Volume XL, No. 4

PDA Letter

April 2004

A Monthly Communication for the Members of PDA—An International Association for Pharmaceutical and Biopharmaceutical Science and Technology

PDA IGs Report from Basel, page 8

Two Great PDA Meetings Bloom This May!

Serving Our Members in the Pacific Rim—Singapore Congress

May 17–21 • The Ritz-Carlton Millenia • Singapore

No other event in the Pacific Rim this year will bring together regulators, industry experts, and academics for podium talks, exhibits and training like the 2004 PDA Pharmaceutical and Biopharmaceutical Manufacturing Science and Technology Congress, Training Courses and Exhibition.

Just Announced! Former PDA President **Edmund M. Fry** (now VP Compliance, IVAX Pharmaceuticals) will discuss U.S. inspection trends and the latest and most important compliance issues facing drug manufacturers doing business in the U.S.

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Training Trainers—The 5th Biennial PDA Training Conference

May 16–21 • Westin Rio Mar • Puerto Rico

CGMP and technical trainers: Don't miss PDA's premier conference designed just for you! This is one of PDA's most popular conferences. In 2002, over 200 participants from around the world attended. This year's conference is expected to draw an even larger group of experienced trainers.

Come and enhance your skills, learn new techniques, network with peers and **choose the winners of the 2004 PDA Trainer's Choice Awards!**

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Time is running out. Register for these events now at www.pda.org.

India: A Billion Opportunities For PDA and Its Members

PDA proudly announces the formation of its newest Chapter, which will serve the world's second most populous country and fourth largest pharmaceutical market—India.

The request for a Chapter by PDA members in India confirms the commitment of that country's pharmaceutical industry to improve the quality of their products and expand product pipelines.

Already one of the most important exporters of active pharmaceutical ingredients (APIs), India's domestic drug market is growing rapidly, as is PDA membership—up nearly 60% since 2001. To better serve these members, the PDA Board of Directors agreed to charter the India Chapter in February.

The India Chapter will connect pharmaceutical professionals from across the country, facilitate their participation in PDA activities and help them benefit from the scientific, technical and regulatory services PDA offers.

Formation of the Chapter comes at a time when the Indian pharmaceutical industry is undergoing a comprehensive transformation involving: **(1)** the liberalization of the marketplace, **(2)** the expansion of domestic product pipelines, **(3)** the refinement of quality manufacturing standards, and **(4)** an overhaul of the regulatory system. These changes are challenging PDA members in India to, among other things, conform with global GMP standards as established by countries like Japan, the EU and the U.S., and upgrade to state-of-the-art manufacturing and quality control technologies and processes.

PDA, a leader in advancing science, technology and regulatory education in the pharmaceutical industry, is uniquely situated to help India's pharma professionals meet these challenges.

A Changing & Important Market

Currently one of the world's largest exporters of APIs, India's domestic market for finished drug products is expanding nearly 10% a year. According to some estimates, India currently ranks as the world's fourth largest pharma market in terms of overall volume and 13th in terms of sales.[1] The industry is regarded by the government of India as the country's most important science-based industry.

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PDA Letter

Important Dates...

- **April 26**—FDA to require certain human drugs and biological product labels to carry bar codes, page 15
- **May 16–21**—5th Biennial PDA Training Conference, cover
- **May 17–21**—Singapore Congress, cover
- **June 1**—EMEA xenogeneic cell therapy medicinal products "points to consider" document becomes effective
- **June 8**—FDA E-Labeling Rule becomes effective
- **July 1**—EMEA Note for Guidance on Minimising Risk of TSE becomes applicable
- **July 5**—Deadline for public comment on FDA CDER Draft Guidance on CMC submissions for drug substances

Advertising Deadline: 1st of each month prior to issue date. Contact Nahid Kiani at kiani@pda.org or +1 (301) 656-5900 ext. 128.

IN THIS ISSUE...

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Neal G. Koller
PDA President

President's Message

The 2004 PDA Annual Meeting: PDA Science and Technology at Its Best!

I am pleased to share with all of you the following quotes from conference evaluation forms about the 2004 SciTech Summit™ and Annual Meeting:

> "This was by far one of the best conferences hosted by PDA that I have attended in the past three years…The content was timely and informative…Those who chose not to attend missed a great opportunity…Please continue to have content of conferences at this level."
>
> "The content…was an improvement over past years."
>
> "Conference content excellent."
>
> "Many [hot topics] were well covered."

This is not to say that everything was exceptional with our first springtime Annual Meeting. For a number of reasons, attendance was below expectations; many members missed an outstanding educational and networking opportunity. Nevertheless, the content of the 2004 program reaffirmed PDA's leadership role in delivering the latest science and technology to the pharmaceutical and biopharmaceutical communities.

A major highlight was the presentation by Roger L. Williams, MD, United States Pharmacopeia CEO and Executive Vice President, updating Delegates on USP's progress to align its nomenclature with that of the International Conference on Harmonization (ICH) and on the harmonization work being carried out via the Pharmacopeial Discussion Group.

An additional highlight was the introduction of PDA's New, Innovative Technologies™ (NIT™) Exhibition Program. NIT™ is our most recent science and technology initiative that utilizes the PDA peer review system to bring the latest innovations to the membership ('latest' meaning introduced either 12 months prior to or 12 months after the conference). I previewed the program in the March PDA Letter. PDA wishes these companies well in their new technology launches and congratulates them for being selected as 2004 NIT™ exhibitors. I encourage all members to visit www.pda.org/exhibits/NIT.html to learn more about the winners and the NIT™ Exhibition Program.

The Conference opened Monday, March 8, with the Disney Institute's Joel Strack, Business Programs Facilitator, engaging and teaching the audience new systems and methods to develop their and their organization's creativity and productivity.

Mr. Strack's message was the perfect launch to the conference that allowed delegates to explore new pharmaceutical and biopharmaceutical science and technology, quality and regulatory issues. Delegates participated in engaging discussions on new manufacturing technologies, innovative delivery systems, nanotechnologies, and much more.

No surprise for PDA, we continued our leadership in aseptic processing; sessions on this topic drew large audiences. Delegates learned first-hand about two new pre-sterilized, closed vial filling operations and their potential to improve sterility assurance and reduce operating costs. Conference delegates were exposed to new methods for terminally sterilizing products and for steam sterilizing bioreactors and related bio-processing equipment. These presentations offered conference attendees insight into and concrete methods to potentially improve the efficiency and quality of their current processes.

A number of presenters reviewed the latest regulatory requirements and issues for aseptic processing. Stephen Bellis, Senior Manager, Global Compliance Management Group, AstraZeneca, compared and contrasted guidance in this area from the U.S. FDA and the EMEA. A progress report on FDA's aseptic processing guidance was given by Richard Friedman, CDER Office of Compliance, Team Leader – Guidance and Policy Team.

Following more than 80 presentations on new science, technology and regulatory developments, D.F. Chowdhury, Project Manager, Manufacturing Operations, Alphon Corporation, closed the conference with a forward looking view of how nanotechnology is already changing the pharmaceutical and biopharmaceutical industries. Chowdhury is the leader of the European Branch of PDA's newest Interest Group, Nanotechnology (*see p. 8 for information on this group's inaugural meeting at the 2004 PDA International Congress*).

In addition to the conference, PDA members devoted time to the Association's critical science, technology and regulatory functions through multiple PDA committee, Interest Group and Task Force meetings.

PDA's two leading peer-review committees, the Science Advisory Board (SAB) and Regulatory Affairs and Quality Committee (RAQC), met. SAB, the steering committee for PDA's science and technology agenda, continued its dedicated work on critical science and technology progressing research and technical reports, including finalization and publication of revised Technical Report #1, revised Technical Report #32 and a number of new Technical Reports for the PDA community. Likewise, RAQC assembled to establish

continues on page 7

Call for Case Studies

The *PDA Letter* is looking for **case studies**. Have you successfully implemented a new technology or test method? Used a new regulatory guidance? Submitted a monograph to a pharmacopeia? Validated a system? Saved resources by using an Audit Repository Center audit? Managed a recall situation? Or accomplished anything else that may be of interest to fellow PDA members? If so, tell us all about it.

The *PDA Letter* wants to publish scientific and regulatory case studies, about 1,000–2,000 words in length. Contact PDA Senior Editor Walter Morris with inquiries at **morris@pda.org** or send submissions directly to **submissions_pdaletter@pda.org**. In the subject line, please write, "Submission for PDA Letter." We look forward to receiving your case studies.

European Members
Don't miss a great opportunity to explore science and technology issues in filtration.

Join the **Filtration Interest Group** Discussions —European Branch, see p. 8

Upcoming Changes

The **"Calendar of Events"** will move permanently from the back page of the *PDA Letter* beginning with the June edition. Since the PDA calendar is maintained and updated regularly on the PDA Web site, the calendar published in the *PDA Letter* is dated by the time it reaches readers' hands. Also, the current unified calendar format, listing all courses and events, is hard to follow. Starting with the June edition, **department-specific calendars** will appear in the *PDA Letter*—one for Programs and Meetings, one for Chapter Events and the third for the PDA Training and Research Institute—and will appear in the appropriate sections of the newsletter.

On PDA.org

The PDA **"Calendar of Events"** is available on PDA's Web site and is updated regularly, as are **registration forms** for all PDA events and the **membership application** and **renewal form**.

Need a PDA technical book or want to see what is available? Don't forget to visit the **PDA Publications E-store**—a one-stop shop for the largest selection of scientific, technical and regulatory resources PDA has offered in its 58-year history. The link to the PDA Publications E-store is on the left-hand side of PDA.org. ■

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https://www.pda.org/pubs/publications/publications_search.asp

***President's Message**, from page 6*

several new task forces for ICH, to review a number of FDA and WHO documents and planned activities to further support health authority/industry initiatives around the world.

Almost all of the PDA Interest Groups gathered during the conference to discuss issues and hear and respond to presentations. Interest groups represent the foundation upon which most of PDA's science and technology initiatives are built. These groups focus PDA's resource to advance the knowledge for future technical publications, including Technical Reports, Points-To-Consider Papers, Concept Papers and *PDA Journal of Pharmaceutical Science and Technology* articles.

A number of PDA task forces, including Lyophilization Validation, Depth Filtration and Viral Removal Filters, also met. Each Task Force discussed specific scientific topics and made decisions on Points-To-Consider Papers, Concept Papers and Technical Reports.

Thursday and Friday were devoted to PDA Training and Research Institute (TRI) courses. Industry professionals were able to capitalize on the TRI courses to take home practical solutions on subjects ranging from new techniques for validating cleaning and disinfection programs, to the ins and outs of environmental monitoring, to the how's of performing thorough compliance audits for cleanrooms and controlled environments.

On behalf of PDA, I would like to thank all the PDA members who attended, all the presenters and moderators for their hard work and all the PDA staff who contributed to the 2004 SciTech Summit™ and Annual Meeting. Especially, I would like to acknowledge the hard work of the program planning committee for delivering the strong program content and their companies for lending PDA their valuable time: Chairs Lisa Skeens (Baxter) and John Shabushnig (Pfizer), Jeffrey Baker (Eli Lilly), Aaron Bartolone (Eli Lilly), E.J. Brandreth (BioMarin Pharmaceutical), Patrice Cloué (La Calhene), Raymond Colton (Validation Resources), Doris Conrad (GlaxoSmithKline), Robert Dana (Elkhorn Associates), Michael Eakins (Eakins & Associates), Kathleen Greene (Novartis), Louise Henry (Vertex), Maik Jornitz (Sartorious), Ronald Kraus (KMI/PAREXEL), Michael Levans (PennWell), Jennifer Marsh (Eli Lilly), Jerold Martin (Pall Life Science Biopharmaceuticals), John McKenney (SEC Associates), Armen Nahabedian (Wyeth BioPharma), Brian Neely (Don Hill & Associates), Anurag Rathore (Amgen), and Robert Seely (Amgen). Again, our deepest thanks for your contributions.

