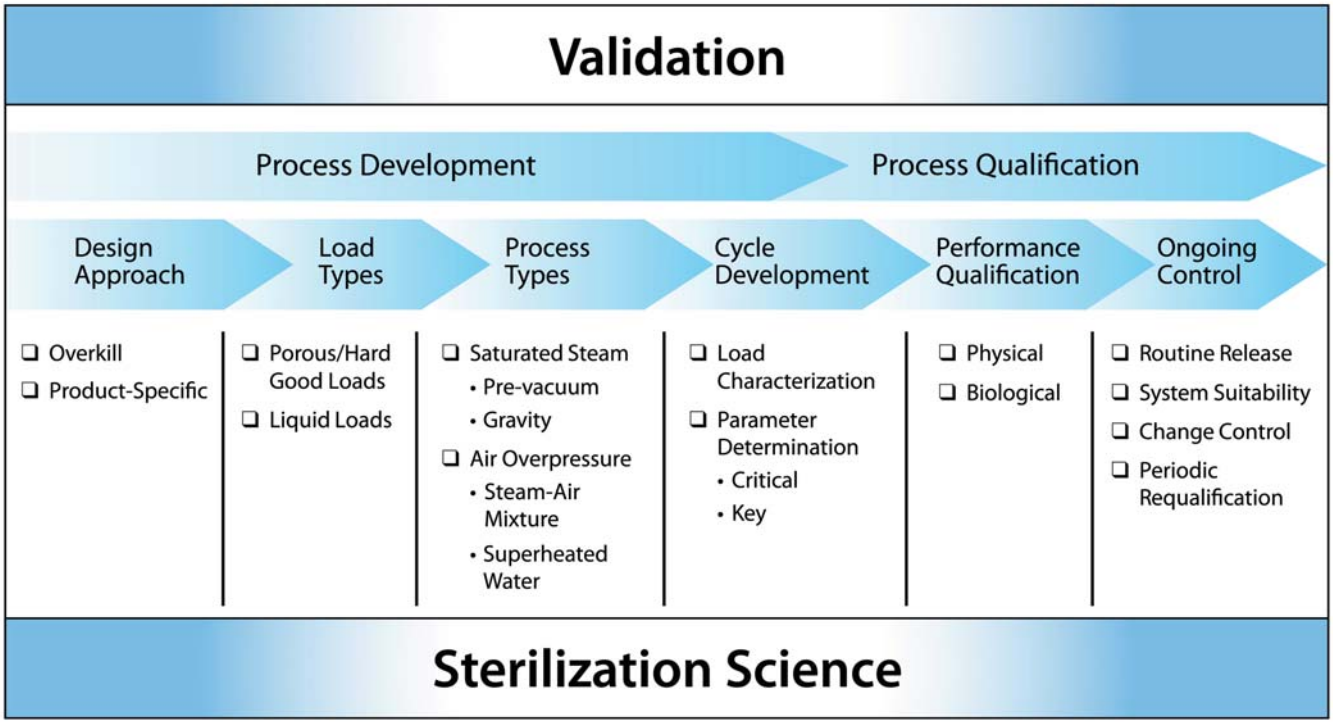

Figure 1: Application of the Science of Sterilization

in the remaining chapters of the technical report, which cover process development and process qualification. Earlier drafts of the document delved into installation qualification (IQ) and operational qualification (OQ), but PDA's Board of Directors decided a year-and-a-half ago to scale back the coverage to keep it more in line with the original 1978 monograph.

In Chicago, Levy noted the addition of a chevron diagram (see figure 1), which provides a visual guide to the process of establishing and qualifying a steam sterilization cycle:

"We tried to go in a life cycle format for the way in which you would go about the validation of a moist heat sterilization process. So we used a chevron diagram, and we set this up in what we thought would be a logical progression of the steps you would take to establish a moist heat sterilization program. We stayed with the original concept of Technical Monograph No. 1, meaning that sterilization was the underpinning, the foundation, and everything we did would have that foundation of sterilization science. The overarching goal was to explore validation. And we divided it roughly into two areas, process development and process qualification. IQ and OQ would be left to another technical report. We then broke this down further into steps we felt people would need to take if they followed best practices to come up with a moist heat sterilization program."

The document outlines best practices but does not establish standards for sterilization validation. It does not always address region-specific regulatory expectations, but provides up-to-date, scientific recommendations for use by industry and regulators.

"That is another key thing to bring up about this document," said Sadowski in Chicago. Throughout a peer-review process that the document was subjected to in 2006 (see "TR-1 Model Adopted for All PDA Tech Reports" in the Science & Technology Snapshot, page 10), he noted that "a lot of folks were asking for us to be very prescriptive on everything from the Z-value of biological indicators, to equilibration time, to you name it. And one of the things we wanted to do again was to present the foundation of science to everybody, so that they had the background to be able to make the appropriate decisions in regards to their sterilization program."

Levy added, "We pride ourselves in having our technical reports be nonprescriptive. They don't tell you, 'you must do these things.' Rather, they really give you insight into best practices, and we wanted to continue that with this document."

While the 2007 revision of TR-1 is intended to be a single-source guide, it includes a comprehensive reference section. Works cited are appropriate and up-to-date scientific publications, international regulatory documents, journal articles, technical papers and books.

In addition, work on Technical Report No. 1 has spurred the revision of several related, existing PDA technical reports and the identification of ➤

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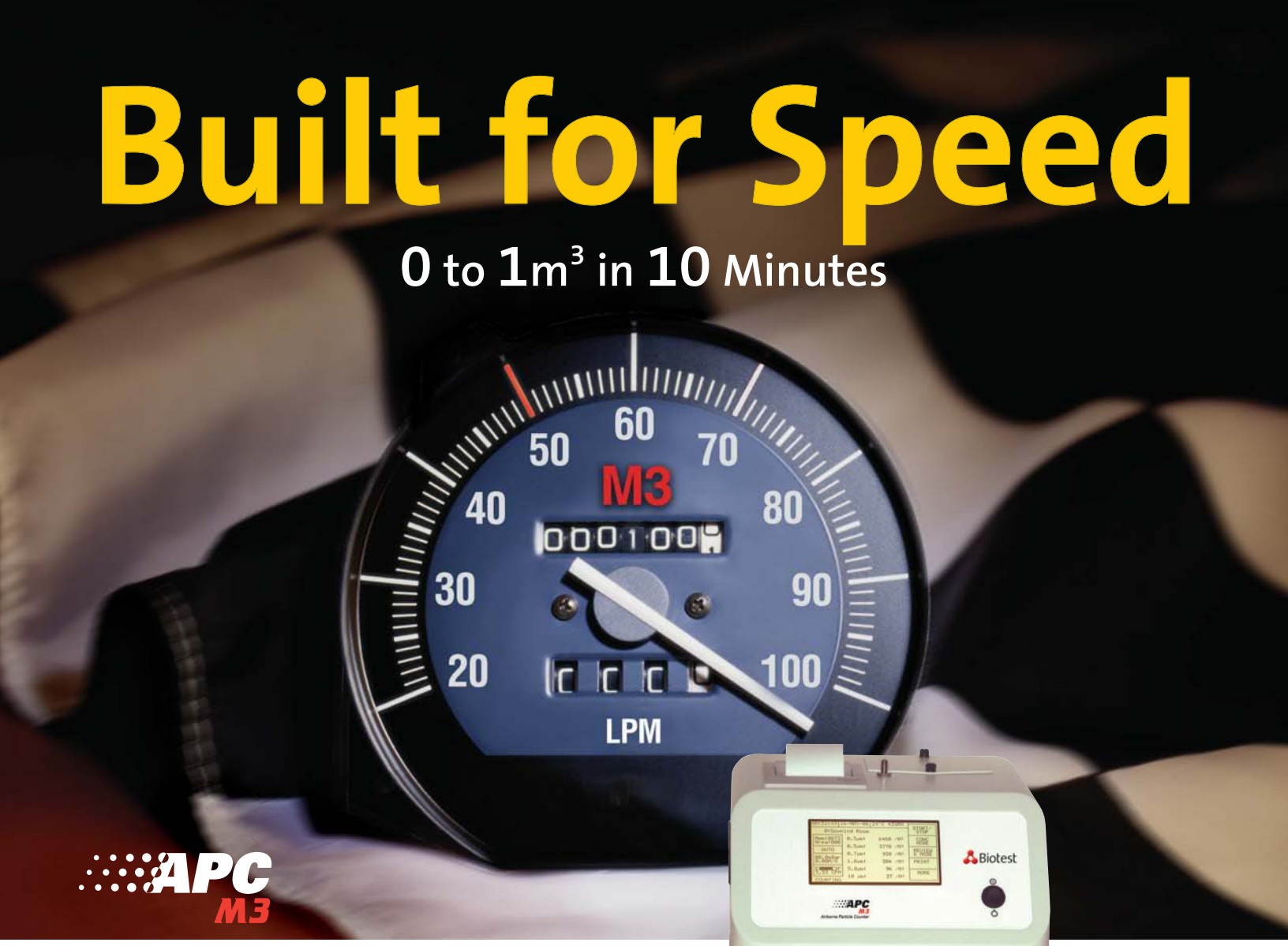

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necessary complementary technical reports. These include:

- Technical Report No. 3 (Revised), *Validation of Dry Heat Processes Used for Sterilization and Depyrogenation*
- Technical Report No. 30 (Revised), *Parametric Release*
- New Technical Report, *Biological Indicators for Sporicidal Gassing Processes: Production, Control and Use*
- New Technical Report, *Steam in Place*
- New Technical Report, *Sterilizer Systems: Design, Commissioning, Operation, Validation and Maintenance*

Several of these projects grew from "a number of the elements dropped off and out of the current Technical Report No. 1 to bring it more in line with the original monograph," stated Levy. "Many people spent quite a bit of time developing the revised TR-1, and we are making sure that we don't lose that good work." The new technical report projects "are all elements that were in varying degrees discussed in some of the earlier drafts."

One dropped topic not to be included in a PDA technical report, Levy noted, is container closure integrity. "We felt that was well-documented and didn't require a technical report. However, that may change in the future."

Furthermore, PDA is publishing the 12th edition of *Microbiology and Engineering Sterilization Processes*, by **Irving Pflug,** PhD, University of Minnesota. Pflug's influential book is referenced a number of times in both the original moist heat sterilization technical monograph and the new technical report. Pflug was recognized as one of the PDA's six outstanding scientists in 2006.

"Irving Pflug brought the science of sterilization to PDA and to the industry from the food industry in about 1977," Myers told workshop attendees in Chicago. "PDA engaged him to educate and train our membership through a series of classes on moist heat sterilization. He has compiled his body of work developed over the years and has recently agreed that we can sell his book to provide users the detailed science of sterilization. It is referenced a number of times in the technical report and justifies much of the science applied today."

Publication of Technical Report No. 1 (Revised 2007) will bring to a new generation of pharmaceutical professionals a greater understanding of the underlying sterilization sciences and how to balance them when designing, developing, qualifying and controlling steam sterilization cycles.

TR-1 Task Force Members and Contributors

A PDA volunteer task force of 40 scientists from North America and Europe worked on Technical Report No. 1 (Revised 2007), producing a technical guide on moist heat sterilization that should be applicable in all regulatory environments.