PDA members can be proud of the science, technology and educational content of the 2004 PDA SciTech Summit™ and Annual Meeting. We look forward to seeing you next spring for the 2005 PDA Annual Meeting. ■

IG Reports From the 2004 PDA International Congress, Basel, Switzerland

Three Inaugural Meetings • A Call For Volunteers • A Refined Agenda

At the 2004 PDA International Congress, Courses and Tabletop Exhibition, the European Branches of several PDA Interest Groups assembled to review current issues. The following groups have submitted reviews of their sessions:

☆☆☆☆☆☆☆☆☆☆
New Interest Group

Nanotechnology Interest Group—European Branch

Leader: **D.F. Chowdhury, Project Manager, Aphton Corporation**
E-mail: **fazc@aol.com**

PDA's new Nanotechnology Interest Group held its inaugural meeting at the 2004 PDA International Congress in Basel. Currently, the European Branch is the first group of PDA members to form an IG on this important advanced technology.

Group leader Chowdhury provided an introduction to nanotechnology and its diverse applications in the pharmaceutical industry, including "nanomedicine." He emphasized that this technological revolution is relevant to PDA members and discussed the role they can play to ensure the successful transition of projects from development stages to the market. Better-known nanotechnologies already have found a niche in the industry. Colloidal milling, for one, produces crystals of the nanometer particle size range, thus 'passively' utilizing the enhanced properties by virtue of being at the nanoscale. This technology can help drug developers improve solubility of difficult-to-formulate drugs.

Next, Chowdhury provided examples of the areas that encompass "nanomedicine," including diagnostics, drug delivery, tissue regeneration and gene therapy. Three examples were discussed emphasizing the diversity of applications, including the use of quantum dots in HIV diagnosis and therapy, optically tunable nanoparticles for cancer therapy and the "bio-capsule" for the self-regulated delivery of insulin.

Furthermore, he discussed how the industry should expect highly sophisticated micro- and nanosystems of the future to develop. He specifically cited the use of nanotechnology to provide diagnosis and delivery of a therapeutic agent all within a single system, perhaps even with continuous remote feedback to a physician or some other central monitoring station.

Single systems like the one cited will further blur the distinction between products of different classifications. As medical products become smaller, classification is expected to become increasingly difficult and confusing. Manufacturers are increasingly capable of combining different types of components to produce a single therapy. The blurring of the "mechanical," "chemical" and "biological" will make it difficult to determine whether a product is a drug, device, biologic or combination product.

In conclusion, Chowdhury stated that there is a need for very early and strong collaboration between industry, academia and the regulatory bodies. Participants agreed that the PDA Nanotechnology Interest Group will play a key role facilitating this.

The second speaker was Dr. Kaspar Baenziger, Department of Physics & Astronomy, University of Basel, who gave a comprehensive description of the nanotechnology initiatives in Switzerland and, in particular, the University of Basel.

Dr. Baenziger noted that "Nanoscale Science" is a National Center of Competence in Research (NCCR), a long-term interdisciplinary research effort focusing on nanoscale structures. The NCCR aims to provide new impact and ideas for the life sciences, the sustainable use of resources, and information and communication technologies.

Within the NCCR, the University of Basel has taken the lead role by maintaining a network of universities, federal research institutes and industrial partners in which scientists from a wide variety of disciplines work closely together. The various research groups focus on the following five subject areas:

- Impact of nanoscale science on life sciences and medicine;
- Molecular machinery and nanorobotics;
- Quantum devices and systems for computing and communication;
- Nanoscale science at the ultimate limits; and
- Nanomaterials ranging from biological systems, carbon-nanotubes to nanoclusters.

More information on this NCCR is available on the Web at: www.nccr-nano.org.

Filtration Interest Group—European Branch

Leader: **Roger Seiler, Manager Business Development, Sartorius**
E-mail: **roger.seiler@sartorius.com**

The European Branch of PDA's Filtration Interest Group held its inaugural meeting at the 2004 PDA International Congress in Basel.

While 15 people attended, there was a noticeable absence of representatives from

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PDA

An International Association For Pharmaceutical Science And Technology

PDA Journal of Pharmaceutical Science and Technology

Call for Papers

From Lee Kirsch, Ph.D., Editor

The *PDA Journal of Pharmaceutical Science and Technology* is one of a few peer-reviewed, widely recognized and respected journals dedicated to the scientific foundations of pharmaceutical product development, manufacturing and quality assurance. It has served to legitimize pharmaceutical product quality practices and to introduce new methods, concepts and technologies into the field.

The *Journal* has historically served both the PDA membership and their colleagues well for over 50 years. Its continued success depends on your participation by submitting research articles and relevant commentary, by encouraging your colleagues to submit their work and by your willingness to participate in the peer-review process.

As Editor of the *PDA Journal*, I am delighted to have the opportunity to serve the PDA membership by facilitating the publication of worthy contributions in their well-respected and oft-cited journal. I welcome the suggestions, comments and advice of the *Journal*'s readers and contributors.

More information about the *Journal*, including author guidelines, is available at www.pda.org/journal/index.html Send manuscripts to:

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Recent Sci-Tech Discussions

"Thermal Mapping of Warehouse" & "USP Testing"

The following, unedited remarks are taken from the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum at www.pda.org. PDA Online Forums are free of charge and open to the public. They serve as a platform for exchanging practical and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. If you are not currently a member of a discussion group, we encourage you to visit our Web site and join.

This month's posting...

Question 1

Does anyone have any experience with or references on thermal or temperature mapping of a warehouse? For how long should the room be mapped—24 hours or a week? Should it be done every quarter in order to assess seasonal variation?

Response 1

When we have temperature mapped warehouses in the past it has been over a one week period as a minimum. This to ensure that any weekend differences are covered. The thermal mapping should be in a matrix covering the warehouse storage space and should include:

- Checking data against the installed monitoring devices.
- Checking warehouse operations, doors opening loading and unloading operations. Therefore logging these operations.
- Checking installed alarms speed of response.

We have only once been asked to check in summer and winter to check on any seasonal differences. I think it would be good practice to do this at least once.

This is our experience of what companies are doing in the UK and Ireland.

Response 2

For warehouses there are only two really critical points of concern that need to be mapped—at the top shelf (just below the roof line)—which is the summer time "hot spot," and near the loading dock—which is the winter time "cold spot."

Constant monitoring at these two extremes should be all the monitoring you need for a general warehouse.

Response 3

Seasonal assessments are really a mandatory thing depending on what it is that is being stored and what the temperature and humidity requirements are. I usually like to start the mapping process in the middle of the week and run it to the middle of the following week. That way you get the weekend and you also get to see what happens when the work week starts.

Be sure that you have sufficient instruments for recording. What I have used in the past is at least five devices (like DataTracers, etc.) every 10 feet of vertical space. One near each corner and one in the middle. In a one story area that would be 10 tracers minimum, one set at floor level and the other at ceiling level.

I did supply a quote on a warehouse once that was huge (300'L x 75'W x 90'H). This required a minimum of 50 devices.

Response 4

We have done temperature mapping for warehouses with data loggers recording every 10 minutes for 7 days. Winter and summer only (don't let people talk you into mapping spring and fall too. Waste of time). The EMEA was expecting to see such studies and I believe it was triggered from a one line requirement in a WHO guideline that warehouses should be mapped. I can't put my hands on the WHO document at the moment but it is very short (only 2 pages).

You are really confirming known hot and cold spots in a warehouse. It's also good information to have to support the placement of temperature sensors of a building automation system if you are using one to monitor your warehouse.

Response 5

Please refer to the Sept.–Oct. 2003 *Pharmacopeial Forum*. There is a new general chapter <1079> Good Storage and Shipping Practices. There is a section on how to establish temperature profiles of the warehouse. It discusses placing a suitable number of monitoring devices throughout the warehouse in divided sections and recording the maximum and minimum temperature achieved during a 24 hour period for a total of 3 consecutive 24 hour periods. The exercise should be conducted in summer and winter seasons. When one profiles, the size of the warehouse and conditions that give rise to extreme temperature (such as locations) should be considered. Even though this is a draft proposal out for public review and comment, it does provide some good sense procedures to use as a reference.

Question 2

Our QA is insisting that errors in the USP tests are not to be propagating in the final calculation and that a single number is to be given, without the errors. I'm just assuming that errors are given uncertainties.

For example, in the USP assay for phenol you make an internal standard solution out of 1ml (+/- error) benzyl alcohol and add methanol to balance in a 500ml flask (+/- error). Next dissolve

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IG Reports, *from page 8*

pharmaceutical companies—only two. The remainder were either from the filter manufacturers (Millipore, Pall and Sartorius) or the U.S. FDA (Kurt Brorson, Staff Scientist, CDER).

During the meeting, we pinpointed the following topics and points of interest:

- Double sterile filtration in Europe;
- Different handling of sterile filters at Up- and Down-Stream Filtration;
- Handling of hydrophobic gas filters with respect to the dryness level; and
- Handling of sterile filters within sterile bulk manufacturing.

Note from Branch Leader: As a moderator of this section, I am of the impression that we have identified a set of good and valuable topics! However, as every participant in this meeting clearly stated, if we do not get enough participants from the pharmaceutical industry to participate in future filtration interest group meetings, this valuable platform should not be continued! It makes absolutely no sense to only have representatives from the filter manufacturers at such a platform.

I therefore request that PDA makes a respective announcement and a call for volunteers for this interest group in the next two or three *PDA Letters*. Only if we can attract enough people from the pharmaceutical industries we can go any further here.

[**Editor's Note:** Roger, PDA hears you and agrees. See page 7!]

Biotechnology Interest Group—European Branch

Leader: **Roland Günther, Biotech Global CMC Coordinator, Novartis**
E-mail: **roland.guenther@pharma.novartis.com**

A summary was given of the "kick-off" meeting for the European Branch of the Biotechnology IG, held in Langen, Germany in October.

At the meeting, participants chose several topics to be covered by the interest group and selected PDA members to lead activities:

- Biosafety (headed by Hannelore Willkommen, Ph.D., VP, Regulatory Affairs–Europe, Clearant, U.S.);
- Harmonization (Joachim Leube, Ph.D., Head, QA/QC, Bayer Biologics, Italy);
- New technologies and source materials, down-stream processing (Philip Blosse, Ph.D., Director, Technical Services, Pall Life Sciences, UK);
- Up-stream processing (Clive Hayler, Director, Primarius Limited, UK);
- Cell banks(Clive Hayler);
- Fermentation (Clive Hayler); and
- Non-human blood and plasma (Leader to be identified).

It was agreed at Langen that the European Branch of the Biotechnology IG will hold a biotech forum on "Harmonization and TSE requirements." The forum is a joint-effort between PDA members active in this IG and in the PDA Italy Chapter. It is scheduled for Monday, May 24, 2004, in Rome. At this one-day forum, presentations will cover the different requirements in Europe, the U.S. and other geographical regions. For detailed information, please contact Dr. Leube via e-mail at joachim.leube.jl@bayer-ag.de.

Further down the road, the Biotechnology IG European Branch has scheduled a meeting on biosafety for September 27, in Basel. Specific topics of discussion may include:

- Methods for virus testing;
- Methods for virus inactivation;
- Virus clearance studies;
- Relevant viruses for virus safety evaluation; and
- Risk assessment of the manufacturing process.

This Forum will be organized by Dr. Willkommen, who can be reached via e-mail at hwillkommen@clearant.com.

Next, participants of the session at the February International Congress refined the list of specific topics to be covered by the European Branch. The list now includes the following…

technical/scientific topics:

- Biosafety,
- Comparability,
- Immunogenicity,
- Protein aggregation (test methods and clinical impact),
- Impurity testing,
- Transgenic production systems (animals/plants), and
- Validation of bioanalytical methods;

regulatory topics:

- CMC requirements for clinical trials (Europe vs. the U.S.),
- ICH "Q5E" on biopharmaceutical comparability, and
- generic biotech products; and

QA/GMP topic:

- GMP requirements: Europe vs. the U.S. (e.g. process validation).

Additionally, the organization of future IG meetings was discussed. If possible, the Biotech IG—European Branch should always meet

continues on page 13

Recent Sci-Tech Discussions, *from page 10*

75mg (+/- error) phenol in 7.5 (+/-error) ml methanol in a 100ml flask. Add 20ml (+/-error) of previous solution to flask; add water to volume (+/- error) and mix.

Take 3µL (+/- error) and measure the area under the peaks (+/-) error (from validation) for phenol and Benzyl Alcohol and designate them as P1 and P2 respectively (standard). Do the same for test preparation and label them p1 and p2. This will have error as well.

My contention is that all the errors need to be propagated into the final calculation of the phenol solution

100*(C/V)*(p1/p2)*(P2/P1)

And the result needs to be reported as value +/- error from propagation.