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Wilf Allinson, GlaxoSmithKline

Thomas J. Berger, Ph.D., Hospira

Frank Bing, Abbott Laboratories (retired)

Göran Bringert, GE Kaye Instruments

Gary Butler, Steris Corporation

Jean-Luc Clavelin, Eli Lilly & Co.

Peter Cooney, Ph.D., FDA (retired)

Phil DeSantis, Schering-Plough

Peter Dürr, F. Hoffmann-La Roche AG

Kristen D. Evans, FDA

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Martin A. Joyce, Ph.D., GeneraMedix Inc.

David Karle, Steris Corporation

Bernard Kronenberg, Bakrona Basel AG

John W. Levchuk, Ph.D., FDA (retired)

Richard V. Levy, Ph.D., PDA

Steen Loevtrup, Novo Nordisk A/S

Timothy F. Lord, Eli Lilly & Co.

Genevieve Lovitt-Wood, G.I. Lovitt & Associates

Russell E. Madsen, The Williamsburg Group, LLC

Vittorio Mascherpa, Ph.D., Fedegari Autoclavi Spa (retired)

David W. Maynard, Maynard & Associates

Robert B. Myers, PDA

James E. Owens, Baxter Healthcare (retired)

Irving Pflug, Ph.D., University of Minnesota (retired)

Dario Pistolesi, Ph.D., Fedegari Autoclavi Spa (retired)

Anthony Pochiro, AG Edwards and Sons

Jarmo Saari, Leiras OY

Michael Sadowski, Baxter Healthcare

John T. Shirtz, Baxter Healthcare

Keith Shuttleworth, Keith Shuttleworth & Associates Ltd.

Finlay Skinner, Skinner Pharm-Assist

Ian Symonds, GlaxoSmithKline

Kevin D. Trupp, Hospira

Dieter Witthauer, Ph.D., Novartis

Richard T. Wood, Ph.D. (retired)

William Young, Baxter Healthcare (retired)

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Review of EMEA Guideline: Limiting Residues of Metal Catalysts

Susan Schniepp, Hospira

The European Medicines Agency (EMEA) recently released for public comment a document titled *Guideline on the Specification Limits for Residues of Metal Catalysts*. The concept of limiting residues of heavy metals was first proposed by the EMEA's Committee for Human Medicinal Products (CHMP) in June 1998 in a similar draft document that was released for public comment in January 2001 and again in June 2002. Since February 2003, the document has been under discussion at the EMEA. The new version was re-released for consultation in January 2007 with a comment deadline of May 23.

The new guideline is very similar in content to ICH Q3C, *Impurities: Guideline for Residual Solvents*. The rationale for the document is discussed in the introduction. It mimics the rationale for the residual solvents ICH guideline indicating metal catalysts offer no therapeutic benefit to the patient. The manuscript's applicability is universal, pertaining equally to established and developed materials, APIs, excipients and drug products.

In the guideline, metal catalysts are divided into three categories, or classes. Class 1 metal catalysts are similar in concept to Class 1 residual solvents. There is a significant patient safety concern should they exceed a permitted daily exposure (PDE) level based on their toxicology profile. Similarly, Class 2 and Class 3 metal catalysts are defined as having low safety and minimal safety patient concerns respectively, consistent with Class 2 and Class 3 residual solvent definitions. Class 2 metal catalysts are acknowledged to be "generally well-tolerated," and can be used for nutritional reasons, while Class 3 metals have well-known safety profiles and are "generally well-tolerated."

The guideline establishes the PDE for these various classes of metal catalysts based upon certain assumptions that are discussed in the introduction section of the manuscript. These suppositions include a 50 kg adult body weight, a 20 m^3 per day breathing volume and an eight hour occupational inhalation exposure among others. The introduction also notes the uncertainty factors from ICH Q3C were used in establishing the exposure limits that are presented in the document. These exposure limits are delineated in Table 1 of the document and are divided into two categories: oral exposure and parenteral exposure. As expected, the PDE levels for parenteral administration are tighter than the oral administration levels. The guideline also offers calculations for setting the concentration limits of the metals in question and recommended reporting levels, which are, again, very similar to the ICH Q3C information.

The guideline is fairly clear and concise, but there are some recommendations or consideration points that could be included in the final version to enhance its acceptance and understanding.

The guideline is fairly clear and concise, but there are some recommendations or consideration points that could be included in the final version to enhance its acceptance and understanding.

One notable absence in the scope of the document is the statement indicating it is only necessary to test for metal catalysts that are used or produced in the manufacturing of drug substances and excipients. Adding this statement to the scope would clarify that manufacturers do not need to test for metal catalysts when they have manufacturing and/or processing knowledge, indicating these elements are not used in the production of their materials and would more closely align the document with ICH Q3C.

Some metals may have a variety of salt forms. These different salts may have different toxicity profiles. The guideline as written does not consider this when determining the PDE for a metal catalyst. A discussion regarding various salt forms and how they can change toxicity profiles of the base metal would be appropriate to include in the final document.

The information in *Table 1: Class Exposure and Concentration Limits for Individual Metal Catalysts and Metal Reagents* could be made clearer. For example, a more detailed explanation could be provided as to how the metals listed were chosen to be included in their specific category. In addition, it is unclear what class 1C represents. An explanation is given for the distinction between class 1A and 1B platinoids, but there is not a discussion regarding class 1C platinoids. The following is a recommendation for text that could be added to address this concern:

Platinoids are in class 1A and class 1B. Class 1A platinoids have well-developed toxicity profiles and available data supporting the recommended level in Table 1. For the platinoids in subclass 1B, a conservative approach has been adopted because there is very limited toxicity data available. Class 1C are

continued on page 27

Regulatory Briefs

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

North America

FDA Announces Availability of Draft Guidance, Q10 Pharmaceutical Quality System

The U.S. FDA recently announced the availability of a draft guidance, entitled Q10 Pharmaceutical Quality System. The draft guidance was prepared under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a model for an effective quality management system for the pharmaceutical industry, referred to as the pharmaceutical quality system

The draft guidance applies to drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle. The draft guidance is intended to provide a comprehensive approach to an effective pharmaceutical quality system that is based on International Organization for Standardization concepts, includes applicable GMP regulations and complements the ICH guidances on Q8 Pharmaceutical Development and Q9 Quality Risk Management.

Comments are due to the FDA by October 11, 2007 (note that comments on the same document are due to EMEA by November 30, 2007).

FDA Issues Dietary Supplements Final Rule

The U.S. FDA announced a final rule establishing regulations to require current good manufacturing practices (cGMP) for dietary supplements on June 22. The rule ensures that dietary supplements are produced in a quality manner, do not contain contaminants or impurities and are accurately labeled.

As a companion document, FDA also is issuing an interim final rule that outlines a petition process for manufacturers to request an exemption to the cGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements.

FDA is soliciting comment from the public on the interim final rule. There will be a 90-day comment period, ending on September 24, 2007.

The final cGMP and the interim final rule are effective August 24, 2007.

Please visit **www.fda.gov** for more information and to view the complete press release.

International Harmonization

Argentinean and South African Health Authorities to Join PIC/S

At the May 15-16 joint committee meeting of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), the committee invited South Africa's Medicines Control Council and Argentina's National Institute of Medicaments to join as new Participating Authorities. Applications for the health authorities in Israel, Lithuania, Thailand and the United States were reviewed.

Among the other business completed at the meeting was the extension of Jacques Morénas term of service as PIC/S chairman until the end of 2008.

Review of EMEA Guideline: Limiting Residues of Metal Catalysts, continued from page 26

metal catalysts that are not platinoids but have data available to support the recommended toxicity level in Table 1.

In addition, consideration should be given to amending Table 1 to delete the sub-column titled "Concentration (ppm)" under the column header "Parenteral Exposure." The levels indicated in the column pose an analytical challenge to companies because current available technology is not capable of detecting to the indicated level.

The Regulatory Assessment section of the document could be improved by adding the concept of accepting higher limits when warranted. Regulatory Authorities should have the ability to approve higher limits when scientifically justified. The addition of the statement "However, tighter limits can be justified on a case-by-case basis" to the end of the Regulatory Assessment section would allow for regulatory flexibility.

This article was intended to present an overview look at the new guideline and make some recommendations for improving its clarity and applicability. The author wishes to acknowledge the efforts of **Lynn Best,** Baxter; **Janeen Skutnik**, Pfizer; and **Jim Lyda**, PDA, for their support and assistance in dissecting the contents of the guideline.

North America Events

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

Conferences

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

October 15-16, 2007
2007 PDA Visual Inspection Forum
Bethesda, Maryland

October 29-November 2, 2007
PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
(Conference, Courses and Exhibition)
Bethesda, Maryland

November 1-2, 2007
PDA/FDA Co-Sponsored Conference Series on Quality Systems
Bethesda, Maryland

November 6-8, 2007
PDA Extractables/Leachables Forum
Bethesda, Maryland

May 19-23, 2008
2008 PDA Biennial Training Conference
New Orleans, Louisiana

Training

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

August 2-3, 2007
Environmental Mycology Identification Workshop

August 7-10, 2007
Developing an Environmental Monitoring Program

August 14-17, 2007
Downstream Processing: Separation, Purification and Virus Removal

September 10-12, 2007
Environmental Monitoring Database and Trending Technologies

October 1-5, 2007
Rapid Microbiological Methods

October 17-18, 2007
Visual Inspection Training Course

October 23-24, 2007
Fundamentals of D, F and z Value Analysis

October 25-26, 2007
Validating a Steam Sterilizer

October 29-31, 2007
Managing Quality Systems

October 31-November 2, 2007
Advanced Environmental Mycology Identification Workshop

Lecture Courses

October 8-10, 2007
Advanced Pharmaceutical Filtrations and Filters

Course Series

October 15-17, 2007
Philadelphia Training Course Series
Philadelphia, Pennsylvania

November 27-29, 2007
San Diego Course Series
San Diego, California

Chapters

July 18, 2007
Puerto Rico Chapter
Quality by Design and PAT Application
Location: TBD

July 19, 2007
West Coast Chapter
Quality by Design
Millbrae, California

September 27, 2007
Delaware Valley Chapter
Pharmaceutical Quality Assurance in Aseptic Processing
Malvern, Pennsylvania

November 14, 2007
Puerto Rico Chapter
Educational Conference
Location: TBD

Europe/Asia-Pacific Events

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

Europe

September 11-12, 2007
Industrial Freeze Drying and Spray Drying
Cologne, Germany

September 12-13, 2007
Technology Transfer
Basel, Switzerland

September 12-13, 2007
Central Europe Chapter
Technology Transfer Conference
Location: TBD

October 9-10, 2007
Cleanrooms/Isolators/RABS
Co-sponsored by PDA and R3 Nordic
Berlin, Germany

October 9, 2007
ICH Q10 Stakeholder Workshops: PDA Review and Input
Milan, Italy

October 11, 2007
ICH Q10 Stakeholder Workshops: PDA Review and Input
Berlin, Germany

October 17-18, 2007
Pharmaceutical Cold Chain
Berlin, Germany

October 25, 2007
Supplier Quality and Global cGMP
Rome, Italy (postoned from June 11, 2007, Bologna, Italy)

November 7-9, 2007
Modern Aseptic Production
Co-sponsored by PDA and R3 Nordic
Stockholm, Sweden

November 13-15, 2007
European Training Course Series in Berlin
Berlin, Germany

November 15-16, 2007
Cork, Ireland Training Course Series
Cork, Ireland

November 27-28, 2007
The Universe of Pre-filled Syringes
Berlin, Germany

December 4-7, 2007
Practical Aspects of Aseptic Processing Training
Basel, Switzerland

December 10-11, 2007
PDA/FDA Co-sponsored Series on Quality Systems
Dublin, Ireland

December 12-14, 2007
Dublin Training Course Series
Dublin, Ireland

January 23-24, 2008
Investigational Medicinal Products: How to Get the GCP/GMP Interface Right
Paris, France

February 20-21, 2008
PDA/EMEA Joint Conference
Budapest, Hungary

Asia-Pacific

July 5, 2007
PDA Japan Chapter
J-Pharmaceutical Affaires Law Update
Tokyo, Japan

July 26, 2007
Australia Chapter
Vendor Qualification
Brice County, Australia

September 13, 2007
Australia Chapter
P.A.T.
Auburn, Australia

September 23, 2007
PDA Japan Chapter
Conference with US Task Force before 2007 PDA/FDA Joint Regulatory Conference
Washington, D.C.