Response 1

Please inform your QA that:

1. The USP "criteria" for reporting do NOT apply to materials and/or drug products UNLESS they are "in commerce" and, in general, a "grab sample" ("the article") of the material or the drug product is evaluated using the appropriate USP monograph's procedures.
2. For all materials covered by cGMP (in-coming, in-process, and release, stability, and, in cases involving "reserve" evaluation, complaint evaluations), what a drug product manufacturer does for such is required to be SCIENTIFICALLY SOUND and APPROPRIATE (21 CFR 211.160(b)).

   "Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: ..."

As you have rightly shown and a previous posting of mine stated, all result values are uncertain and it is not scientifically sound to report some "average" result value without its reporting the uncertainty in that result value just as it is not scientifically sound to make a singlicate measurement in a way that precludes any valid estimation of the uncertainty in the measurements used to compute a result value.

Fundamentally, your contention is supported by the sound science incorporated into the beginning "quantitative analysis" courses in any recognized college or university Chemistry program.

In some cases, such as material purity, you may be justified in reporting the MINIMUM purity and your confidence in that MINIMUM purity instead of reporting the calculated "mean" purity value and its "nn % confidence level" confidence-interval limits about your "mean" estimate of its purity.

Such as they are, the USP's procedures governing the reporting of result values:

a) ONLY apply to "in commerce" raw materials and drug products and
b) are NOT required to be scientifically sound.

Hopefully, the preceding will assist you in your attempt to educate your QA with respect to both sound analytical science and the applicable drug product cGMP regulations.

P.S.: You may want to have your QA read the USP General Notices section that clearly states that:

a) the USP monographs ONLY apply to the "in commerce" entity or entities defined in the USP monograph,
b) the sampling plans used are not statistical sampling plans, and
c) in general, other tests should be used for in-process and batch-release testing.

Response 2

The USP test results are reported with an error that is either calculated from the repetitions of the measurements or it was assessed by the validation of the assay in your laboratory. Both are holistic approaches. It is possible to measure the error of any single procedure and compile the final error. I did this in the past, it give a fairly good match with the holistic results. If you decide to use the error propagation (I think it is a very clumsy approach), than the error propagation is the square root of the sum of squares of the single errors (look the exact formula up). I recommend to stick with the results of your multiple measurements or with the error estimate that was obtained from the validation (USP - methods have to be validated for the use in the specific laboratory just as any method transfer).

Response 3

Actually, the point I was trying to get to was that any result needs to report the errors associated with it. The main use for propagation (I believe) is for calculation of yields (I know, this is not analytical) however, I believe with multiple samples, the error of those samples or the validation error should be calculated and reported (including N samples and Standard Deviation) or Confidence Interval.

Response 4

I agree with you that any reporting of a QUANTITATIVE analytical result should, AT A MINIMUM, include the result value, the standard deviation, and the number of measurements used to compute both the "mean" result value and its uncertainty.

Reporting that the Assay of a sample is "100 %" of the target values does not convey any estimate of the validity (quality) of that result.

When the permitted range is, for example, from "95 %" to "105 %," is it the result of averaging:

a. "99.0" and "101."
b. "95.5 %" and "104.5 %," or
c. "99.5," "99.7," and "100.8"?

At a minimum, the precision of each of the three preceding "100 %" results is very different.

Moreover, each predicts a very different distribution of values in the population from which the samples were taken.

After all, we both would rather receive lot of API with an assigned "as is" weight-percent purity of 98.5 +/- 0.5 % than one with an assigned "as is" weight-percent purity of 98. +/-1.9 % or worse, as many suppliers do, a "USP Assay" of 98.5 %.

Hopefully, your notes and those of others such as myself will help the group to see not only the necessity of, at a minimum, reporting the result, its uncertainty, and the number of measurements made but also the value of receiving such in the Certificates or Reports of Analysis that he or she receives from his or her suppliers. ■

IG Reports, *from page 11*

following forums with biotech topics. To discuss the organizational structure of the IG in more detail, a separate meeting for interested people will be conducted by the end of April in Basel.

Visual Inspections—European Branch

Leader: **Markus Lankers, Ph.D., Head, R&D, APSYS GmbH**
E-mail: **markus.lankers@apsys.de**

This was the inaugural meeting of the European Branch of the Visual Inspection Interest Group. Fifteen participants shared their experiences at this meeting.

After a brief opening by group leader Markus Lankers, a summary of regulatory news and a ranking of the most interesting topics in the field of visual inspection was specified. Besides the common topics in visual inspection like validation and inspector training documentation, most of the attendees were interested in the review of regulatory guidelines and uncertainties. One particular concern is the commonly used phrase, "essentially free from visible foreign particles."

In the discussion, it was found that an exchange of experiences on how to handle false rejects and how to define minor, major and critical defects would be very helpful. The exchange of reject rates and root cost should be addressed in a session, perhaps a Q&A, at the next meeting of the European Branch.

Special interest was also focused on the inspection of specialized containers, like syringes and blow-fill-seal units, and on dosage forms, like suspensions and sterile powder.

Lastly, participants discussed an upcoming workshop on visual inspections, planned for October 4–5 in Berlin, Germany. It was agreed that all the issues raised at the Basel meeting should be topics on the agenda for that meeting. ■

PDA Interest Groups & Leaders

The following is a list of PDA Interest Groups (IGs). Starting in 2004, PDA began establishing "Branches" of each IG in the various regions of the world that we serve. The list below includes the names of the Leaders for each Branch of the IG, the Leader's affiliation and their e-mail address. More detailed information on PDA's Interest Groups and contact information is available on the PDA Web site at: www.pda.org/science/IGs.html.

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Regulatory Briefs

Important Dates

April 26 **FDA** to require certain human drugs and biological product labels to carry bar codes

June 1 **EMEA** xenogeneic cell therapy medicinal products "points to consider" document becomes effective.

June 8 **FDA** E-Labeling Rule becomes effective.

July 1 **EMEA** Note for Guidance on Minimising Risk of TSE becomes applicable.

July 5 Deadline for public comment on FDA **CDER** Draft Guidance on CMC submissions for drug substances.

EMEA

EMEA Makes Available a Mock Application for a Fictitious Biotechnology Product Under Clinical Trials Directive (2001/20/EC). A mock application for a fictitious biotechnology product is now available. This is provided to give an indication of the type of information expected for a product of this type in early stage development. A copy of a completed application form and a protocol overview is also provided. The protocol overview is only intended to give an outline of the proposed trial and should not be regarded as a model for a protocol summary.

U.S. FDA

FDA To Require Certain Human Drugs and Biological Product Labels to Carry Bar Codes. The bar code for human drug products and biological products (other than blood, blood components, and devices regulated by the Center for Biologics Evaluation and Research) must contain the National Drug Code (NDC) number in a linear bar code. The rule is intended to reduce the number of medication errors in hospitals and other health care settings. The rule also requires the use of machine-readable information on blood and blood component container labels to help reduce medication errors. The rule becomes effective April 26, 2004. The complete rule is available in the Feb. 26 *Federal Register* or on the Web at: www.fda.gov/ohrms/dockets/98fr/04-4249.htm.

FDA Announces Measures to Improve Generic Drug Access. In the coming months, the Agency will provide more information to the public to help generic drug applicants determine if they are eligible for 180-day marketing exclusivity for their products. This period of marketing exclusivity is generally provided to the first generic drug that challenges a patent for the innovator product. This marketing exclusivity is an effective incentive for generic drug development provided under the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act. With better, more transparent information, generic manufacturers will be able to plan their development of additional generic products more effectively. FDA also announced a process to effectively implement the major reforms in the Hatch-Waxman law contained in the Medicare Modernization Act of December 2003.

"The steps we are announcing today will further spur the development and availability of generic drugs, which are an increasingly important way to provide the American people with safe, effective and affordable medical treatment," said FDA Commissioner Mark B. McClellan, M.D., Ph.D., at the Generic Pharmaceutical Association's 2004 Annual Conference. "We have the most competitive generic drug industry in the world with some of the lowest generic drug prices in the world, and we intend to enhance it to help consumers."

In response to two citizen petitions, FDA will now disclose on its Web site the date on which the first substantially complete generic drug application containing a challenge to a patent listed for the innovator drug was submitted to the Agency. FDA had previously posted on the Web site certain other information regarding generic drug applications. The Agency also had provided additional information in response to individual inquiries—a burdensome and ineffective approach. By displaying the submission date along with the trade and generic name of the drug, its dosage form, and the strengths of the drug products, the Agency will provide a fairer, more transparent way for all interested parties to gain access to this information.

In addition, the Agency will publish a *Federal Register* notice seeking public comment on how best to implement reforms to the Hatch-Waxman Amendments that were outlined in the recently enacted Medicare Law. These reforms are designed to clarify the conditions under which 180-day marketing exclusivity can be given. The Medicare Law also established a limit on how long approval of generic drugs can be delayed while patent rights are being litigated in court. FDA is requesting public comment within 60 days, so the Agency can continue to effectively implement these important legislative reforms that speed the approval of generics. The Agency will also issue a *Federal Register* notice revoking a regulation the Agency had issued last year that limited how long approval of a generic drug can be delayed while patent rights are litigated in court. The intent of FDA's regulation is fully reflected in the reforms to the Hatch-Waxman amendments that were subsequently enacted into law, with technical assistance from the FDA. Thus, as a result of the subsequent Congressional action, last year's regulation is no longer necessary to improve access to generics.

FDA plans to begin posting generic drug application dates soon at www.fda.gov/CDER/ogd/ppiv.htm.

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***India: A Billion Opportunities**, from cover*

With over a billion people to support, India's pharmaceutical industry is extremely large and fragmented. Some industry analysts estimate that over 20,000 drug firms currently operate there, with a mix of competitive large, less competitive medium and very small-scale producers. About 250 large companies stand at the forefront of the industry, with a 70% market share and following at least basic international quality and GMP standards. Overall, nearly half a million people are employed by the Indian pharmaceutical industry according to the Organization of Pharmaceutical Producers of India.

Indian pharmaceutical companies produce predominantly generic drugs, primarily as a result of weak product patent protection and rigid price controls. The 1970 Indian Patent Act (IPA) recognized patent protection only for manufacturing processes as opposed to the product protection found in most industrialized nations. The 1970 Drug Price Control Order (DPCO) was enacted to prevent free-pricing of medicines, ensuring that the public could purchase drugs at a reasonable rate. Both policies have discouraged new, more effective medicines from entering India's market.

India's pharmaceutical industry is extremely large and fragmented.

All this has been changing in recent years. In 2002, the Indian government started liberalizing the pharmaceutical market by reducing the number of drugs subject to price control and by opening the market to foreign investment. These changes were based on recommendations by India's Pharmaceutical Research and Development Committee, established to find ways of modernizing the pharmaceutical market.

Under the new policies, the number of drug products subject to price control has fallen from 74 in 2002 to 28 today. Those still covered by DPCO are deemed essential, such as insulin and Rifampicin (for treatment of leprosy and tuberculosis, both of which are widespread in India). The government has revised tax laws to encourage R&D and it has changed investment laws to permit 100% foreign direct investment in pharmaceutical companies. Additionally, customs duties on 88 drugs have been removed, as were duties on drugs imported for clinical trials. The complete liberalization plan is available on the Web at http://nppaindia.nic.in/may-2002/policy-02.html.

More changes will occur in 2005 when India—per commitments to the World Trade Organization—implements a product patent regime. Consumers should benefit greatly with the anticipated introduction of new and more effective therapies as a result of the new patent protection regime.

Liberalization of the market already is changing India's pharmaceutical industry. Large companies, like Ranbaxy Laboratories, Dr. Reddy's Laboratories, Cipla, Sun Pharmaceuticals, Zydus Cadila, Wockhardt and Nicholas Piramal, have begun investing heavily in R&D. Both Ranbaxy and Dr. Reddy already have succeeded in bringing new chemical entities to market. In addition, multinationals like Glaxo and Aventis have initiated marketing agreements with companies like Ranbaxy and Nicholas Piramal. Moreover, the government of India has begun targeting money for research into biopharmaceuticals and genetic/cell-based therapies.