November 13, 2007
Australia Chapter
PDA/TGA Meeting
Caulfield Racecourse, Australia

November 13-14, 2007
PDA Japan Chapter
Annual PDA Japan Chapter Meeting
Tokyo, Japan

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Know Your Regulators: EMEA Inspections Sector

Jim Lyda, PDA

The EMEA's Inspections Sector deals with a number of tasks laid down in Regulation (EC) 726/2004. Specifically, the Sector coordinates the verification of compliance with the principles of GMP, GCP and GLP and with certain other aspects of the supervision of authorized medicinal products in use in the European Community. The Sector's activities are summarized in Chapter 4 of the EMEA's work program and annual reports.

The Sector coordinates inspection requests by the Committee for Human Medicinal Products (CHMP) or Committee for Veterinary Medicinal Products (CVMP) in connection with the assessment of marketing authorization applications or for matters referred to these committees. These inspections may cover GCP, GLP, GMP, Pharmacovigilance or they may be performed in the context of Vaccine Antigen Master File (VAMF) and Plasma Master File (PMF) certification. They may be necessary to verify specific aspects of the clinical or laboratory testing or manufacture and control of the product and/or to ensure compliance with GMP, GCP, GLP or Pharmacovigilance quality assurance systems.

The Sector organizes and chairs regular meetings of European Economic Area (EEA) GCP and GMP inspectors where harmonization of inspection-related procedures and guidance documents are developed. [Note: The EEA includes all EU member states together with Iceland, Liechtenstein and Norway but not Switzerland.] This includes development of the new EudraGMP database and organizational and scientific support to the joint CHMP/CVMP Quality Working Party. The Sector also coordinates the EMEA Process Analytical Technology (PAT) Team, a forum for dialogue and understanding between the Quality Working Party, Biologics Working Party and the group of GMP Inspection Services with the aim to review the implications of PAT.

> Jim is contributing this series of occasional articles to inform PDA members and readers of the regulators who are responsible for ensuring a safe, effective and high-quality supply of healthcare and medicinal products. In this issue, we focused on the EMEA Inspections Sector. Thanks are in order to **David Cockburn**, Principal Scientific Administrator, EMEA Inspections Sector, for contributing the information on which this article is based.

The Inspections Sector, in cooperation with the European Directorate for the Quality of Medicines and Healthcare (EDQM), operates a sampling and testing program to coordinate the supervision of authorized medicinal products under practical conditions of use. In addition, it supports communication and action by member states in response to suspected quality defects relating to centrally authorized medicines.

The Inspections Sector issues Certificates of Medicinal Products, in accord with the World Health Organization requirements, which confirm the status of centrally authorized medicinal products and compliance of the manufacturing sites of the pharmaceutical forms. It also coordinates activities in connection with the GMP annexes of the various mutual recognition agreements (MRAs) that have been negotiated between the European Community and non-EEA countries. International cooperation includes work with the U.S. FDA and the International Conference on Harmonisation (ICH).

While most scientific activities of the EMEA are divided between medicinal products for human and for veterinary use, the tasks of the Inspections Sector are common to both types of products. As such, the Inspections Sector forms part of the Veterinary Medicines and Inspections Unit within the Agency.

As of March 2007, the staff members of the Sector were as follows *(Name is followed by home member state and year of joining EMEA)*:

Head of Sector

Emer Cooke, Ireland, 2002

Background: Pharmacy, pharmaceutical chemistry, business administration; 22 years experience in industry and regulatory positions including EFPIA and the Pharmaceuticals unit of the European Commission
Duties: Leads the Inspections Sector

GMP Group

David Cockburn, UK, 2002

Background: Pharmacy, 15 years working as GMP and GCP inspector for the UK authorities
Duties: Organizational and scientific support of the GMP Inspection Services group and the EMEA PAT team; manages the GMP related enquiries that come into the EMEA GMP mailbox

GMP Inspections/Quality Defects/ EudraGMP

Brendan Cuddy, Ireland, 2002

Background: Chemistry, industry
Duties: Coordination of GMP and GLP inspections; procedures relating to defective medicinal products; represents EMEA at the biannual meetings of the Heads of Medicines Agency Working Group of Enforcement Officers (HMA WGEO)

Piotr Krauze, Austria, 2004

Background: Chemical engineering,

specialization in biotechnology, biochemistry and food technology; industry experience in biotechnology
Duties: Coordination of GMP inspections, support QWP and GCP administrators, EMEA-wide Risk Management for Inspections Sector, Agency Integrated Quality Management

François-Xavier Lery, France

Note: On temporary assignment from EDQM to EMEA

Background: Pharmacist, PhD in organic chemistry, eight years regulatory experience with quality aspects (assessment, inspection, analysis) of medicinal products
Duties: Scientific administrator coordinating GMP inspections for centrally authorized products; actions following quality defects affecting these products

Francisco Peñaranda Fernandez, Spain, 1997

Background: Chemist, MS in quality management; 9 years industrial chemical and pharmaceutical experience in research and quality management
Duties: Principal Scientific Administrator, GMP inspections of Plasma Master Files (PMF), EudraGMP database for GMP certificates and Manufacturing Authorizations, and product defects/recalls for centralized products

Quality Working Party

Riccardo Luigetti, Italy, 2003

Background: PhD in Biochemistry, specialization diploma in Regulatory Disciplines; Italian authorities as Quality Assessor and GMP Inspector
Duties: Secretariat of the Joint CHMP/CVMP QWP and of the Herbal Medicinal Products Committee (HMPC) Quality Drafting Group; PAT team secretariat; QWP question mail box

GCP/Pharmacovigilance/EudraCT

Fergus Sweeney, Ireland, 1999

Background: Physiology and pharmacology; clinical research; GCP compliance auditor and manager
Duties: Coordination of GCP and Pharmacovigilance inspections; Chair of the GCP Inspection Services Group; the EudraCT database

Ana Rodriguez Sanchez Beato, Spain, 2003

Background: PhD in Pharmacy, work on molecular microbiology; pharmaceutical clinical trials
Duties: Scientific Administrator; coordination of GCP and Pharmacovigilance inspections; secretariat of GCP Inspection Services Group; support for EudraCT database and Telematics Implementation Group meetings

MRA/S&T

Claudio Facchini, Italy, 2001

Background: Regulatory authorities in both Italy and UK
Duties: Sampling and testing of Centrally Authorised Products, Certificates of Medicinal Products intended for non-EEA countries

Katrin Nodop, Germany, 1997

Background: Atmospheric physics at University Munich and Frankfurt University; environmental research in European countries and international organizations
Duties: GMP support; operations relating to Mutual Recognition Agreements (MRA) between European Community and third countries; improvement of sampling and testing program of centrally authorized products; secretariat for the EEA Joint Audit Programme of GMP inspectorates

Certification

Miguel Rodriguez, Spain, 2002

Duties: Issuing Certificates of Medicinal Products which confirm the status of centrally authorized medicinal products and GMP compliance of the manufacturing sites

Lucie Valaskova, Czech Republic, 2007

Duties: Day-to-day production of Certificates of Medicinal Products and related activities

Finance

Stefanos Voutselas, Greece, 2001

Duties: All financial matters for Sector; determine eligibility for incentives available to small/medium-sized enterprises

Secretariat

Maria Born, Germany, 2006

Duties: Administrative support for Head of Sector, GCP meetings, EU Expert Database and Rapid Alert System

Diana Jaritz, Germany, 2003

Duties: Team assistant, support to QWP and GMP inspection coordination

Marketa Liskova, Czech Republic, 2006

Duties: Support to scientific administrators

Julie Reignier, France, 2006

Duties: Support to scientific administrators

Veronika Watkins, Czech Republic, 2004

Duties: Administrative assistant; support to scientific administrators

Useful Information

What's New? Find out what is new within the Inspections Sector's areas of responsibility by going to the EMEA website at www.emea.europa.eu/Inspections/index.html.

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Trains, Planes, Automobiles, 500 Mice and a Torrential Downpour

Lindsay Donofrio, PDA

Since joining PDA, I have found there is no better way to learn about the people who drive the association than by traveling to chapter events. Along the way, by plane, train and automobile, I have encountered 500 experimental mice, survived torrential rains and, most importantly, seen firsthand why these local groups are vital to the health of the Association.

New England Chapter Facility Tour and Dinner Meeting

My first "Tales of the Trail" starts in February with my trip to the New England Chapter's facility tour and dinner meeting. After a short flight to Boston, I drove with Chapter President **Myron Dittmer** to Charles River Laboratories. Chapter Secretary **Melissa Smith** was extremely accommodating in helping me plan my visit, even arranging for my transportation from the airport with Dittmer.

Many participants, including myself, were excited for their first opportunity to see a large testing facility. A tour guide lead us through an isolator room, which housed approximately 500 mice, explaining the care procedures and breeding technology used in the laboratories. Many other chapters offer facility tours, and I can now recommend participating in them whenever possible.

After the facility tour, attendees gathered for a networking session, dinner and presentations, which were also held at the Charles River facility. Highlights of the evening included presentations by **Stephen Notarnicola,** PhD, who discussed revisions to TR-14, *Industry Perspective on the Validation of Column-Based Separation Processes for the Purification of Proteins,* and **Susan Schniepp,** who concluded the evening with her presentation "Global Validation Requirements."

[Editor's Note: An article based on Sue Schniepp's talk from this meeting will appear in the October issue of the *PDA Letter*.]

Metro Chapter Symposium

The New England Chapter's hospitality was replicated during my trip to the PDA Metro Chapter Day Symposium on pharmaceutical compliance. This one-day symposium, which addressed quality systems, liability, auditing and validation, was held at the Somerset, N.J., Ramada Inn on April 17, 2007.

While terrible flooding threatened the success of the chapter's event, a dedicated PDA crowd of more than 50 managed to nearly fill the room with their spirits intact. In fact, flooding was so bad that I was unsure I would be able to reach the hotel. After an uneventful ride on the Amtrak train from Washington, D.C., to Iselin, N.J., I hailed a cab for what I thought would be a quick ride to the site of the next day's event. However, with nearly every major road closed, it took nearly two hours to travel just 15 miles.

The next morning, attendees arrived for registration and breakfast with stories of their treacherous morning commutes. Symposium Chair **Robert Seltzer** opened the event with a moment of silence in memory of the victims of the previous day's massacre at Virginia Tech. On a lighter note, Metro Chapter Vice President **Naomi Baer** welcomed guests and acknowledged the state's flooding: "Good morning everybody. It has been a challenge to get here, and we're all going to collect stories and maybe publish a book….But we're all here, and we're all safe." The all-day event featured six presentations and included exhibits from Sparta Systems and STERIS Corporation. Seltzer continued by introducing the day's first speaker, former PDA Science & Technology V.P. **Russell Madsen**.

Madsen's talk "The Quality Systems Approach to Real Compliance" focused on the critical differences between product quality and regulatory compliance. This presentation updated one he gave at the 2000 PDA Annual Meeting on the differences between "real" and "regulatory" compliance. "Since then," he said, "there has been a significant shift in the way regulatory agencies perceive quality, cGMP compliance and their roles regarding each." He noted that this shift is a result of the development of Process Analytical Technology (PAT), ICH Q8 (pharmaceutical development) and pharmaceutical cGMPs for the 21st century.

(L-R) Metro Chapter Leaders Nancy Tomoney (Secretary) and Naomi Baer (VP) chat with attendees over lunch

"Product quality can be broadly defined as fitness for use or fitness for intended purpose. Regulatory compliance is simply compliance with regulations and guidelines," explained Madsen. "Compliance with regulations may or may not result in a quality product. It is certainly possible to have one without the other. However, when the two concepts are aligned, manufacturing efficiency is optimized, and the consumer receives the highest quality product at the lowest cost." Madsen stressed that "creating this alignment is the purpose of the cGMP initiative, PAT and ICH Q10 (quality systems)." His concluding recommendations for achieving real compliance included the following:

- Knowledge plus control equals compliance
- Cease dependence on inspection to achieve quality
- Systems and procedures should be principle-based, not rule-based

Former PDA President **Leon Lachman**, PhD, followed Madsen. He generated interesting discussion with his presentation "Corporate Responsibility and Liability for GMP Compliance." Participants raised questions regarding an individual's responsibility when a company is in violation of the Food, Drug and Cosmetic Act (the Act). "Does [responsibility] stop at the president, or does it continue down?" asked an attendee. Lachman answered, "It goes down to anyone who's been involved in performing this activity, and you'll see in consent decrees it goes right down to the operating people."

Lachman referenced *United States v. Dotterweich* (1943) to emphasize that "the offense is committed by all who have a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into interstate commerce, adulterated or misbranded drugs." Lachman continued by examining *United States v. Park* (1975). He noted, "The violation of a provision of the Act can lead to a criminal penalty in the absence of the accuser's intention to commit a violation of the act, even without knowledge or the ability to know of the commission of an act for which he is held responsible."

After a short morning break, Sparta Systems's **Steven Cagle** spoke on the benefits of implementing a quality management system, specifically Sparta's TrackWise. "Managing, tracking and responding to all different types of compliance and quality issues require a quality systems approach. In other words, we don't need to look at different types of business processes and silos. The expectation is that there is a way to consolidate that and have more of a global view," said Cagle. "TrackWise serves as a central system to collect, process and integrate all quality and regulatory management data into valuable information to improve efficiencies, visibility and decrease regulatory risk."

Following lunch, a talk was delivered by Metro Chapter Past President **Frank Settineri** and Seltzer; the presentation was entitled "Auditing the Microbiology Laboratory." Settineri began by sharing his experiences as an auditor: "When I audit a micro lab, I like to do it in two parts. One is what I call the paper part, and one is the actual auditing part or the touring part….I like to do the paper audit first for three reasons. Number one…I like to see what's going on during a typical work day. Number two, when I sit down and do the paperwork first, it gives me an idea of just how organized the laboratory is." He jokingly continued, "And number three is, if you do the walk through first and come back and get lunch, then you have to sit down and do the paperwork right after lunch. And that's snooze time for me."

Seltzer's part of the presentation included a discussion of reference standards. "This is a topic that falls more within an analytical chemistry lab, but you can force the category of reference standards into a microbiology setting," said Seltzer. "Reference standards could include DNA or RNA standards that are used in polymerase chain reaction. And that's becoming a new assay of choice in many labs. In many advanced labs, you'll find molecular microbiology laboratories in very select locations."

The next speaker needed no introduction, but Seltzer provided one anyway: "If you haven't met or if you haven't heard **Jim Agalloco** speak before, I don't know where you've been hiding all this time."

Agalloco's presentation, "Application of Risk-Based Compliance Approaches in Validation Activities," started on the run with a string of rhetorical questions: "How do you guys feel about risk? Who's used a cell phone while driving in the last week? Who's exceeded the speed limit in the last month? and Who's jumped out of a perfectly good airplane?" With few attendees raising their hands, Agalloco wittingly responded, "You guys are qualified to be quality people. You don't take excessive risks."

In order to best understand the future direction of validation, Agalloco elaborated on his interpretation of industry's attitude throughout the last three decades. "We went through a change in validation, and I've been around for these 30 odd years," noted Agalloco. "In 1977, we didn't know what we were doing. We were stumbling along. In 1987, we kind of understood the elephant amount of work that was out there. Ten years later, boy, we were suffering under the burden. Now, it's time to reinvent it….We cannot tolerate validation the way it is. It will kill us, it is killing us—just too many things, too many pieces of paper. The more you control things, the more deviations you ultimately have because you can't do everything letter-perfect." Agalloco concluded that firms and regulators must accept some risk in manufacturing.

Rick Perlman, American Society for Quality Food Drug and Cosmetic Division Past Chair, concluded the day with his presentation "Risk-Based Approach to Supplier Quality Management." His discussion focused on the supplier-quality relationship and how to manage the risk associated with this relationship. "If you've identified the contract manufacturer as high risk, and you need to do business with them, you may want to put somebody in the plant…making sure they're following the rules and doing the right things. High-risk plants require a lot more oversight than some of the others. You'll want to review all of the batch record, not just bits and pieces. You want to make sure there are no surprises that could come back to haunt you in the future," said Perlman. "Again, it is a very high-maintenance type of relationship."

(L-R) Metro Symposium Chair Robert Seltzer presented each speaker with a gift; here with Jim Agalloco

In order to develop a successful supplier-quality relationship—high, normal or low risk—Perlman suggests:

- Using common sense
- Following your gut feeling
- Monitoring trends—review warning letters
- Listening to the Agency
- Being flexible

While various aspects of pharmaceutical compliance were discussed, a common thread throughout the day's presentations was the importance of using good science and common sense.

Both the New England and Metro Chapters serve as examples of how PDA's chapters deliver well-planned, relevant and informative programming at a value their members have come to expect. As long as volunteers like those I have met in my travels continue to serve PDA, the health of the Association will flourish.

Who's Who?

Jim Agalloco, Metro Chapter Nominations and Financial Audits Chair; President, Agalloco & Associates

Naomi Baer, Metro Chapter Vice President; Sr. Applications Specialist, Millipore

Steven Cagle, VP, Marketing & Product Development, Sparta Systems

Myron Dittmer, New England Chapter Member-at-Large; Owner & Principal Consultant, MFD & Associates

Leon Lachman, PhD, Chairman & President, Lachman Consulting Services

Russell Madsen, President, The Williamsburg Group

Stephen Notarnicola, PhD, Principal Scientist, Biogen Idec

Rick Perlman, Quality Audit Manager, Bayer Healthcare

Susan Schniepp, Quality Standards Manager, Hospira

Robert Seltzer, Metro Chapter Day Chair; Compliance Manager-GMP, Schering-Plough

Frank Settineri, Metro Chapter Careers Liaison & Immediate Past President; President, Veracorp

Melissa Smith, New England Chapter Secretary; Principal Consultant, MJ Quality Solutions

DAY 1: inoculate test media, incubate **DAY 2:** agitate, examine, wait **DAY 3:** agitate, examine, wait **DAY 4:** agitate, examine, wait **DAY 5:** agitate, turbid? subculture **DAY 1:** inoculate test media, incubate **DAY 2:** agitate, examine, wait **DAY 3:** agitate, examine, wait **DAY 4:** agitate, examine, wait **DAY 5:** agitate, examine, wait **DAY 6:** agitate, examine, wait **DAY 7:** agitate, examine, wait **DAY 8:** agitate, examine, wait **DAY 9:** agitate, examine, wait **DAY 10:** agitate, examine, wait **DAY 11:** agitate, examine, wait **DAY 12:** agitate, examine, wait **DAY 13:** agitate, examine, wait **DAY 14:** read results

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New Look, New Opportunities: PDA Career Center Gets a Facelift

Julia Onder, PDA

Are you actively looking to change careers? Are you happy with your current job, but curious as to what other opportunities might exist? If so, the PDA Career Center can help.

The Career Center has a new look, more jobs and a special resource section designed to make your transition into a new position easy and effective. Revamped in April 2007, the PDA Career Center website has already successfully matched employers with qualified job seekers, and continues to grow with the PDA membership.

PDA Career Center navigation is now easier than ever, with separate portals for job seekers and employers. New career opportunities are posted every day. Additionally, the PDA Career Center hosts four career fairs annually. Three of these career fairs are "virtual," and one is a face-to-face event at the PDA Annual Meeting each spring. PDA has also added a "Useful Resources" section, which includes the Salary Wizard. This tool helps visitors determine the salary range appropriate for their position.

Don't wait, visit www.pda.org/careers

The PDA Career Center is a benefit for PDA members, nonmembers and companies in the pharmaceutical and biopharmaceutical industry. Similar to other online networks such as Monster® and HotJobs®, the Career Center is designed to build and advance the careers of its jobseekers and provide highly-qualified applicants to the employers who sponsor the Career Center. However, unlike Monster® and HotJobs®, the PDA Career Center exclusively focuses on providing new career opportunities to its members in the pharmaceutical and biopharmaceutical fields.

Puerto Rico Chapter Inaugural Event a Success

Manuel Meléndez, PDA Puerto Rico Chapter; Amgen

I am proud to announce the success of the Puerto Rico Chapter's first educational and election event—an important milestone for the chapter. The half-day event, which was held on April 19 in San Juan, exceeded attendance expectations with nearly 100 participants. I still remember

Board of Directors (l-r): Miguel Montalvo (Member-at-Large), Expert Validation Consulting; Thomas Kelleher, PhD (Member-at-Large), Amgen; Iris Acosta (Member-at-Large), Wyeth-Lederle; Manuel Meléndez (President), Amgen; Evelyn Marchany (President-Elect), Schering-Plough; Frederick Fontanez (Treasurer), GlaxoSmithKline; Adalberto Ramirez (Member-at-Large), Amgen [not pictured, Gloria Martinez (Secretary), Amgen]

brainstorming at our first committee meeting how to define the events calendar, invigorate the chapter and identify members willing to work hard to advance PDA in Puerto Rico.

President-Elect Evelyn Marchany, Schering-Plough, presents the newly elected board at the April 19 meeting

We knew the inaugural event would establish the tone for future activities, helping the Puerto Rico chapter take roots and grow in the future. The team's dedication, commitment and long hours paid off, and we can say with pride: We did it!