The Quality of Public Perception

As the pharmaceutical market opens up, India's consumers face the daunting challenge of finding reliable medicines on pharmacy shelves. Counterfeits, or "spurious" drugs as officials there call them, and substandard products are flooding the marketplace. According to the government of India, about 10% of the products tested by State authorities between 1995 and 2003 were substandard and about half a percent (.05%) were counterfeit.[2]

Although its findings for counterfeits are not particularly eye-popping, the government is very concerned about counterfeits in light of international perceptions that India is a hotbed of fake drug production. For example, the U.S. Trade Representative asserted in a document called "2003 Special 301 Report" on intellectual property: "Counterfeiting is rife in the Indian marketplace, for example in the auto, pharmaceutical, consumer goods and apparel industries. Particularly troubling are extensive public health and safety risks posed by counterfeit medicines and auto parts."[3] Perception about India's market took a nosedive in 2001, when an article in *The Lancet*[4] cited a WHO statistic that India was the source of "35% of the world's production" of fake and substandard drug products on the world market.

However, international perceptions about counterfeits may be out of balance. For instance, the claim made in *The Lancet* article was unsubstantiated. In fact, the WHO representative to India, Dr. S.J. Habayeb, maintained in a letter to the Indian government (dated August 11, 2003)[5] that no WHO study exists concluding "35 percent of the world's spurious drugs are produced in India." Despite the WHO's intervention in the matter, the 35% figure is often cited in pharmaceutical, international trade and other literature.

Nevertheless, India recognizes the need to deal with the problem of substandard and counterfeit drug products. The government has initiated a study to comprehend the extent of the counterfeiting problem and to develop sound strategies to combat it.

PDA's Role

As the market continues to open and grow, India's pharmaceutical industry will be challenged to improve

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its image and the quality of the products offered.

As key players in the international API market, many of the largest pharmaceutical manufacturers in India already meet or are striving to meet cGMP standards of the WHO, the U.S. FDA, the EMEA and other health authorities worldwide. A number of these companies are looking to move beyond APIs and tap into the U.S. generic drugs market. They also want to compete for contract manufacturing business from large multinational pharmaceuticals.

This new focus on international quality control standards explains the rapid growth of PDA membership in India over the last few years. With membership growing at 20% a year since 2001, it is clear that pharmaceutical professionals in India seek the scientific, technical and regulatory education services that PDA provides.

pharmaceutical professionals in India seek the scientific, technical and regulatory education services that PDA provides.

The new India Chapter, led by Darshan Markhey, Ph.D., VP of Regulatory Affairs, Nicholas Piramal, will serve as a focal point for PDA members. As their companies seek to upgrade quality and manufacturing systems with new technologies:

- PDA's meetings and training will become invaluable resources for learning and networking; the India Chapter will arrange meetings and facilitate speakers from the U.S. FDA, the WHO, the EMEA and other health authorities.
- PDA's technical reports and other publications will help them upgrade their knowledge and advance their careers; the Chapter will promote these materials and make them more widely available.
- PDA's members in India, as they are all over the world, will become leaders within their companies and help the pharmaceutical industry continue to improve the quality of products; the Chapter will bring them together to share experiences and improve knowledge.

Besides helping to serve PDA's members in India, the Chapter will bring the best scientific and technical knowledge in India to members elsewhere. The Chapter leadership will, among other things, encourage PDA members to contribute to the *PDA Journal of Pharmaceutical Science and Technology*, attend and speak at PDA conferences, participate in Interest Groups, Task Forces and other committees, and comment on regulations from the India government and elsewhere.

Regulation: A Two-Tiered System

PDA members in India and elsewhere can play an important role in helping achieve the crucial goal of delivering safer, more effective and quality medicinal products to the Indian population.

This goal is not only shared by drug manufacturers in India, but also by its government and the international community. India's government, for example, has been seeking to improve its drug regulatory and enforcement policies for many years. Recently, the effort has gained momentum as a result of the growing international attention on substandard and counterfeit drugs.

The current system divides responsibility for enforcing India's 1940 Drugs and Cosmetic Act between the Central government and 26 State governments. India's Central Drug Standard Control Organization (CDSCO), a branch of the Indian Ministry of Health and Family Welfare, is responsible for the following:

- Approval of new drugs and clinical trials;
- Registration and control of the quality of imported pharmaceuticals;
- Establishing regulations per the Drugs and Cosmetics Act;
- Establishing standards for drugs, cosmetics, diagnostics and medical devices and updating the Indian Pharmacopeia;
- Approving licenses for the manufacture of large volume parenterals and vaccines, for the operation of blood banks; and
- Coordinating the activities of the States and advising them on uniform enforcement of the drug laws.

The States' Drug Inspectors carry out the following activities:

- Licensing manufacturing operations and retail outlets;
- Carrying out inspections of licensed facilities;
- Drawing samples for testing and monitoring of drug product quality; and
- Enforcement actions, i.e., suspension or cancellation of licenses and legal actions.

In January 2003, CDSCO formed a broad-based "expert committee" to examine all aspects of the regulatory infrastructure for drug products and define the extent of the spurious/counterfeit drug problem in the country. Members of the committee came from industry, law enforcement, the scientific community, trade and consumer groups, and relevant government agencies (Central and State levels). The expert committee published an interim report in August 2003.[6]

The expert committee wrote that the current regulatory system for pharmaceutical products is outdated and ineffective. A key observation was that enforcement of the Indian Drugs and Cosmetic Act "has been far from satisfactory" at the State level. The committee identified non-uniformity in interpretation and implementation and

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incompetence among regulatory officials as characteristics undermining adequate regulation. The committee also noted that some States have appointed a full-time, well-qualified expert to lead the drug inspectorate, while others have only administrative staffs. All States suffer from a lack of adequate staffing to handle the heavy workload, which includes inspections.

> A key observation was that enforcement of the Indian Drugs and Cosmetic Act "has been far from satisfactory" at the State level.

The committee also pointed to "inadequate or weak drug control infrastructure at all levels" as a major problem. Shortcomings include inadequate testing facilities, shortage of drug inspectors, lack of proper databases and unreliable data concerning the industry. For example, the committee wrote, only 15 of the 26 States had properly functioning drug testing laboratories. Out of those 15, only seven were "reasonably" equipped and staffed. The remainder were "poorly staffed and did not even have the bare minimum equipment."

New Central Drug Administration

To improve the regulatory structure for pharmaceuticals, most experts in India, including India's National Human Rights Commission, State authorities, Ministry of Health and Family Welfare (MHFW) and CDSCO, endorse the creation of a stronger "world class" Central Drug Authority that assumes most of the regulatory and enforcement functions currently performed by the States.

However, this concept has been raised before and no tangible action taken. In 1999, the MHFW appointed a consultant to provide solutions to the regulatory shortcomings of the Indian system. The consultant concluded, according to the 2003 expert committee report, that the government of India needed to withdraw State Governments' powers "in order to have uniform implementation of various drug laws in all the States and territories," and, instead, "vest" those powers in a centralized authority. Regardless, the government of India announced in 2002 its preference for a stronger CDSCO that would oversee the State enforcement agencies.

Despite the government's support of the dual-system, the CDSCO's expert committee noted in its 2003 report that there is broad support for a centralized system. The expert committee surveyed the 26 State authorities; 15 indicated a "definite need to strengthen the central administration." Most of the States supported centralizing the critical regulatory functions, including statutory licensing, post-market surveillance, clinical trials monitoring, promotional material regulation, regulatory and lab personnel training, and nationwide tracking.

The committee identified a number of challenges to the establishment of a centralized authority. Most daunting is the need for "significant and highly qualified human capital" and additional funds from the government of India.

International Help For India...

In the effort to revamp its regulatory system and improve the quality of drug products, the government of India will not be acting alone. In 2003, The World Bank (henceforth, the Bank) announced it would provide a $54 million (U.S.) credit to India as part of a new "Food and Drugs Capacity Building" program. The program carries three components: (1) policy development, (2) program coordination and monitoring, and (3) food safety and drugs quality and safety.[7]

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USP Update

New Monographs • New Chapters • A Search for "A Few Good Men"

The USP **guidelines for submitting** requests for revisions, including the development of new monographs, is now available on our Web site, www.usp.org. These guidelines were developed by USP staff in collaboration with the USP Council of Experts and stakeholders. The guidelines apply to USP monographs for non-complex drug substances and products, excipients, biological and biotechnological substances and products, and vaccines. These guidelines incorporate the concepts and recommendations of several International Conference on Harmonization (ICH) quality guidelines, including the impurity series (Q3A, Q3B, Q3C) and the specifications series (Q6A and Q6B).

The Jan.–Feb. 2004 *Pharmacopeial Forum* (PF) contains many interesting items. For example, the **First Interim Revision Announcement to USP 27 and NF 22** addresses monographs for gemfibrozil, loperamide hydrochloride oral solution, lovastatin and quinidine gluconate extended-release tablets. These revisions are now *official* (as of February 2, 2004).

The in-process section of the Jan.–Feb. *PF* lists **17 new proposed monographs**. Most notable are four new monographs in the blood and blood products area: antrithrombin III human, whole blood, red blood cells, and platelets. This constitutes the first entries in USP of full monographs for these products. In the NF

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The Bank will disperse the no-interest loan to the government of India over five years, ending 2009. Approximately $21 million (U.S.) will go towards: "Activities to strengthen the government's oversight and regulatory capacity for ensuring drugs quality and safety, to educate consumers on matters related to drugs quality and safety, and to upgrade related skills in the private sector."

With respect to improving the regulatory system, the program specifically targets the training of over 600 regulatory staff and of additional qualified staff, the construction and equipping of a new Central drug testing laboratory and five State labs, and the renovation and equipping of an existing Central testing lab and 12 State labs.

For the private sector, the program calls for training approximately 2,000 industry personnel in cGMPs and GLPs. The Bank also wants funding to be steered toward updating and disseminating pharmaceutical standards.

...And An Opportunity for PDA

As part of the effort to carry out the "Food and Drugs Capacity Building" program, The World Bank is calling for: "Increased participation of industry associations in government efforts to improve quality of foods and drugs." Among other things, the Bank sees a role for industry associations to conduct policy reviews, hold workshops and provide consultation. Also, associations can play a role in providing cGMP training for regulatory and private-sector personnel and in updating and disseminating pharmaceutical standards.

With its 58-year history of advancing pharmaceutical and biopharmaceutical technology internationally by promoting scientifically sound and practical technical information and education for industry and regulatory agencies, PDA can play an authoritative and constructive role in helping India implement The World Bank program. The new India Chapter, serving a growing PDA membership, will play a key role in this process. PDA members from around the world, who donate generous amounts of time volunteering to improve their industry, will find new and challenging opportunities to become involved in this process.

Over the next decade, pharmaceutical companies and PDA members alike will have a lot to look forward to in India. Most importantly, India's billion consumers will benefit greatly from a growing pharmaceutical market, a renewed focus on quality drug products, and a reforming regulatory regime. ■

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— Walter Morris, with market statistics compiled by Dr. Darshan Makhey, VP Regulatory Affairs Nicholas Piramal India Limited, and Gautam Maitra

***Regulatory Briefs**, from page 15*

WHO

The World Health Organization Releases Two Draft Guidances Addressing Bioequivalence Testing. The one document is meant to establish a general method for the dissolution testing of oral, immediate release (IR) solid drug products containing highly soluble, highly permeable drugs, as defined by the BCS (Biopharmaceutics Classification System), which could be used to evaluate the biopharmaceutical properties of the products and for quality control purposes. WHO explains in the draft that pharmacokinetic studies are often regarded as the "gold standard" to establish the bioequivalence of multisource products. However, in many countries the costs of conducting such studies are prohibitive, and in some cases, there are no laboratory facilities available to conduct them. Even in countries where these problems are not overwhelming the need for pharmacokinetic testing for every approval of a multisource product has been challenged on the basis of cost reduction and avoidance of unnecessary testing on human subjects. In response to these concerns, the U.S. FDA allows a waiver of *in vivo* bioavailability and bioequivalence testing when the following criteria are met:

1. The drug substance belongs to Class I (highly soluble, highly permeable).
2. The drug product releases at least 85% of its content within 30 minutes at pH 1.2, 4.5 and 6.8.
3. The dissolution profile of the test product is similar to that of the reference product, as shown by the f2 method.

No waiver is allowed for certain drugs with low therapeutic indices or other specific concerns. Moreover, use of excipients which may lead to decreased drug absorption may rule out the possibility of a biowaiver.