The event consisted of two lectures, a chapter election and a networking social activity. The two topics, OOS final guidance and future changes to the process validation guideline, were of great interest to the audience.

Johnny Guerra was the evening's first speaker with his presentation on the OOS final guidance. The second speaker was **Miguel Montalvo,** who discussed future changes to the process validation guideline.

The two lectures were engaging and well-received by the audience. Positive feedback was immediate and attendees indicated that the topics selected were pertinent to their careers. The Puerto Rico chapter thanks Guerra and Montalvo for their support and commitment.

If you would like more information on the PDA Puerto Rico Chapter, please contact Chapter President **Manuel Meléndez,** Amgen, for more information at manuelm@amgen.com.

Johnny Guerra (right), Industry Consultant, talks with a meeting participant following the evening's presentations

Who's Who

Johnny Guerra is the president of the Guerra Consulting Group. Prior to this position, he spent 20 years at the U.S. FDA, San Juan District Office.

Miguel Montalvo is president of Expert Validation Consulting. Montalvo has over 23 years of valuable experience in the areas of cGMP compliance, quality systems and validation.

Japan Chapter Hosts GMP Training Course

Yoshiaki Hara, PDA Japan Chapter; Sartorius

On April 25, 2007, **Chizuko Itoh,** Mochida Pharmaceutical, of the PDA Japan Chapter presented "GMP Training Strategies Grounded in Field Experience Related to Local Regulations" to approximately 130 trainees, including ten investigators.

Based on attendee feedback, Itoh's lecture was a success; 80% of attendees ranked the course as either excellent or very good.

An interactive Q&A session followed her presentation. Listed below is a sample of questions asked by the trainees:

Chizuko Itoh, Mochida Pharmaceutical, offers training to a room of more than 100 attendees

- How do you provide GMP training to plant managers and directors?
- How do you persuade production managers to support GMP training for employees?

The PDA Japan chapter plans to coordinate more field-based training courses regarding local regulations in the future.

Operational Challenges Discussed at West Coast Chapter Dinner

Clarion Hotel, Millbrae, California • May 17, 2007

Kristina Nordhoff, Genentech

"Quality, cheap, or fast—which two would you pick?" These and other provocative questions were posed at the PDA West Coast Chapter's *Operational Challenges in a GMP Environment* dinner meeting following presentations by a panel of local industry professionals.

This particular topic was chosen from an informal table-top survey taken at the November 2006 dinner meeting. Recent studies indicate billions of dollars may be wasted every year in pharmaceutical manufacturing costs alone, making the topic relevant and timely. Given the choice, many professionals would choose "quality" over "cheap" or "fast," but in reality quality may be sacrificed in the interest of the other options. What can management do about conflicting messages of "fast vs. cheap vs. good quality"?

The evening began with a registration/reception hour where attendees enjoyed beverages, appetizers and networking. Chapter President **John Ferreira** welcomed attendees during the dinner portion and opened with the meeting announcements and the introduction of the evening's moderator, **Paula Shadle,** PhD; PDA Chapter Liaison **Henry Kwan,** PhD; and **Randall Tedder,** who represented the event's sponsor TechniKrom.

Following the introductions, Shadle gave a brief overview of the topic and panel/Q&A format and then introduced the three panelists: **Maninder Hora,** PhD; **Alison Moore,** PhD; and **Peter Watler,** PhD.

Each panelist began by presenting an overview of his or her current methodology and experience. The members of the panel explored issues faced when manufacturing in a GMP environment, shared ways to confront and solve operational challenges, and provided approaches that can lead to productive relationships with internal and external partner groups. The panel members also shared more efficient and effective approaches to structuring plant operations, such as in areas of process analytical technology, decision making, deviation handling and testing.

Dinner Panelists (l-r): Chapter Board Member Paula Shadle, PhD, Shadle Consulting; Maninder Hora, PhD, PDL BioPharma; Peter Watler, PhD, JM Hyde Consulting and Alison Moore, PhD, Amgen

The panel members unanimously agreed that without quality there is no product.

The panelists stressed that it is important to have up-to-date knowledge of product and process, as a mix-up with previously-used process steps, assays or formulations could confuse agency inspectors, and that a company must be able to respond quickly to issues on the floor or risk restarting or stopping production runs. Other thoughts included the importance of trained and experienced staff, validation strategies and the holy grail of error-free manufacturing.

After the presentations, Shadle opened the Q&A portion of the evening by asking the panel members the provocative question quoted above: "Quality, cheap, or fast—which two would you pick?" The panel members unanimously agreed that without quality there is no product. The panel also fielded several questions from the audience.

Following the Q&A session, Ferreira thanked the audience for attending and invited them to return on July 19, 2007, for a "Quality by Design" dinner and networking event, featuring a presentation by **Gail Burnett,** Genentech. He closed with the following message: "I wish to thank [the panelists]… Their cumulative experience and expertise regarding the special challenges that face pharmaceutical and biopharmaceutical manufacturers operating in a GMP environment provided valuable insight to our membership."

About PDA's West Coast Chapter

WCC-PDA's goal is to have at least six dinner meetings each year, and to alternate between featured speaker presentations and multi-panelist discussion formats. Recent talks include "Current Training and SOP Trends" presented by **David Gallup**, EdD; "OOS Final Guidance: What

Chapter Leader Visits PDA Headquarters

West Coast Chapter President **John Ferreira** visited PDA headquarters on May 14, 2007. As a newly elected chapter leader, Ferreira saw the importance in gaining an understanding of the philosophy of the national organization. Ferreira, who had never been to PDA's Bethesda, Md., office, felt a visit would offer the perfect opportunity to interact with the PDA staff. "You can't get this from email," said Ferreira.

During Ferreira's visit, he had the chance to tour the PDA headquarters and meet with staff from various departments, including PDA's President, **Bob Myers,** the Membership Services & Sales department, the Marketing department and the Science & Technology department. Ferreira returned to his chapter better equipped to promote PDA's mission of advancing science and regulation for the pharmaceutical and biopharmaceutical industry.

Chapter President John Ferreira, Bänziger Systems, poses with staff during his visit to the PDA headquarters

Over the next two years as chapter president, Ferreira hopes to grow the West Coast Chapter while increasing PDA's visibility as one of the premier professional associations in the industry. Ferreira's visit to the PDA headquarters introduced him to some of the underutilized tools PDA offers for its chapters, including TRI programs at chapter meetings and the variety of marketing opportunities available to the PDA chapters.

PDA welcomes chapter leaders and volunteers to visit its headquarters and meet the people who support PDA's day-to-day operations.

Who's Who

Gail Burnett, Senior Director, Clinical Quality, Genentech

Joseph Chen, PhD, Associate Director, Genentech

Jennifer Cheung, Associate Director, Genentech

John Ferreira, West Coast Chapter President; President, Bänziger Systems

David Gallup, EdD, Principal, Training & Communications Group

Maninder Hora, PhD, Vice President, Process Development, PDL BioPharma

Henry Kwan, PhD, PDA Senior Chapter Liaison; Principal, Kwan Consulting

Paul McKim, Vice President, PAREXEL Consulting

Alison Moore, PhD, Vice President, Fremont Site Head, Amgen

Paula Shadle, PhD, West Coast Chapter Member-at-Large; Principal Consultant, Shadle Consulting

Randall Tedder, West Coast Chapter Past President; Authorized Mfg's Rep., TechniKrom

Lynn Torbeck, President, Torbeck & Associates

Kirsten Vadheim, PhD, Principal, BioCompliance Consultlng

Peter Watler, PhD, Vice President, West Coast Operations, JM Hyde Consulting

Has Changed?" presented by **Lynn Torbeck**; "FDA Industry Trends" presented by **Paul McKim,** and a panel discussion on "Aseptic Processing: FDA Industry Trends" featuring **Joseph Chen,** PhD; **Jennifer Cheung**; and **Kirsten Vadheim**, PhD.

In addition to the July event, WCC-PDA has dinner presentations scheduled in September and November as part of their professional dinner meetings series. Topics and speakers will be announced on the chapter's website and via email in the upcoming months. Meetings are held at the Clarion Hotel, Millbrae, Calif., from 6:00 p.m. – 9:30 p.m. For more information on the chapter, including a list of chapter leaders, please visit the chapter website at www.wccpda.org.

PDA Welcomes New Members

Cristina Alves, Hovioney

Yaya Abdullahi, Abraxis BioScience

Mike Aboyoun, Wyeth

Ayumi Aisaka, Dainippon Sumitomo Pharma

Noriko Akagi, Nichia Pharmaceutical Industries

Frank Alicea, Wyeth

Piers Allin, European Biopharmaceutical Enterprises

May Al-naib

Gor Amar, Manufacturing Genzyme

Claude Ammann, Apoxis

Christopher Anderson, Cardinal Health

Stephen Andrews, Wyeth

Siddiq Ansari, Health Canada

Mitsuo Aoki, Otsuka

Massimo Argentero, Novartis

Vania Armani, Nordtest

Chiaki Asai Sankyo, Organic Chemicals

Anette Asher, Life Science Information Technology Global Institute

Ge Bai, Amylin Pharmaceutical

Deborah Baillie, Xenova Biomanufacturing

Terry Bates, CDC

Holly Battaglia, Chesapeake Biological Laboratories

Volker Baur, Cilag

Suzanne Behnke, Genentech

Kornelia Berghof-Jaeger, Biotecon Diagnostics

Tamar Berustein, Teva

Enrico Bettetini, Sicor

Anand Bhate, Eisai

John Bianchi, DSM Pharmaceutical Products

Silvana Biraghi, Applied Biosystems

Bryan Black, Alkermes

Matthew Bond, Pfizer

Kenneth Boone, Tyco Healthcare/ Mallinckrodt

Aimee Bosch, Geron

Annick Bouchereau-Meunier, Omega Laboratories

Stanley Boylan, Eagle Group

MarJean Boyter, Fresenius Medical Care

Michael Brandye

Lorri Brooks, Cardinal Health

Elizabeth Bruce, MIT

Deborah Brusini, Rapid Micro Biosystems

Steven Bryant, BioConvergence

Chistan Burnett, sanofi pasteur

Michael Burt, CIBA Vision Sterile Manufacturing

Donna Cabral-Lilly, Celator Pharmaceuticals

Cliff Campbell, Campbell Informatics

Krista Canales, Avid Bioservices

Karen Cangiamila, Biogen Idec

Xiaoliang Shirley Cao, Threshold Pharmaceuticals

Maurizio Cosimo Caputo, Bristol-Myers Squibb

Alina Caraballo, Cordis

David Carmon, Rafa Laboratories

Jason Carr, Chesapeake Biological Laboratories

Chiara Carraresi, Novartis

Ignasi Carrera, Proctor & Gamble

Sandy Cascone, DynPort Vaccine Company

Boriana Cavicchia, American Red Cross

Paola Cazzaniga, SRA Instruments

Chin-Ming Chang, Allergan

Joon Shik Chang, NKBIO

Emmanuel Chantelot, European Biopharmaceutical Enterprises

Ben Chen

Hui Mei Chen, Genentech

Lin Chen, Pfizer

Paul Chow, Jacobson Medical

Edward Church, ISTA

Tim Cirbo, Eli Lilly

Linda Clark, UCB

Rose Cook, Johnson & Johnson

Lisa Corya, Cook Pharmica

Rachel Czuba, Ben Venue Laboratories

Armand R Dacanay, Human Genome Sciences

Joseph Dallapiazza, Pall Corporation

Aron Damen, Organon

Lisa Davis, Abraxis Bioscience

Samantha Davis, Wyeth

Veronique Dengis, Lonza

Niraj Desai, MedImmune

Karen Diaz, Daiichi Sankyo

Latty Didier, Baxter

Massimo Dipietri, GlaxoSmithKline

Megan Dodson, GlaxoSmithKline

Niamh Doherty, Allergan

James Donnell, Cardinal Health

Patrick Donnelly, PharmaBioStorage International

Christian Doriath, Eli Lilly

Peter Doyle, Eli Lilly

William Dsokoczynski, Bristol-Myers Squibb

Patrick Eaton, Amylin Pharmaceuticals

Esther Elmalm, Rafa Laboratories

Donald Esherick, Wyeth

Jason Esper, Precision Pharma Services

Robert Esterbrook, USFK

Mitch Eyster, Actavis

Abed Faruga, Cure Medical

Alessandro Fava, Fabrica Italiana Sintetici

Carlo Favazza, Sepracor

Kevin Feeheley, ESA Biosciences

Ping Feng, Cogenesys

Ornella Finocchiaro, Industria Farmaceutica Serono

Christopher Fore, Envirotainer

Nick Fotis, Cardinal Health

Marc Frederic, Millipore

Hitoshi Fujioka, Takeda

Cristina Funaro, Pfizer

Junko Furukawa, Santen Pharmaceutical

Stephen Gacheru, Bristol-Myers Squibb

Gerry Gaeta, Lonza

Milind Ganjawala, Wyeth

Nicholas Geary, P&G

Kaoru Gengyo, Toa Eiyo

Samir Ghosalkar, Biocon Biopharmaceuticals

Nicole Gibelin, sanofi pasteur

Joseph Giertych, Baxter

Ted Gilbert, Nucleonics

Mark Girdwood, SciTech Engineering

Paolo Golfetto, Nuova Ompi

Alex Golkarov, Teva

Maria Gonzalez, Hovione FarmaCiencia

Ariel Gonzalez, Quality Fenwal International

Linda Graf, Wyeth

Itai Grajcer, Teva

Thomas Graves, CSL Behring

Charleston Gray, Pfizer

Scott Groene, Wellstat Biologics

Frida Grynspan, Gamida Cell

Rao Gurijala, Bausch & Lomb

Angela Haag, GlaxoSmithkline

Kristie Haddox, Alcon Laboratories

William Han, Baxter

Philip Hanebutt, Eli Lilly

Takeshi Hashimoto, Toaeiyo

Eugene Helsel, Sangart

Emma Helyer, Pall Life Sciences

David Hemmerlin, Novartis

Ivette Hernandez, Quality Fenwal International

Stephen Holland, Wyeth

Tomoko Hongo, Asahi Kasei Medical America

John Horvath, sanofi pasteur

Christoph Huber, Cilag AG Schaffhausen

Bechet Isabelle, Eurogentec

Chikako Ishigai, Hfreund

Hilary Jeffreys, Biogen Idec

Kenneth Jimenez, Bayer

Enric Jo Cardoso, Reig Jofre

Caroline Johansson, Q-MED

Chyreese Jones, Eli Lilly

Scott Jordan, BioMarin

Hirai Jun-ichi, Shionogi

Matthew Kahn, Brown University

Toshi Kajiro, Daiichi Sankyo

Masato Kakiuchi, Abbott

Fumitaka Kano, Yamasa

James Kasselmann, Genentech

James Kerr, Merck

Fumihiro Kihara, Daiichi Sankyo

Ki Yon Kim, ChoongWae Pharma

Miki Kimura, Daiiti Yakuhin Kougyou

Kori King, Abbott

Susan Knight, GlaxoSmithKline

Yoshihiro Komine, Taisho Pharmaceutical

Kazuhiko Kondo, Yamasa

Takeshi Kondo, Central Glass

Michael Kopp, GCA Critical Environment Services

Ryan Kortz, AstraZeneca

Ingeborg Kramer Pittof, F. Hoffmann-La Roche

Stephan Krause, Favrille

Christine Kujawa, Eagle Group

Niranjan Kumar, Novavax

Tomomi Kuwana, Kewpie

Edward Kwong, Genentech

Karen Lally, Schering-Plough

Jacques Lalonde, GlaxoSmithKline

Soraya Landers, Genzyme

Didier Latty, Baxter

Keith Leamy, Wyeth

Francois Leduc, Alternatives Technical Pharma

Anthony Liccione, STS Consulting

John Liebe, LifeConEx

Alblas Lisbeth, Xendo

Leona Louderback, Dade Behring

Gerald Lyons, Getinge

Shahar Magen, Teva

Miguel Mansilla, Laguia Quimica Sintetica Dulcinea

Krystal Marinaro, Genzyme

Deborah Mathias, LifeConEx

Liam McConlogue, sanofi pasteur

Thomas McCoy, Micro-Virology Laboratories

Ben McLaughlin, Altus Pharmaceuticals

James McLaughlin, Neurotech

Mike McManus, Baxter

Gary Meddock, Mentor Biologics

Jawahar Mehra, Dr. Reddy's Laboratories

Bama Menon, Pharmaniaga

Tesfu Mezghebe, Human Genome Science

Colleen Milan, Precision Pharma Services

Wayne Miles, Agilent Technologies

Elizabeth Mitchell, GlaxoSmithKline

Jaime Mitchell, sanofi pasteur

Hidehiko Miura, Kyorin Pharmaceutical

Masaki Miyanaga, Yamasa

Takanori Miyashita, Yamasa

Rebecca Molanick, Baxter

Jang Ho Moon, Penmix

Daniel Moore, AmerisourceBergen

Michelle Moore, sanofi pasteur

Suzanne Moore, Reckitt Benckiser Healthcare

Erick Moreira, MeadWestvaco

Nina Moreno, Nelson Labs

Patricia Moretti, Health Canada

Hideshi Mori, Japan Tissue Engineering

Mary Morton, Fidelis BioPharm

Charles Motley, Jr., American Biologistics

Susan Mozgai, Wyeth

Lisa Musso, Tulane University

Tim Myott, Wyeth

Fusayo Nakagawa, Rohto Pharmaceutical

Hiroyuki Nakata, Daiich Sankyo

Ivan Natali, Dompe

Claude Neve, GlaxoSmithKline

Wes Newgard, Pfizer

Eric Newman, Falvey Cargo

Bond Ng, Bayer HealthCare

Lance Nguyen, Particle Measuring Systems

Eddie Nieves, Invensys Validation Technologies

Hirokazu Nishida, Benesis

Miwako Nishiguchi, Santen Pharmaceutical

Kenji Nishiwaki, Astellas Pharma

Tanveer Nizami, Cibavision

Alain Nonn, Eli Lilly

Camilla Nordlund, Pfizer

Taku Numazawa, Daiichi Sankyo

Karen O Hanlon, National University of Ireland

Viola Okoye, University of Nigerian Teaching Hospital

Betsey Oliver, Alexion

Ann-Britt Onnered, AstraZeneca

Lisa Ortiz, Shire Pharmaceuticals

Samuel Oustric, sanofi-aventis

Heather Owens, Merck

Roger Pak, Infinity Pharmaceuticals

Jeffrey Palmer, Schering-Plough

Traci Palmer, The Cambridge Group

Pouria Panahi, Behestan Daru

Frank Panofen, Millipore

Darshana Patel, Merck

Alessandro Pauletto, Charles River Laboratories

Esperanza Pena, Aula GMP

Linda Petrarca, Baxter

Alicia Pierson, Biogen Idec

Vitaly Pilkin, Redox Technologies

Paul Pluta, Abbott Laboratories

Patrick Poisson, RxElite

Loredana Pollicino, Wyeth

Dean Pontikes, Abbott

Annette Post, Boheringer Ingelheim

Thomas Pracht, Novartis

Praveen Ram, Prasanna Tufts University

John Pratsinakis, Merck

Holly Prentice, Momenta Pharmaceuticals

Declan Quinlan, Genzyme

Adalberto Ramirez, Amgen

Massimo Rastelli, GlaxoSmithKline

David Ray, Sensitech

Manas Ray, Shire

Matthew Rice, Alkermes

Lorrie Roberts, Agilent Technologies

Priscilla Robinson, Merck

Roxanne Robles-Torres, Bausch & Lomb

Gabriele Sabine Roidl, BioMartin Pharmaceuticals

Paul Roosen, Helvoet Pharma

Charlene Rose, American Red Cross

Karen Rossington, Shield Medicare

Paula Rothwell, Vertex Pharmaceuticals

Alexander Ruijs, DSM Biologics

Alicia Ruiz, Instituto de Capacitacion Quamico Farmacoutico

Mike Russell, David Begg Associates

Trisha Russell, Pfizer

Shamena Russum, Global Biologics Supply Chain

Rut Rydell, Pfizer

Elizabeth Ryland, Amgen

Melissa Sabatos, Alexion

Paolo Saccà, Kedrion

Yo Sakuma, Maruishi

Patricia Sampson, Bayer

Sandra Samuels, Bayer

Michiro Sasaki, Ajinomoto Medica

Norbert Schuelke. Millennium Pharmaceuticals

Caleb Shiffer, Sanofi Pasteur

David Shiplacoff, DHR International

Joseph Shulman, Acusphere

Kerri Shultz, Dentsply

Antje Siegel, F. Hoffmann-La Roche

Sunil Singh, Matrix Laboratories

Jeff Sippola, Trace Life Sciences

Paulette Smariga, PEServices

Brian Smith, Cilag

Ira Smith, Pharmaceutical & Healthcare

Douglas Standley, Purdue Pharma

Todd Stem, sanofi pasteur

Katie Stewart, Human Genome Sciences

Elyssa Sugar, World Trade Group

Nagalla Suresh, Zenotech

Lucia Tagliaferri, Novartis

Peter Tainsh, American Biologistics

Hiroshi Takahashi, Central Glass

Ronald Taticek, Genentech

Eric Teel, Keller Graduate School of Management

Jacob Tesfai, Bayer

Beng Ti Tey, University of Putra Malaysia

Peter Thaler, Sandoz

Ann-Marie Thomas, sanofi-aventis

Mandy Tisdale

Sam Torkaman, BAPB

Emiliano Toso, Merck Serono

Kouta Toyoda, Denki Kagaku Kogyo Kabushiki Kaisha

John Turanin, Zogenix

Robert Turok, Anhydro

Corey Tyler, Baxter

Satoshi Uchino, Daiichi Sankyo

Ryoichi Uemura, Genentech

Els Van, Rompaey

Peter van Doornik, Netherlands Vaccine Institute

Barbara VanRenterghem, Controlled Environments Magazine

Michaela Vardi, Teva

Lewis Vinson, INO Therapeutics

Juan Vintimilla, Organon

Sheryl Vitale, F. Hoffmann-La Roche

Jason Vorhees, Amgen

Satoshi Wada, Dainippon Sumitomo Pharma

Akemi Wakisaka, Japanese Red Cross Plasma Factionation

James Wallin, NSF

Bruno Wandji, Millipore

Jason Ward, Commissioning Agents

Anne Warnke, Abbott

Tsuyoshi Watanabe, Sumitomo 3M Limited

Giovana Webb, Novozymes Delta

Guy Weerasekera, Nektar Therapeutics

Ted Wheeler, ISTA Pharmaceuticals

Matthew White, Baxter

Jeffrey Whyte, MDS Nordion

Agneta Wickman, AstraZeneca

Eric Wiechert, ASI

Hugh Wight, Altus Pharmaceuticals

Lory Wikstrom, GE Healthcare

Allie Willard, Vistakon

Lane Williams, ABM Industries

Todd Williams, BioCryst Pharmaceuticals

Donald Wolf, Wyeth

Tracy Wolfe, Zingaro

Linda Wong, Baxter

Chritopher Wong, TNTC

Tomoo Yamada, Otsuka Pharmaceutical

Toshio Yamada, Yamasa

Hiroshi Yamahara, Tanabe Seiyaku

Yoshimi Yamamoto, Astellas Toyama

Tetsuya Yamazaki, Meiji Dairies

Niamh Yates, Wyeth

Sun Yi, Centocor

Shinya Yokoyama, Iwai Kikaikougyou

Atsushi Yoneda, Banyu Pharmaceutical

Michael Yoshida, Amgen

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Wai Yung Yuen, Genentech

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Anne Zavertnik, Bausch & Lomb