In order to establish a method that could be applied worldwide, the following points were additionally taken into consideration:

1. Use of readily available equipment.
2. Use of biorelevant media (pH, volume) and one key test condition, if possible.
3. Use of readily obtainable and inexpensive ingredients for making the media.
4. Mild agitation conditions.
5. Choice of sampling times which can be used to generate a dissolution profile for product approval purposes, with conformity to BCS specifications (85% release of label claim in 30 minutes).
6. Easy reduction of the method to one-point sampling for quality control purposes.
7. Methodology that is easy to standardize.

The second guidance announces a search of the public domain for all solubility and permeability data relevant to orally administered drugs belonging to the WHO Model List of Essential Medicines. According to the quality and consistency of the data, drugs were then either assigned to a BCS class (as defined by the FDA), given a provisional assignment, or not assigned. The basis for this study was the WHO Model List of Essential Medicines, Core List, 12th edition (revised April 2002).

Research on the solubility and permeability of the drugs on the List that are orally administered was carried out using PubMed Central, the general pharmaceutical literature and information obtained from pharmaceutical firms and authorities. Whenever possible original literature was consulted in order to evaluate the quality of the data and to make the classification as transparent as possible. Data from secondary sources were included for completeness or when original literature could not be located. ■

—compiled by Vicki Dedrick, Gautam Maitra and Walter Morris

***USP Update**, from page 21*

section, two new monographs are proposed, Alfadex and L-Asparagine. USP stakeholders are encouraged to comment on monographs of interest. New general information chapters include <1082> Genotoxicity Testing and <1184> Sensitization Testing.

Pharmacopeial harmonization continues to advance! The harmonization section of the Jan.–Feb. *PF* includes **three monographs at Stage 4** of the PDG (pharmacopeial discussion group) process, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, and magnesium stearate. In the previews section, a new monograph is proposed, pepsin, and a new general information chapter is proposed, <1092> The Dissolution Procedure: Development and Validation.

USP will be holding its first annual meeting, the USP 2004 Annual Meeting, September 27–29, at the Sheraton Woodbridge in Iselin, N.J. Check the USP Web site for additional information on the program and to register.

The **First Supplement of USP 27-NF 21 became *official* April 1, 2004**, unless otherwise indicated. The first supplement has 30 new monographs.

USP is calling for candidates for the 2005–2010 Revision Cycle. You can apply on-line at www.usp.org. USP is **looking for a few good men and women to serve as volunteers**, either as chair of Expert Committees or as members of Expert Committees. There are 36 Expert Committees distributed across very diverse disciplines, technologies, and expertise. ■

—Roger Dabbah, Ph.D., USP

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Israel Chapter Hosts Course

On March 2, 2003, over 60 PDA members attended a one-day course hosted by the Israel Chapter at the Tel Aviv Hilton. The course was titled, "How to Prepare for an Inspection by European Authorities" and was taught by expert German Inspector Dr. Joerg Neuhaus, Bezirksregierung Koln.

Dr. Neuhaus provided an instructive overview of how the European Community functions and explained the differences between the European Community and The European Economic Area. He discussed how the European Parliament operates, its legislation and the status of "Directives," "Decisions," "Regulations," and "Recommendations." The legislative power of The Council of Ministers was clarified, and participants were introduced to the lesser known Council of Europe and the EDQM—the body responsible, amongst other things, for issuing the European Pharmacopoeia and Certificates of Suitability. PIC and its evolution into PICS were also elucidated.

Next, Dr. Neuhaus engaged participants with a presentation concerning European Inspections, triggers for inspections and different techniques for conducting inspections. Products manufactured once a year or once every two years trigger intense scrutiny, while cancelled and out-of-specification batches will almost certainly be reviewed. He provided insight into how, when inspecting manufacturers, he seeks entrance to "technical areas" which are often used to store machinery that the company doesn't want the inspector to find in production during the inspection. He also spoke of his technique of using binoculars to view clean rooms when firms deny him permission to enter for fear of contaminating product.

Dr. Neuhaus also gave pointers on process validation. He addressed process variables including employee behavior (a factor that is seldom taken into consideration) and a validation strategy that eliminates as many variables as possible by converting them to constants or demonstrating that they have negligible impact on the process, e.g., single vendors, specifically defined equipment, process defined in detail and conditioned environment.

Overall, participants indicated that they had a thoroughly interesting and enlightening day in the delightful environment of the Tel Aviv seashore. The Israel Chapter wishes to express its gratitude to PDA and to Gautam Maitra, in particular, for arranging Dr. Neuhaus' visit, and of course to Dr. Neuhaus for braving the news reports to visit with us on our home ground. ■

—compiled by the Israel Chapter leaders

[Note: The Chapter Events Calendar is on p. 44.]

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- ❑ Medical Device Manufacturing
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- ❑ Pharmacy
- ❑ Recruiter
- ❑ Other

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- ❑ Aerosols
- ❑ Analytical Chemistry
- ❑ Biologicals
- ❑ Biotechnology
- ❑ Computers
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- ❑ GMP Compliance/Inspection Trends
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- ❑ Microbiology
- ❑ Ointments
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- ❑ Packaging
- ❑ Parenterals
- ❑ Quality Assurance/Quality Control
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New member contact information is forwarded to Chapters on an ongoing basis. For immediate notification of Chapter events, please contact your local representative and ask to be placed on the Chapter mailing list.

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***Singapore**, from cover*

Participants will hear Dr. Beh Swan Gin, Second Director, Biomedical Sciences, Singapore Economic Development Board, talk about **Singapore's "Biopolis,"** a state-of-the-art research facility set to become the center of privately and publicly-funded pharmaceutical and biopharmaceutical discovery in Asia.

PDA's involvement in **biopharmaceutical science and technology** will be discussed by two members of the PDA Science Advisory Board (SAB):

- **SAB Chair James Fernandez** (Fernandez and Associates) will address the challenges of **technology transfer** for biopharmaceuticals.
- **SAB's Gail Sofer** (Director, Regulatory Services, BioReliance) will discuss viral clearance and validation. Mrs. Sofer chairs the PDA **Viral Filtration Nomenclature Standardization Task Force**, which is developing a test method for identifying viral-retentive filters using bacteriophage (see the *PDA Letter*, November 2003, cover).

This session will conclude with expert insight into validating biopharmaceutical processes from Yuan Xu, Head of Worldwide Biopharmaceutical Process Development at GlaxoSmithKline.

Where else can PDA members hear **health authority officials** from China, Europe, Japan, and Singapore all in one place?

Keynote addresses will be delivered by Dr. Chor Hiang Tan, CEO, **Health Sciences Authority, Singapore,** and David Cockburn, Principal Scientific Administrator, **Inspections Sector, EMEA**.

A presentation on Drug Development and Pharmaceutics will be provided by Dr. Ding Jian Hua, Deputy Director, Division of Pharmaceuticals for the **State Food and Drug Administration, China**. Japan Pharmacopeia issues will be the topic of a presentation by Dr. Tsuyoshi Tanimoto, Director, Division of Drugs, **National Institute of Health, Japan**. Speakers have also been invited from the Japan Ministry of Health, Labour and Welfare to speak on compliance and drug development issues.

Additional sessions at the conference will cover process analytical technologies (PAT), outsourcing, aseptic processing, regulatory affairs, national compendia and international harmonization.

Networking Opportunities

The conference offers attendees ample time to converse and connect with colleagues. A traditional Singapore High Tea will be offered in the exhibit hall and lunch is provided for the attendees on both Monday and Tuesday. All attendees are also invited to attend the Gala Reception at the Ritz-Carlton Millenia Hotel on Monday night.

Educational Courses

The PDA Training and Research Institute will be offering a variety of courses in conjunction with the 2004 PDA Congress in Singapore. Course topics include:

- A Practical Approach to Aseptic Processing and Contamination Control
- Qualification and Validation of API Manufacturing Operations
- Requirements and Preparation of Pharmaceutical Grade Waters
- PDA Computer Product Supplier Auditing Process Model: Auditor Training.

Look for more information on these courses on page 34. ■

Volunteer

for the Singapore and Training Conferences

PDA Volunteer Corps Wants You

Attend the Singapore Congress or the Training Conference at Half Price!

PDA once again encourages PDA members to volunteer at our conferences. In exchange for volunteering a few hours at the registration desk or as a room monitor, PDA members can receive a 50% discount to the conference. This is a wonderful way to become involved with PDA, attend a conference and save your company money! Note: PDA limits the number of volunteers to 10 on a first come, first served basis, and the PDA Volunteer Corps is for PDA members only.

If you are interested in taking advantage of this offer, please e-mail KiKi Coffman at coffman@pda.org who will coordinate your assignment. We look forward to seeing you in Singapore and Puerto Rico!

2004 PDA Pacific Rim Congress Exhibitor List

Sartorius Singapore Pte Ltd

SciMed (Asia) Pte Ltd

Pall Filtration Pte Ltd

Saint-Gobain (Singapore) Pte Ltd

Shield Medicare

To exhibit, please contact Nahid Kiani at kiani@pda.org or +1 (301) 656-5900 ext. 128.

***Training**, from cover*

The finalists for this year's awards will be available for conference participants to meet. Review their work and vote for the winners in each category. See below for a complete listing of this year's finalists.

This year's conference, called "No Trainer is an Island—Developing and Leveraging Your Training Network for Success," is designed for cGMP and technical trainers in the pharmaceutical, biotech, medical device and related industries. Attendees can choose from over 20 concurrent sessions covering curriculum design, innovative classroom techniques, developing e-learning, building training communities, and establishing trainer qualifications, to name a few.

Learn from the award-winning author of *Telling Ain't Training*, **Harold Stolovitch, Ph.D.**, a leader in the field of human performance technology. He will present two sessions: one based on his bestseller and the other on his book, *Order Taker to Performance Consultant*.

Dave Arch (the Bob Pike Group) is back by popular demand. He will lead a full-day session called "Beat the Blahs: The Blended Learning Solution." Dave has authored these popular training resources: *Tricks for Trainers*, volumes 1 & 2, *First Impressions/Lasting Impressions*, *Showmanship for Presenters*, and *Red Hot Handouts*.

Of course, we have assembled a distinguished panel of U.S. FDA speakers to discuss the Agency's new risk-based cGMP initiative. Participants will learn about inspectional trends, the new Pharmaceutical Inspectorate, training at CBER and CDER, and innovative programs and activities happening in the districts. This valuable information will help trainers establish programs that are truly beneficial to pharmaceutical professionals.

There will be many formal and informal opportunities to network and interact with your peers, regulatory experts, leading speakers on training, and vendors of training materials and services. The vendor exposition, which will be located in the foyer directly outside the meeting rooms, has been closely integrated into the conference with 15 exhibitors participating.

Your learning opportunity doesn't have to stop once the official conference is over! Immediately after the conference, from May 20–21, choose to attend a PDA Training and Research Institute course, specifically targeted for trainers.

Join us in Puerto Rico for this unique learning experience and delight in the ambiance of the Caribbean in May. More than 500 years of rich history and a vibrant blend of cultures await your arrival. There is something for everyone in this bustling hub of the Caribbean. Indulge yourself in the perfect setting for this year's conference, the world class Westin Rio Mar Beach Resort & Golf Club and its captivating 500 acres on one mile of secluded tropical beach.

Register now! Our 2002 conference, with over 200 trainers, was a huge success and we expect attendance to increase this year. Don't miss this exciting opportunity! ■

—compiled by Training Conference Committee Vice-Chair, Joanne Cochran, GMP Trainer, Merck 2004

Featured Vendors at the Training Exhibition

Cardinal Health

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Plateau Systems Ltd

PML Microbiologicals

Quality is Learned Inc.

Skillsplus International Inc.

Softek Export

Veltek Associates, Inc.

Working Words Inc.

2004 PDA Trainers Choice Awards—Finalists

Multimedia Presentation Entries

"What's Wrong with This Picture?"—Deb Browne, Aventis Behring

"Preparing for & Participating In A Regulatory Authority Clinical Trial Investigator Site Inspection"—Linda Morgan, Johnson & Johnson

Classroom/Training Manual Entries

"GMP Seminar Series I"—Gretchen Dixson, AstraZeneca

"Millennium's Central Files—Core of Compliance"—Bruce Leicher & Deb Glancy, Millennium

"On the Right Track"—Terry Poole, Aventis Bio Services

E-learning Program/Web Page Design Entries

"Equipment Handling & Segregation in the GMP Production Facility"—John Sauers, Abbott Bioresearch

"Development & Training Webpage"—Joanna Gallant & Bill O'Connor, Bristol-Myers Squib Medical Imaging

Experimental Training/Interactive Training Entries

"DC-opoly"—Malcolm O'Neal, Wyeth Pharma

"Aseptic Processing, 5th Annual Requalification"—Gail Gosson, G.C. Hanford Mfg. Company

Photos From the International Congress in Basel, Switzerland

Klaus-Jörg Dogwiler, Executive Director, SwissMedic, discusses the new Swiss agency

Phillipe Gomez (left), Biopharmaceutical Specialist, Sartorius, Jean Louis Saubion (right), RA Manager, UFCM-BP, Nikki Mehringer, Neal Koller, and Gautam Maitra sign the French Chapter charter.

Erich Sturzenegger (Central Europe Chapter President and International Congress Conference Chair) and Dr. Dogwiler (SwissMedic) with PDA's Nikki Mehringer, Kathleen Greene (Conference Co-Chair), and Neal Koller.

Didier Meyer, VP, La Calhene, moderates the Aseptic Processing session.

Volker Eck, Ph.D., Director, Analytical Development, Pharmacia Italia, SAB and Italy Chapter member.

Erich Sturzenegger, Nikki Mehringer, Darshan Makhey, President, PDA India Chapter, Georg Roessling, Neal Koller, and Gautam Maitra.

Klaus Haberer, Ph.D., Geschaettsfuehrer, teaches the PDA Training and Research Institute course on Risk Estimation in Aseptic Processing.

Risk Assessment roundtable discussion.

Aseptic Processing roundtable discussion.

Jon Voss, Director, QA, Genzyme Corporation, teaches the PDA Training and Research Institute course on Pragmatic Cleaning Validation.

PDA Chair Nikki Mehringer takes a whirl with PDA Treasurer Georg Roessling.

Gautam Maitra socializes with delegates.

PDA and R3 Nordic Bring Senior FDA Officials to Stockholm

2004 PDA/R3 Nordic Conference
June 7–8, 2004 • Hilton Stockholm Slussen • Stockholm, Sweden

This conference provides a unique chance for decision makers at European pharmaceutical companies to learn about the latest regulatory developments regarding aseptic processing from FDA without traveling far from home.

Don't miss this unique opportunity to hear senior FDA officials address a variety of crucial regulatory issues impacting aseptic processing:

- **CDER's Brenda Uratani, Ph.D.**, Consumer Safety Officer, will discuss the application of **risk analysis to aseptic processing**;
- **CDER's Christopher Watts**, Process Analytical Team, will explore how **Process Analytical Technology will impact aseptic processing**;
- **CDRH's Daniel Schultz, Ph.D.**, Medical Office Supervisor, will look at the most recent **regulatory concerns with biopharmaceuticals and medical devices**; and
- **CDER's Anthony Mire-Sluis, Ph.D.**, Senior Chemist, will close the conference with advice on implementing **risk-based approaches to biopharmaceutical development and manufacture**.

The conference will also have representation from various regulatory agencies in Europe:

- **EMEA:** Emer Cooke, Section Head, Inspections, will address the European regulatory expectations for pharmaceutical manufacturing and medical devices;
- **Sweden Medical Products Agency:** Tor Gråberg, Acting Chief Inspector, will discuss the role of PIC/S in Europe; and
- **France Unite de Fabrication:** J.L. Saubion, Ph.D., Regulatory Affairs Manager, will discuss enforcement problems.

Expert insight into various scientific and regulatory areas will be given by senior industry executives from leading U.S. and European companies, including:

Pfizer: Mats Johansson, Sr. Manager, and Norman Winskill, Ph.D., V.P., Global Manufacturing Services, will discuss ACAT, a tool for cGMP compliance in aseptic production steps;

AstraZeneca: Stephen Bellis, Global Compliance Management Group, will address industrial issues in sterile product maufacturing;

Bovis-Lend Lease Pharmaceuticals: Gordon Farquharson, Principal Consultant, will explain ISO & CEN cleanroom standards and their relationship with GMPs; and

IVAX Pharmaceuticals: Eric Dewhurst, Head of Quality, will provide the industrial view of advanced technologies.

This important two-day conference is being offered by PDA in cooperation with the Nordic Association for Contamination Control and Clean Rooms—R3 Nordic—and with KTH, Kungl Tekniska Högskolan (The Royal Institute of Technology) in Sweden. KTH, is responsible for one-third of Sweden's capacity for engineering studies and technical research at post-secondary level.

Registration for this conference has begun! Go to www.pda.org for more details and for registration information for this conference. ■

PDA Audio Conference Program—Keeping You Current

In today's world, businesses must take advantage of practical and cost-effective communication technologies to stay competitive. Audio conferences help thousands of professionals learn how to save money and improve productivity without leaving the office! PDA is committed to becoming your source for a quick and easy exchange of the most critical and complex information facing the drug industry now.

Information on rapidly advancing technology, regulations, products, markets and science can be delivered rapidly and affordably in real-time, with minimal disruption to your daily responsibilities.

One speaker phone in a central location allows for as many listeners as the room can accommodate for one low registration fee.

In the coming months, look for events that provide solutions to maintain computer systems compliance, apply risk management tools to CAPA programs, prepare and conduct an effective quality product recalls and much more! Check www.pda.org for more information. ■

2004 PDA/FDA Joint Regulatory Conference—Leveraging 21st Century Initiatives to Improve Quality: Architecture for the Future

September 20–24, 2004 • Omni Shoreham Hotel • Washington, DC

Mark your calendars for the must-attend PDA conference for regulatory professionals in 2004!

Topics will include:

- Quality: Enrolling Senior Management
- Inspections: Preparing for, Managing and Recovering from
- Regulatory Inspections for a Global Market: FDA Foreign Inspection Team
- Process Analytical Technologies (PAT) Case Studies/Implementation of PAT
- Compendial Issues: USP and Other Pharmacopeias
- Change Control: Make your Own SUPAC
- Change Control for BioTech Products
- Regulatory Update from FDA

The program planning committee for the conference, led by chair Allen Burgenson, Sr. Regulatory Affairs Associate, Cambrex Bioscience Walkersville, is working hard to guarantee that this year's PDA/FDA conference is one of the best ever. Watch for more updates on the conference in the *PDA Letter* and at www.pda.org.

Educational Courses

The PDA Training and Research Institute will be offering a variety of courses in conjunction with the 2004 PDA/FDA Joint Regulatory Conference. Course topics include:

- Change Control & Documentation
- Auditing Pharmaceutical Microbiology Laboratories
- Basic Concepts in Cleaning & Cleaning Validation
- Compliance Auditing of Cleanrooms and Controlled Environments
- Qualification and Validation of API Manufacturing Operations
- Auditing Techniques for CGMP Compliance. ■


Mello

VP's Message

Rising to the Challenge

PDA, An International Association for Pharmaceutical and Biopharmaceutical Science and Technology: This is what we are, an *international* association.

If you think it is easy going "*global*," take it from me, it is anything but easy. It is a true challenge. And it is a challenge that we at PDA have accepted because our membership has demanded it. We exist in a global economy. Our companies have divisions or subsidiaries across the globe. Here at the PDA Training and Research Institute, we are rising to that challenge.

I want to express my thanks on behalf of PDA-TRI to Millipore Corporation for their continued support of the Milli-Q water system at our home laboratory in Baltimore. By providing timely service, technical support and ongoing system supplies, the ongoing laboratory training programs at the Institute have continued to operate efficiently. Thanks, again, Millipore for your continued and long standing support of PDA and the Training and Research Institute.

—Bob Mello

In my January message, I broadly outlined our plans for course offerings in 2004. I placed additional emphasis on the fact that I was trying to implement a more global approach to our training program. In recognition of tighter budgets for travel and training, we are actively planning to bring training programs closer to you.

This February, in Basel, Switzerland, we offered a series of five courses covering topics on cleaning validation, bioprocess cGMPs, HVAC and airborne contamination, the clinical trials directive and risk assessment. I took the first step and offered these courses in Europe, taught predominantly with European faculty. I was gratified with the response of our membership. Registrants for the Basel course series came from a total of 17 different countries, 76% of which were European.

While most of the Basel course registrants were European, they represented only 45% of the countries where PDA has members. Our goal is to be able to say that we are reaching all of Europe with our courses.

The challenge for us now is to continue offering training in locations convenient to our members. We also need to keep developing courses that are current, on topic and that will provide you with the information you need *now* to perform better in your workplace. We have only begun and there is much more work to do. As we move forward I welcome your comments and suggestions on this topic.

Having started the year in the U.S. with our Lake Tahoe series (registrants from 17 U.S. states and three foreign countries) and in Europe with the Basel course series, we are now turning our attention to our next international course series—in Singapore—this May.

Four courses will be offered from May 19–21, 2004, as part of the PDA International Congress being held at the Ritz-Carlton Hotel:

- **Ted Meltzer, Ph.D.**, an established authority on both filtration and pharmaceutical water will present a three-day course on the requirements and preparation of pharmaceutical grade waters.
- **Dan Gold, Ph.D.**, a respected expert on both the manufacturing *and* control of active pharmaceutical ingredients, will be providing two days of training on the qualification and validation of API manufacturing operations.
- **Andrew Jelen, a certified auditor** in the PDA audit process detailed in Technical Report #32, will offer the auditor training course on the PDA computer product supplier auditing process. This course, generally given in the U.S. has been attended by several of our Asia-Pacific members.
- The fourth course will cover practical approaches to aseptic processing and contamination control, **taught by yours truly**. With over 16 years in the field of aseptic processing and contract manufacturing, I am looking forward to an interactive discussion of the topic, as well as the presentation of a comprehensive case study.

Asia-Pacific, we are coming to you! You have seen how Europe has responded to our course offerings. Are you ready to rise to the challenge as they did? If you work in this part of the globe, don't miss this great opportunity to attend. Of course, you are welcomed to attend even if you are located in Europe, Africa or the Americas—Singapore is a great place to visit no matter where you work and live. I hope to see a lot of PDA members there in May.

For the complete brochure and registration information, visit www.pda.org/pdf/meetings/04singapore-bro.pdf. ■

Upcoming Course Series

May

3–5: PDA Training and Research Institute **San Diego Course Series**—Sheraton San Diego Hotel & Marina

16–21: 2004 PDA Biennial **Training Conference, Courses and Vendor Exhibit**—The Westin Rio Mar Beach Resort & Golf Club, Puerto Rico

17–21: PDA 2004 **Pharmaceutical & Biopharmaceutical Manufacturing Science & Technology Congress, Training Courses and Exhibition**—The Ritz-Carlton Millenia, Singapore

June

15–17: PDA Training and Research Institute **Toronto Courses Series**—The Westin Harbour Castle, Toronto

2004 Aseptic Processing Training

The 2004 dates for the PDA Training and Research Institute laboratory course on Aseptic Processing have been established. Due to the intensive hands-on nature of this course, class registration must be limited to 20 students per session. In response to the overwhelming registration requests for the four session dates in 2003, PDA Training and Research Institute has added a fifth session for 2004. This extremely popular two-week course sells out rapidly, so we urge you to register early. The registration information is now available on our Web site, www.pda.org/PDF/TRI-Courses/TRI-04-Aseptic-RegForm.pdf.

The remaining 2004 dates are as follows:

Session III
Week 1 May 24–28
Week 2 June 14–18

Session IV
Week 1 August 16–20
Week 2 September 13–17

Session V
Week 1 October 4–8
Week 2 November 1–5

$7,800 members/$9,300 nonmembers; *Faculty:* John Lindsay and David Matsuhiro ■

For Hotel Information, go to www.pda.org

Upcoming PDA Training and Research Institute Education Courses

Course No.	Title/Topic	Dates
142	**Designing, Operating and Controlling High-Purity Water Systems for Regulatory Compliance**	May 5–7, 2004 October 25–27, 2004
230	**Environmental Mycology Identification Workshop**	May 13–14, 2004 December 2–3, 2004
NEW	**Pharmaceutical Microbiology Workshop**	July 27–30, 2004
NEW	**Developing a Moist Heat Sterilization Program Within FDA Requirements**	August 9–11, 2004
NEW	**Advanced Environmental Mycology Workshop**	September 1–3, 2004
301	**Fundamentals of D, F and z Value Analysis**	October 14–15, 2004
NEW	**Rapid Microbiological Methods**	October 18–22, 2004
NEW 319	**What You Need to Know to Select Adequate Thermal Validation Equipment**	November 22–23, 2004
NEW	**Developing and Validating Cleaning and Disinfection Programs**	November 18–19, 2004
400	**Cleaning Validation**	November 15–17, 2004
NEW	**Remediation of Existing Computer Systems**	November 18-19, 2004

These courses will be held at the PDA Training and Research Institute in Baltimore, Maryland, unless otherwise noted. **For course content information,** call the PDA Training and Research Institute directly at +1 (410) 455-5800. For registration information, call PDA's world headquarters in Bethesda, Maryland at +1 (301) 656-5900.