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

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

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2007 Visual Inspection Forum: An Opportunity to Learn

Bethesda, Maryland • October 15 – 18, 2007 • www.pda.org/visinspect

Program Co-Chairs: John Shabushnig, PhD, Pfizer; Markus Lankers, PhD, rap.ID

Visual inspection continues to be an important element of the manufacturing process and the quality assurance of injectable products. Product inspection provides necessary information for lot release, and, coupled with defect identification, contributes to a strategy of continuous process improvement. Since 2000, PDA has organized the Visual Inspection Forum to discuss new technical and regulatory developments in this field. This meeting alternates between the United States and Europe; this year's meeting will be held October 15-18 in Bethesda, Md.

The meeting will provide a forum to present and discuss new developments in the field of visual inspection, including contributions to a basic understanding of the sampling and inspection process, preparation and use of inspection standards, practical aspects of manual and automated methods, and the regulatory and compendial requirements that govern them. This is an excellent opportunity to learn more about visual inspection and to discuss inspection challenges with the experts.

As in past years, the meeting will feature an exhibition where attendees can see the latest in commercial inspection hardware and discuss production needs with key suppliers of inspection systems and services.

We are also pleased to add an optional two-day training course offered through PDA's Training and Research Institute, covering the basics of developing and running a manual inspection program and elements of validating automated inspection systems. This course will be held immediately following the Visual Inspection Forum on October 17-18 in the same location.

For more information on the Visual Inspection Forum and related TRI course, visit www.pda.org/visinspect.

We look forward to seeing you at this exciting and informative meeting.

Micro Meeting to Explore International Pharmacopeial Harmonization

Bethesda, Maryland • October 29 – November 2, 2007 • www.pda.org/microbiology2007

Program Co-Chairs: Jette Christensen, Novo Nordisk; Bryan Riley, PhD, FDA

On behalf of the program planning committee, we are delighted to invite you to attend PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology, October 29-November 2, 2007, in Bethesda, Md. Following the success of the inaugural conference in 2006, the planning committee has been focusing on making the best possible program for this year's meeting. In recognition of the global nature of the pharmaceutical industry, we have endeavored to provide an international program that will meet attendees' needs as microbiologists in this challenging industry. The theme we have chosen for 2007 is *Microbiology throughout the Product Life Cycle*. The opening plenary session will include a keynote address by **Anthony Cundell,** PhD, Schering-Plough, who will provide an overview of the microbiological issues confronting the pharmaceutical industry from formulation development through post-marketing changes.

The initial day of the conference will also include presentations by pharmaceutical microbiologists describing their experiences with the following issues:

- Innovative technologies for aseptic processing
- Water system design and control
- Selection and validation of alternative test methods
- The use of disposable systems in aseptic manufacturing
- Water activity for non-sterile products

The second day of the conference will be dedicated to pharmacopeial presentations. The subjects will include the continuing efforts at global harmonization as well as presentations on specific chapters in the various pharmacopeias. Speakers representing USP, EP and JP will be on hand to give presentations and to participate in a panel discussion at the end of the day. The final day of the conference will begin with sessions devoted to presentations by regulatory officials addressing hot topics related to their areas of authority. Finally, the program will conclude with a panel discussion, giving the audience an opportunity to ask questions of the regulatory speakers.

The format of the conference has been designed with a focus on interaction between meeting attendees and speakers, who are authorities from the field of pharmaceutical microbiology.

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Connect with Colleagues New and Old

This year's **PDA/FDA Joint Regulatory Conference** offers a variety of networking opportunities that capitalize on the local surroundings and bring you together with colleagues, FDA representatives and exhibitors in a fun and entertaining environment.

Visit www.pda.org/pdafda2007 for information on how to register and any additional fees for the following events.

Monday, September 24

New Member Breakfast
7:30 a.m.-8:30 a.m.

Welcome new PDA members! If you joined PDA on or after January 1, 2007, you are invited to kick-start your PDA membership by attending this year's New Member Breakfast hosted on-site at the 2007 PDA/FDA Joint Regulatory Conference. This is a wonderful opportunity to learn more about PDA and to meet other new members, board members and staff.

Please RSVP by August 22, 2007, by emailing **info@pda.org** or calling **Hassana Howe** at +1 (301) 656-5900, ext. 119. Please direct any questions regarding the breakfast to the contact information above.

Reception in Exhibit Area
5:30 p.m.-7:30 p.m.

Join fellow conference attendees and exhibitors for a cocktail reception immediately following the last session on Monday. Explore the exhibit area and get a first-hand look at the latest pharmaceutical and biopharmaceutical technologies available.

> "As a newcomer to the pharmaceutical industry, PDA has truly helped me develop my industry skills, while also providing me with networking events to meet my professional colleagues. The New Member Breakfast was both very interesting and helpful in getting me connected—the food was even top-notch! I'd definitely recommend participating in this event if you've just joined PDA."
>
> —**Stephen Leung,** Contec; *2007 PDA Annual Meeting New Member Breakfast attendee*

Tuesday, September 25

Gala Event at the National Music Center
6:30 p.m.-9:30 p.m.

Enjoy a night of great food, dancing and entertainment with your friends and colleagues at the Historic Carnegie Library, home of the National Music Center. Engross yourself in the classic Beaux Arts architecture of the early 20th century and stride across an original map of Washington, D.C., in the Map Room, the National Music Center's elite dance floor that is lighted from below.

Visitor Information/Getting around the Nation's Capital

Washington, D.C., is one of the easiest cities to navigate and a terrific city for touring. With one of the safest, cleanest and most efficient public transportation systems in the country serviced by Metrorail® and Metrobus®, Washington, D.C.'s many attractions and neighborhoods are easily accessible. One of the best ways to experience the city's attractions, including the inspiring monuments and museums found on the National Mall as well as the intimate museums, world-class theatres and splendid gardens, squares and circles throughout the District, is on foot. A number of guided tours of the city are available.

For more information about Washington, D.C., including events, maps of the area and restaurants, visit www.washington.org.

Extend Your Learning: Attend the Japanese Regulatory Workshop

Washington, D.C. • September 26-27, 2007 • www.pda.org/pdafda2007
Robert Dana, PDA

Building on the success and outcomes of the Japanese Regulatory Workshop at PDA's Annual Meeting in March 2007, this workshop will be offered at the 2007 PDA/FDA Joint Regulatory Conference and will address regulatory topics crucial to those companies that manufacture and/or market pharmaceutical products in Japan.

Representatives from the Japanese Ministry of Health, Labor and Welfare (MHLW) and the Japanese pharmaceutical industry have been invited to present the latest information regarding the expectations of the Japanese regulatory authorities and the application of those expectations by the industry.

Topics to be covered during the Japanese Regulatory Workshop include the regulatory landscape of Japan; ICH Q8, Q9 and Q10 in Japan; and inspection programs, including areas of emphasis, examples of frequent observations and analysis of inspection findings. The program includes real-world case studies and a panel discussion that will further explore these topics.

This workshop will take place in two, half-day sessions on the afternoon of Wednesday, September 26, 2007, and the morning of Thursday, September 27, 2007.

For more information, visit www.pda.org/pdafda2007.

Conference Sept. 24-26 | Exhibition Sept. 24-25 | Training Courses Sept. 27-28

2007 PDA/FDA Joint Regulatory Conference

Evolution of the Global Regulatory Environment: A Practical Approach to Change

WASHINGTON, D.C.

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Working Words Inc. 19

PDA Meeting Examines a Changing Environment: Extracables and Leachables

Bethesda, Maryland • November 6 – 8, 2007 • www.pda.org/extractables

Committee Chair Diane Paskiet, PhD, West Monarch Analytical Labs

Drug product leachables can have a negative impact on patient safety, and, since leachables are typically a subset of extractables from processing systems and container closure systems, the physical as well as chemical attributes of the components must be defined. In addition, a drug is considered adulterated under the Federal Food, Drug and Cosmetic Act if its container is composed of any toxic substances that can pose harm to our health.

The component requirements bring about a complex array of issues for a pharmaceutical development team when selecting a system and providing appropriate leachables and extractables (L&E) information from a materials and safety perspective. The L&E landscape continues to evolve, and the recent GMP guidance document, *Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations,* has impacted the qualification process. According to CFR part 211.94: "Device containers should not be reactive, additive or absorptive as to alter the safety, identify, strength, quality or purity of the drug beyond the official or established requirements." Application of the GMP quality by design principles, design space and risk assessments have further enhanced the strategies for component qualification.

Where does industry stand now on this much-publicized L&E topic? Find out how the regulatory authorities, pharmaceutical companies, container closure suppliers and trade organizations have been working together to recognize and attempt to resolve some of these issues at the PDA Extractables/Leachables Forum: *Confronting Extractables and Leachables Issues in an Evolving Industry*, November 6-8, 2007, in Bethesda, Md. This conference will provide valuable information and industries best practices to material scientists, formulators, packaging engineers, chemists, toxicologists, quality assurance specialists, regulators and material purchasers/suppliers.

The scientific rationale for qualifying components can and has varied widely due to the diversity of the dosage forms and routes of administration and regulatory expectations. Recommendations are communicated through regulatory guidance documents, including the 1999 FDA guidance for industry, *Container Closure Systems for Packaging Human Drugs and Biologics*. Today, more than eight years later, recent regulatory expectations, new guidance documents, consensuses documents, industry guidelines, supplier interactions and the global market have caused the industry to mature beyond this guidance document.

The concept of packaging qualification has evolved relative to the efforts to modernize GMP industry experience by providing required L&E information and addressing adverse events related to container closure sources. The PDA Extractables/Leachables Forum will address the latest industry experiences in three plenary tracks: quality/regulatory, chemistry/toxicology and materials. Extractables—those species that can be forced out of container closure systems components under extreme conditions—are intended to provide information to establish the safety of the system based on the qualification of leachables—those species that have migrated or interacted with the drug product.

The chemistry/toxicology session will review the Product Quality Research Institute recommendations for safety qualification and L&E studies, which introduce the threshold concept as presented in past and upcoming workshops explaining L&E for inhalation products. The session will provide case examples as well as U.S. and EU regulatory perspectives on the application of analytical and safety thresholds used to evaluate and qualify L&E in drug products.

The materials session will focus on L&E issues related to various dosage forms and packaging systems such as oral solids, large-volume parenterals (LVP), syringes and bioprocess systems. The session will also provide discussion of the impact of material selection and supplier controls on extractables. The QA/RA track will cover current submission requirements and compliance/inspectional focus on L&E. Quality by design approaches to defining the design space for L&E for drug products will be an underlying theme. U.S. and European regulators and industry representatives will present regulatory perspectives. The applicability of quality by design approaches to L&E issues will also be covered from a quality and regulatory perspective in complementary tracks throughout the meeting.

Moheb Nasr, PhD**,** FDA, and **Kumudini Nicholas,** Health Canada, will provide keynote addresses. Panel discussions with regulatory authorities are also planned. Representatives from the PDA European chapters will attend to offer the EU perspective. An optional breakfast session, "Extractables and Leachables 101," will be offered at the conference on Tuesday, November 6, 7:00 a.m. – 8:30 a.m., as a refresher or initiation into the field of L&E. More than 25 posters will

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Plant Tour to Follow Pharmaceutical Freeze and Spray Drying Workshop

Cologne, Germany • September 11 – 12, 2007

Mark your calendar for a PDA workshop dedicated to important technologies used heavily in the pharmaceutical industry: spray drying and freeze drying. These technologies are becoming more important than ever, as an increasing number of pharmaceutically active molecules show reduced stability when stored in aqueous solution. Hear how freeze drying and spray drying can improve shelf life and how some relevant physicochemical properties of the API and pharmaceutical product can be modified. A tour of GEA Lyophil, a major equipment manufacturer, will follow the meeting.

Topics include:

- Introduction to the basics of unit operations (API/drug product characteristics, process parameters and best development strategies)
- Unit operations during the complete process, from dissolution to filling
- Liquid filling vs. powder filling and associated challenges
- Scale-up
- GMP issues

The workshop will offer a better understanding of the advantages and risks of the two technologies in the context of the complete process, and how either might offer a solution to recurrent process problems.

Micro Meeting to Explore International Pharmacopeial, continued from page 47

Morning and afternoon refreshment breaks will offer occasions for participants to visit the exhibitors and to meet with other microbiologists. On-site lunches and evening receptions will also provide ample networking opportunities. In addition, the PDA Training and Research Institute will offer several courses beginning October 31, designed to further an understanding of various aspects of pharmaceutical microbiology.

For more information on PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology and its related courses and exhibitions, visit www.pda.org/microbiology2007.

We hope you will join us for what we anticipate to be an informative and enjoyable conference.

PDA Meeting Examines a Changing Environment: Extracables and Leachables continued from page 50

be displayed showing industry's advances and representing L&E from case studies of various dosage forms and devices.

This two-and-a-half-day conference will be packed with useful information related to inhalation devices, injectables, LVP, small-volume parenterals, solid and liquid dosage forms and biotech products. For more information and to register in advance, please register online at www.pda.org/extractables.

[**Editor's note:** **Douglas Ball,** Pfizer; **Michael Gross,** PhD, Chimera Consulting; **Lee Nagao,** PhD, Drinker Biddle & Reath; **Dan Norwood,** PhD, Boehringer Ingelheim; and **Ed Smith,** PhD, Wyeth, also contributed to this article.]

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

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PDA/R³ Nordic Conference and Exhibition:

Modern Aseptic Production

7-8 November 2007 | Stockholm, Sweden

AstraZeneca Conference Centre, Södertälje

This two-day conference will provide the most current information on both the scientific and regulatory aspects of aseptic production. Hear what thought leaders have established as the most advanced production technologies and strategies. Visit AstraZeneca's most modern Blow-Fill-Seal manufacturing suite as well as its Nexium® plant at Gärtuna. Sessions will focus on:

- Designing a modern aseptic production suite
- Putting into operation a multipurpose aseptic production plant
- Latest developments in Blow-Fill-Seal manufacturing technologies
- Recent solutions to recurring microbiological challenges
- Practical interpretations of regulatory requirements in aseptic manufacturing

Register by 7 September and save!

www.pda.org/europe

Faces and Places

QbD for Pharmaceuticals • Bethesda, Maryland • May 21 – 22, 2007

(L-R) Kowid Ho, PhD, Afssaps, who spoke on "Developing EU Perspectives for Biologicals," with PDA President Bob Myers and Program Co-Chairs Rebecca Devine, PhD, Consultant, and Anurag Rathore, PhD, Amgen

(L-R) Opening Plenary Session: QbD from Past to Present: Moderator Gail Sofer, GE Healthcare; Harry Lam, PhD, Genentech; Tony Mire-Sluis, PhD, Amgen; David Narum, PhD, NIH

Moderator Rohin Mhatre, Biogen Idec (at podium), leads Breakout Session 2: Establishing Product Design Space; pictured here (l-r) Mary Oates, PhD, Pfizer; Janet Woodcock, MD, FDA; Chris Joneckis, FDA

Global PAT Conference • Bethesda, Maryland • May 22 – 23, 2007

Program Chair Michael Miller, PhD (center), poses with FDA's Joseph Famulare (left) and Moheb Nasr, PhD (right), following the Opening Plenary Session: The Case for PAT

Plenary Session 3: Case Studies – PAT in Manufacturing: (l-r) Moderator Michael Lennick, Global Biologics Supply Chain; Aaron Garrett, Eli Lilly; Bikash Chatterjee, Pharmatech Associates; Joseph Zajac, Eli Lilly

R^3 Nordic Symposium and Exhibition • Oslo, Norway • May 14 – 15, 2007

Rich Levy, PhD, PDA, presents his talk, 2007 Revision of Technical Monograph No. 1, to session attendees

Meeting attendees visit booths and talk with exhibitors at R^3 Nordic's 38th annual meeting

TRI Inspections Course Caters to Novices and Veterans

Lindsay Donofrio, PDA

At this year's Annual Meeting in Las Vegas, Nev., I attended the Training and Research Institute (TRI) course "Preparing for and Managing U.S. FDA Inspections." The session's instructors **David Chesney** and **Paul McKim,** both former FDA inspectors, provided an interactive and comprehensive two-day course, which included an introduction to the FDA's organization and terminology, FDA inspection procedures, logistics of managing an FDA inspection and common regulatory sanctions that may result from inspections.

Thirteen professionals from fields throughout the industry attended the course. While the students' titles varied from a QA training specialist to an assistant vice president of compliance to a manufacturing manager, Chesney and McKim held attendees' interests the entirety of the program with practical lectures, attention-grabbing anecdotes and thought-provoking case studies.

The tremendous amount of discussion not only between the students and the faculty but among the students was a testimony to the course's success. As a PDA staff member turned TRI student, I gained a first-hand look at why TRI is so successful. The intimate course setting accompanied by knowledgeable and experienced faculty resulted in an invaluable experience for class participants and for me.

As someone relatively new to the industry, I was impressed at how well the instructors reviewed basic information about the FDA, yet at a pace that kept the most experienced students in the class engaged. When the course moved on to the specifics of managing an inspection, enough information had already been covered that even a novice like me could follow along easily.

In the end, many students commented that they had taken other courses on preparing for FDA inspections, but none had been as beneficial as this TRI course.

For sure, all participants returned to their companies—large and small—better equipped to prepare for and manage an FDA inspection.

About the Instructors

The success of many TRI courses is due largely to the quality of the faculty. "Preparing for and Managing FDA Inspections" is no exception.

David Chesney is Vice President of Strategic Compliance for PAREXEL Consulting. Prior to joining the firm, he served 23 years with the U.S. FDA. He began his FDA career in 1972 at the Boston District Office as an Investigator. In 1991 he was appointed as the District Director in FDA's San Francisco District Office. Chesney also served as an FDA Law and Evidence Development Instructor at the national level for over ten years. Since joining PAREXEL, he has provided GMP and FDA inspection readiness consulting, auditing and training services to clients worldwide.

Paul McKim is a Vice President with PAREXEL Consulting. As a consultant, McKim has directed and consulted on successful compliance remediation programs for facilities under consent decree and license suspension. Prior to joining PAREXEL, McKim was the FDA Director of Investigations in San Francisco where he planned, organized and directed FDA investigations and inspections related to the Food, Drug, and Cosmetic Act and the Public Health Service Act. With 29 years of professional experience, he has consulted, taught and lectured in eight countries in Europe and North America.

2007 PDA/FDA Joint Regulatory Conference Training Courses

September 27

A Comprehensive Guide to OOS Regulations, Lynn Torbeck, *Torbeck and Associates*

Biopharmaceutical QA/QC Strategy for Senior Management, John Geigert, PhD, RAC, *Biopharmaceutical Quality Solutions*

Change Control: A Practical Workshop, Peter Smith, *PAREXEL Consulting*

Pharmaceutical Cold Chain Distribution Best Practices (New Course!), Tom Pringle, *SCA Packaging North America*

September 27 – 28

API – Qualification and Validation of API Facilities and Processes, Daniel Gold, PhD, *D.H. Gold Associates*

September 28

ANSI/ASQ Z1.4 Attribute Inspection Sampling in a CGMP Environment, Lynn Torbeck, *Torbeck and Associates*

The Basics of Auditing (New Course!), Elaine Lehecka Pratt, *Lehecka Pratt Associates*

Preparing for Regulatory Inspections for the FDA and EMEA (New Course!), Peter Smith, *PAREXEL Consulting*

What Every Biotech Startup Needs to Know About CMC, John Geigert, PhD, RAC, *Biopharmaceutical Quality Solutions*

For more information, please contact **Jessica Petree,** PDA, at +1 (301) 656-5900, ext. 200

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For more information on our TSB or any other of our full line of microbiology products and process solutions please call us at 800-222-0342 or visit our website.

www.emdchemicals.com/microbiology

EMD

Visit us at the 2007 PDA/FDA Joint Regulatory Conference in Washington, DC, Sept. 24–25 — Table 74

After evaluating 25 vendors, the European Medicines Agency (EMEA) selects TrackWise as its enterprise Quality Management System (QMS).

Claus Christiansen...
Integrated Quality Management Auditor for the EMEA,
gave these reasons for the selection:

- "Quick and smooth implementation."
- "Overall breadth of the TrackWise solution."
- "Ease of configuration."
- "Ability to integrate with existing software."
- "Audit trail and electronic signature."
- "Pharmaceutical industry experience."
- "Manages critical quality processes and global risk analysis."

TRACKWISE®
The Ultimate Quality Management Software

ABOUT THE EMEA

The European Medicines Agency coordinates the evaluation and supervision of medicinal products for its 25 European Union (EU) member states. It has implemented TrackWise to replace paper based and spreadsheet systems used by the agency to manage its quality processes. Implementation took only four months, meeting set timetables and budget goals.

ABOUT SPARTA SYSTEMS' TRACKWISE SOFTWARE

Sparta Systems is the recognized global leader for enterprise quality and compliance management software. Over 200 companies and 300,000 users rely on TrackWise, including quality assurance, manufacturing, customer support and regulatory professionals. TrackWise is a complete solution with unlimited flexibility to meet the precise needs of each customer. Sparta Systems also offers full support services and best practices for implementation.

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SW-1522

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