PDA Training and Research Institute Global Education

This spring, the PDA Training and Research Institute is taking its courses to you. Look for these upcoming events in your local area. Take home practical solutions specifically designed to help you on the job.

San Diego Course Series
May 3–5, 2004
Sheraton San Diego Hotel & Marina
San Diego, California USA

2004 Pharmaceutical & Biopharmaceutical Manufacturing, Science & Technology Congress, Training Courses and Exhibition
May 19–21, 2004
Ritz-Carlton Millenia
Singapore

2004 PDA Biennial Training Conference, Courses and Tabletop Exhibit
May 20–21, 2004
The Westin Rio Mar Beach Resort & Golf Club
Puerto Rico

Toronto Course Series
June 15-17, 2004
The Westin Harbour Castle Toronto
Toronto, Canada

Visit www.pda.org for more details and to register.

TR-32 Update

Sparta Systems Reports Value of PDA TR-32 Audits

by K.R. Karu, Sparta Systems and Harvey F. Greenawalt, ARC

Sparta Systems, the makers of TrackWise Quality Management System (QMS) software, has seen a drop in audits as a result of two reports available in the Audit Repository Center (ARC). Sparta was one of the first software suppliers to sign on with ARC and has never looked back.

The audits were conducted according to the PDA Supplier Audit Model (PDA *Technical Report #32, Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*, available through the PDA Publication E-store, www.pda.org).

Sparta was first audited in 2001, and then again in late 2003. These audits have been reviewed and accepted by many major pharmaceutical companies in lieu of conducting audits on their own.

"The tremendous time and effort saved by our customers and our company, preparing and conducting these audits has been immeasurable," said Ran Flam, President and CEO of Sparta Systems.

The TrackWise system is the most widely used QMS software in the life sciences industries. It enables organizations to track and report on key events that impact quality and compliance, giving customers a major advantage in meeting regulations from the U.S. FDA and other health authorities. TrackWise is a 21 CFR Part 11 compliant, off-the-shelf, fully user-configurable solution for tracking and managing "nonconformance reports," investigations, customer complaints, CAPA, change authorizations, and all other cGxP requirements. Sparta and its flagship TrackWise product line have been serving the industry for many years, achieving great return on investment and proven results.

Sparta Systems has recently released version 6.0 of TrackWise, with enhancements based on requests from its customer base in the life science industries. "Our new features such as multi language support, integration with content management systems, AutoTrending™ and more, are a direct result of working with our customers in the FDA-regulated industries," said Sparta COO Rafi Maslaton.

"Our continued association with the PDA Audit Repository Center and undergoing the stringent PDA supplier audit model underscore our commitment to this industry," continued Maslaton. "Sparta Systems is proud to be the first and only company that has opened its doors to this process, and the use of this audit by the industry underscores the value of our continued commitment to PDA and ARC. This process improves our product and our commitment to quality."

About Sparta Systems

Sparta Systems has positioned itself as a leader in providing 21 CFR Part 11 compliant, off-the-shelf, fully user-configurable solutions for the management and tracking of deviations, nonconformance, investigations, customer complaints, audit observations, regulatory commitments, corrective and preventive actions (CAPA), change control, and other cGxP requirements by FDA-regulated companies, specifically in the pharmaceutical, biotechnology, and medical device industries. Sparta Systems has over 85 FDA-regulated customers, including most of the major pharmaceutical manufacturers.

Sparta Systems is headquartered in Holmdel, N.J. For more information about its software, visit www.sparta-systems.com.

Availability of Audits

Currently fifty-eight (58) audits are either under consideration, in process or available for distribution. Thirty audits are available for immediate distribution (see table, p. 38).

For more information about the audit repository, audits and their availability, visit ARC's Web site at www.auditcenter.com. ■

continues on page 38

TR-32 Update, from page 37

Supplier Name	Supplier Product
Access360, Inc.	enRole 4.0 (Provisioning Software)
Agilent Technologies	Cerity for Pharmaceutical QA/QC. Network data system for analytical laboratories.
Alacris, Inc.	idNexus, Alacris products are designed to simplify identity management and maximize trust associated with Public Key Infrastructure (PKI) implementation and security technologies.
Applied Biosystems, Inc.	SQL*LIMS™ Software - Laboratory Information Management System
Automation Tooling Systems, Inc.	Custom programming services for Process Control Software
Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set.
Docent	• Docent Learning Management Server • Docent Content Delivery Server
Documentum, Inc.	• Content Authentication Services (CAS) • Documentum eContent Server • Document Control Manager (DCM) • GXPharma
Documentum, Inc.	• Document WebDAV Server • Document Media Services • Documentum Digital Asset Manager • Document Desktop for Macintosh
Documentum, Inc.	• Documentum DocApp Installer • Documentum Administrator • Documentum Application Builder • Documentum DeskTop • Documentum Website Manager • Documentum WebTop • Web Development Kit • Documentum Workflow Manager
Epicentric, Inc.	Foundation Enterprise Server 4.0, which is a tool for coordinating information from disparate sources and for disparate uses.
First Consulting Group, Inc.	Custom information based strategy software, operations improvements, management and integration services
Fisher-Rosemount Systems, Inc.	Distributed Factory Automation, Delta V product line
Foss NIRSystems, Inc.	SLE Near-infrared analysis of chemical and physical properties
GE Kaye Instruments, Inc.	Thermal validation systems, monitoring systems, thermocouple references and turbine temperature monitoring equipment - LabWatch™, ValProbe™ and the Validator®2000 systems.

Supplier Name	Supplier Product
Inktomi Corporation	Enterprise Search. Providing performance, scalability, and ease-of-use, Inktomi Enterprise Search is a comprehensive information retrieval platform that delivers access to content across the enterprise, regardless of location, language, or file format.
Innovatum, Inc.	DataThread™ - Data audit, workflow, 21 CFR Part 11 and E-signature solution for AS/400 applications, without programming changes.
Interwoven, Inc.	Web Publication Management
Lexign Corporation	Lexign Flow™ EPR Software
LoftWare, Inc.	Loftware Print Server (LPS) Label Printing System
MARC Global Systems	Warehouse Execution Systems
Merant	PVCS Dimensions & PVCS Replicator Software Configuration Management Tool
Mercury Interactive	Test Management Tools: • QuickTest Professional • Astra QuickTest • Astra LoadTest • Astra FastTrack • LoadRunner • LoadRunner TestCenter • TestDirector • WinRunner
Propack Data GmbH	Enterprise Production Management System, PMX 3.2 with Solutions MES and CTM.
Rational Software Corporation	Rational Suite® Enterprise • Rational ClearQuest (for team-based change request and defect management) • Rational ClearCase (configuration management for smaller development teams)
Serena Software, Inc.	• ChangeMan (ZMF) (DS) • StarTool (STL) • TeamTrack (TT)
Sparta Systems, Inc.	TrackWise®. Training, Configuration, Installation and Support for TrackWise®.
SSA Global Technologies, Inc.	Mid Range ERP software for manufacturing, supply chain and financial application domains.
The Sycamore Group	Custom IT Solutions. Integration suite of COTS products and services to bridge data across multiple internal computer systems, including e-Commerce, LIMS, ERP, enterprise databases, mainframes and wireless and portable devices.
Waters Corporation	Empower™ chromatography software and Connections AQT - HPLC System, System Components, Data Management

NEW Technical Books

at PDA...your source for scientific, technical, and regulatory information.

Pocket Code of Federal Regulations

ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients—Q7A

This booklet encapsulates the cGMPs for active pharmaceutical ingredients (APIs) as established by ICH. This pocket-size booklet is produced by PDA to serve as a handy reference to this important regulation. Health Authorities around the world have adopted Q7A as their GMP standard for APIs. No API supplier can operate without knowing this information!

Reproduced in pocket size by PDA. 68 pages; $4 U.S. members/$10 U.S. nonmembers **Item No. 13005**

Coming Soon ...New PDA-DHI Technical Books

- ***Filtration Handbook: Filtration of Liquids***, *by Maik W. Jornitz and Theodore H. Meltzer*

Already available from these authors—

Filtration Handbook: Integrity Testing, This complete guide explains the proper performance of filter integrity testing by clarifying its relationship to bioburden concerns and assessing its role in filter validation. It offers practical approaches to appropriate use of integrity testing, wetting and temperature requirements, the Bubble Point test, diffusive airflow testing and much more. Numerous regulatory citations and references complete this invaluable book. 2003; 150 pp; $185 U.S. member/$229 U.S. nonmember **Item No. 17197**

- ***Pharmaceutical Quality***, *edited by Richard Prince*

Already available from this editor—

Microbiology in Pharmaceutical Manufacturing, Providing valuable knowledge for the novice and the expert alike, many of the world's greatest pharmaceutical microbiologists and engineers, as well as other prestigious thought leaders, have invested their considerable talents in developing this comprehensive collection of timely information on this critically important subject. This book encapsulates current knowledge in a truly wide array of microbiological applications for the reader. This book is intended to demystify the field of microbiology by describing it plainly and systematically from various scientific, technical, and functional perspectives. 900 pp; $240 U.S. members/$299 U.S. nonmembers; hardcover **Item No. 17185**

- ***Cleanroom Clothing***, *by Bengt Ljungqvist and Berit Reinmuller*

Already available from these authors—

Microbial Risk Assessment in Pharmaceutical Clean Rooms This monograph clearly explains the Limitation of Risk Method (LRMethod). When a systematic risk analysis is performed and sampling locations are selected and evaluated in a rational manner using this method, comprehensive monitoring will reduce the number of microbiological samples necessary and provide quality improvement. Contents include information about: Airborne contaminants; Guidelines for Pharmaceutical Production; Contamination sources; Dispersion of airborne contaminants; Microbiological monitoring in the cleanroom; Risk assessment; and Limitation of Risks (LR-Method). Tables and charts help complete this text. 2001; 17 pp; $75 U.S. members/$90 U.S. nonmembers **Item No.17175**

***For complete descriptions, visit our Web site,* www.pda.org.**

PDA-DHI Press Books

Item No.	Title	Author/Editor	Price		
			Member	Nonmember	Government
17173	Practical Change Control for Healthcare Manufacturers	Angie Jamison	$120	$149	$ 50
17174	Understanding GMP: A Practical Guide	Martyn Becker	$170	$209	$ 70
17175	Microbial Risk Assessment in Pharmaceutical Clean Rooms	Bengt Ljungquist/ Berit Reinmuller	$ 75	$ 90	$ 30
17176	Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections	Lucia Clontz	$170	$209	$ 70
17177	Electronic Records and Electronic Signatures Compliance Assessment	Chris Reid/ Barbara Mullendore	$ 90	$109	$ 40
17179	The Internal Quality Audit	Monica Grimaldi/ Janet Gough	$120	$149	$ 50
17180	The External Quality Audit	Monica Grimaldi/ Janet Gough	$120	$149	$ 50
17181	Media Fill Validation Environmental Monitoring During Aseptic Processing	Michael Jahnke	$ 90	$109	$ 40
17182	Introduction to Environmental Monitoring in Pharmaceutical Areas	Michael Jahnke	$ 90	$109	$ 40
17183	Steam Sterilization: A Practitioner's Guide	Jeanne Moldenhauer	$215	$269	$175
17184	Rapid Analytical Microbiology: The Chemistry and Physics of Microbial Identification	Wayne P. Olson	$195	$239	$130
17185	Microbiology In Pharmaceutical Manufacturing	Richard Prince	$240	$299	$160
17188	Understanding Active Pharmaceutical Ingredients	Siegfried Schmitt	$ 80	$109	$ 35
17189	Change Control	Soren Schwartze	$ 75	$ 90	$ 30
17199	GMP in Practice: Regulatory Expectations For The Pharmaceutical Industry Third Edition	James Vesper	$105	$129	$ 75
17192	Hosting a Compliance Inspection	Janet Gough	$120	$149	$ 50
17193	Microbiological Monitoring of Pharmaceutical Process Water	Michael Jahnke	$ 90	$109	$ 65
17194	Sorting Out the Critical Variables: A Worked Example for the Non-Statistician	Alfred Wachter	$ 90	$109	$ 40
17195	Validation Master Plan, The Streetwise Downtown Guide	Trevor Deeks	$ 80	$109	$ 60
17196	Laboratory Systems Validation Testing and Practice	Paul Coombes	$120	$149	$ 50
17197	Filtration Handbook: Integrity Testing	Maik W. Jornitz/ Theodore H. Meltzer	$185	$229	$ 75
17198	Quality and Safety of Gene Medicines: A Practical Guide	Anthony Meager	$155	$189	$ 65
17200	Commercial Off-The Shelf Software Validation for 21 CFR Part 11 Compliance	David Nettleton/ Janet Gouch	$185	$229	$ 75
17201	Laboratory Validation: A Practitioner's Guide	Jeanne Moldenhauer	$250	$309	$170
17203	The Essence of GMPs: A Concise Practitioner's Guide	U. G. Barad	$185	$229	$ 75
17204	Supply of Chemicals in the Pharmaceutical Industry: Regulatory Guidelines and Rulings	Mark Selby	$185	$229	$ 75
17205	Excellence Through Validation: A Practitioner's Guide	U. G. Barad	$160	$199	$ 65

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Selected PDA Technical Reports

Points to Consider for Aseptic Processing Volume 57 Number 2 Supplement This document represents over 18 months of dedicated work by the Task Force members. It presents the issues framed as problem statements with both a recommendation and a rationale for the recommendation provided. Some of the topics included in this 72-page report are: airflow velocity and patterns; critical area environments; differential pressures; HEPA filter testing and patching; setting environmental monitoring alert and action levels; the relationship of environmental monitoring results to batch release; investigation of environmental monitoring excursions; critical surfaces; process simulation acceptance criteria; incubation of normally excluded units; interventions; duration of process simulation tests; and number of media-filled units. 2003; 72 pp; $75 members/$550 nonmembers **Item No. 03004**

Technical Report No. 34 Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products This technical report addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. It covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials. 2001; 25 pp; ; $75 members/$550 nonmembers **Item No.01034**

Technical Report No. 13 (REVISED 2001) Fundamentals of a Microbiological Environmental Monitoring Program This document identifies microbiological and particulate control concepts and principles as they relate to the manufacture of sterile pharmaceutical products. It expands substantially upon the first edition of Technical Report No. 13, *Fundamentals of a Microbiological Environmental Monitoring Program*, published by PDA in 1990. This document serves as a source on cleanroom environmental test methods, and although some non-viable particulate and endotoxin testing data are included, its primary focus is microbiological control. The focus is environmental monitoring as it relates to facility control and compliance. This document was compiled to aid in setting up a program that is meaningful, manageable, and defendable. 2001; 37 pp; $75 members/$550 nonmembers **Item No. 01013**

Technical Report No.26 Sterilizing Filtration of Liquids This report presents a comprehensive view of the factors influencing sterilizing filtration of liquids, including validation of sterilizing filtration processes. The document includes sections on validation and integrity testing which, for the first time, provide guidance on correlating integrity test results to bacterial retention as well as setting integrity test limits for product-wetted filters. 1998; 31 pp; $75 members/$550 nonmembers **Item No. 01026**

Technical Report No. 29 Points to Consider for Cleaning Validation This document provides guidance relative to the validation of cleaning for a broad range of processing systems and product types within the pharmaceutical industry. The report includes perspectives on the application of cleaning validation guidance in the areas of finished pharmaceuticals, bulk pharmaceutical chemicals, biopharmaceuticals and clinical products. It is the pharmaceutical companion to "Cleaning and Cleaning Validation: A Biotechnology Perspective" published by PDA in 1996. 1998; 22 pp;$75 members/$550 nonmembers **Item No. 01029**

Technical Report No.32 Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. 1999; 277 pp.
Item No. 01032 ..... $100 member/$575 nonmember (Paper version)
Item No. 01132 ..... $75 member/$550 nonmember (CD-ROM version)

Technical Report No. 36 Current Practices in the Validation of Aseptic Processing—2001 The validation of aseptic processing continues to be a major area of interest within the pharmaceutical industry. Five years have passed since the last PDA survey on this subject. While there have been no new broadly applicable regulations or regulatory guidance since that time, there has been continued controversy over the details of aseptic processing and process simulation practice. Industry practices largely adhere to current regulations and guidelines on aseptic processing by the European Union, ISO, and FDA. The impact of PDA's Technical Report No. 22 on *Process Simulation Testing for Aseptically Filled Products* is also apparent. 2002; 34 pp; $75 members/$125 nonmembers **Item No. 01036**

Environmental Monitoring: A Compilation of papers from the PDA Journal of Pharmaceutical Science and Technology A Compilation of Papers from the *PDA Journal of Pharmaceutical Science and Technology*. In response to a need for finding historical papers, members of the PDA Microbiology Committee conducted a review of the PDA Journal of Pharmaceutical Science and Technology from 1985 to 1995, and selected these papers which should have value for those working in this field. 1996; 220 pp; $100 member/$575 nonmember **Item No.01151**

PDA Book

Cleaning and Cleaning Validation: A Biotechnology Perspective Roger Brunkow, David DeLucia, George Green, Shane Haft, John Hyde, John Lindsay, Jill Myers, Robert Murphy, John McEntire, Karen Nichols, Ray Prasad, Brenda Terranova, Jon Voss, Caroline Weil, Edward White; This book is intended to serve as a source of practical technical information for those persons in the biotechnology industry. Case studies and/or actual industry examples are used to support the text wherever possible. While much of the material contained within this text is equally applicable to non-biopharmaceutical processes, the emphasis has been focused directly upon biopharmaceutical manufacturing. Section I provides an in-depth analysis of the design concepts that lead to cleanable equipment. 1995; 190 pp; $125 member/$320 nonmember **Item No.13002**

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Chapter Events Calendar

April

19: **Central Europe Chapter**, EuroForum on PAT
Basel, Switzerland

26: **Canada Chapter**, "Current Regulations and Compliance"
Holiday Inn – Midtown, Montreal, Quebec

27: **Delaware Chapter**, "Clean Room Velocities, Air Flow and Media Fill Studies from PDA Training and Research Institute"
Malvern, Pennsylvania

28: **UK & Ireland Chapter**, "What to Do When Things Go Wrong"
London, England

May

4: **New England Chapter**, topic to be announced
Cambridge, Massachusetts

24: **Italy Chapter**, EuroForum on Biotech
Florence

June

7: **Italy Chapter**, Aseptic Processing—European and U.S. Perspective: A round table to be held during "Pharmintech" week (June 8–11)
Bologna

9: **Metro Chapter**, "Disinfection/Sanitization"
Clark, New Jersey

21–22: **Central Europe Chapter**, EuroForum on "Common Technical Document –Learning by Doing"
Basel, Switzerland

TBD: **Taiwan Chapter**, Annual Meeting
Taipei

September

6–8: **Central Europe Chapter**, "Aseptic Processing Course"
Basel, Switzerland

27: **Central Europe Chapter**, EuroForum on Biosafety
Basel, Switzerland

October

4–5: **Central Europe Chapter**, Course on Visual Inspection
Berlin, Germany

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***Calendar of Events**, from back cover*

June 17:
Analytical Problem Solving for CAPA Systems
GMP Fundamentals
How to Develop Validation Protocols
Radiation Dosimetry and Calibration

21–22 PDA EuroForum *Common Technical Document—Learning by Doing* (UBS Ausbildungs-und Konferenzzentrum, Basel, Switzerland)

July

27–30 PDA Training and Research Institute Course *Pharmaceutical Microbiology Workshop* (PDA Training and Research Institute, Baltimore, MD)

August

9–11 PDA Training and Research Institute Laboratory Course *Developing a Moist Heat Sterilization Program Within FDA Requirements* (PDA Training and Research Institute, Baltimore, MD)

16–20 PDA Training and Research Institute Laboratory Course *Aseptic Processing Training Program—Week 1* (PDA Training and Research Institute, Baltimore, MD)

30 PDA EuroForum *Visual Inspection* (Location TBA, Berlin, Germany)

September

1–3 PDA Training and Research Institute Laboratory Course *Advanced Environmental Mycology Identification Workshop* (PDA Training and Research Institute, Baltimore, MD)

6–8 Pan European PDA Training and Research Institute Lecture Course *Fundamentals of Aseptic Processing* (UBS Ausbildungs-und Konferenzzentrum, Basel, Switzerland)

13–17 PDA Training and Research Institute Laboratory Course *Aseptic Processing Training Program—Week 2* (PDA Training and Research Institute, Baltimore, MD)

20–24 2004 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits (Omni Shoreham Hotel, Washington, DC)

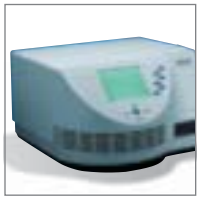
Conference: September 20–22
Courses: September 23–24
Tabletop Exhibit: September 20–21

PDA Training and Research Institute Lecture Courses:

September 23:
Change Control & Documentation

September 23–24:
Auditing Pharmaceutical Microbiology Laboratories
Basic Concepts in Cleaning & Cleaning Validation
Compliance Auditing of Cleanrooms and Controlled Environments
Qualification and Validation of API Manufacturing Operations

September 24:
Auditing Techniques for CGMP Compliance



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Be sure to see us at:
PDA SciTech Summit, Booth 501, and
INTERPHEX, Booth 1421

Calendar of Events

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For the most up to date information on all PDA meetings and conferences go to **www.pda.org**

2004

May

3–5 PDA Training and Research Institute *San Diego Course Series* (Sheraton San Diego Hotel & Marina, San Diego, CA)
May 3:
Conducting Compliant Deviation Investigations for the Pharmaceutical Industry
Environmental Monitoring in Pharmaceutical Manufacturing
May 3–4:
A Practical Approach to Aseptic Processing and Contamination Control
Pharmaceutical Water Systems: A Practical Approach
May 4:
Good Documentations Practices
May 4–5:
Assessing Packaging & Processing Extractables/Leachables
Sterile Pharmaceutical Dosage Forms: Basic Principles
May 5:
Achieving cGMP Compliance during Development of a Biotechnology Product
Analytical Problem Solving for CAPA Systems
Design and Validation of a Cleaning and Disinfection Program

5–7 PDA Training and Research Institute Laboratory Course *Designing, Operating, and Controlling High Purity Water Systems for Regulatory Compliance* (PDA Training and Research Institute, Baltimore, MD)

11–12 PDA Training and Research Institute Laboratory Course *Validating a Steam Sterilizer* (PDA Training and Research Institute, Baltimore, MD)

13–14 PDA Training and Research Institute Laboratory Course *Environmental Mycology Identification Workshop* (PDA Training and Research Institute, Baltimore, MD)

16–21 2004 PDA Biennial Training Conference, Courses and Vendor Exhibit (The Westin Rio Mar Beach Resort & Golf Club, Puerto Rico)
Conference: May 16–19
Courses: May 20–21
Vendor Exhibits: May 16–19
PDA Training and Research Institute Lecture Courses:
May 20:
Maximizing SOPs—An Untapped Resource of Training Solutions
Training for Performance
May 20–21:
Developing & Administering GMP Training
SME (Subject Matter Expert) to STAR (Superior Trainer and Reviewer)
May 21:
Designing Training That Works
Regulation Without Motivation: Spark a Change without Shorting Your Circuit

17–21 PDA 2004 Pharmaceutical & Biopharmaceutical Manufacturing Science & Technology Congress, Training Courses, and Exhibition (The Ritz Carlton Millenia, Singapore)
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
PDA Training and Research Institute Lecture Courses:
May 19–21:
Requirements and Preparation of Pharmaceutical Grade Waters
May 20–21:
A Practical Approach to Aseptic Processing and Contamination Control
PDA Computer Product Supplier Auditing Process Model: Auditor Training
Qualification and Validation of API Manufacturing Operations

24 PDA EuroForum *Biotech Forum on Harmonization* (Biotech Interest Group—European Section, Location TBA)

24–28 PDA Training and Research Institute Laboratory Course *Aseptic Processing Training Program—Week 1* (PDA Training and Research Institute, Baltimore, MD)

June

3–4 PDA Training and Research Institute Lecture Course *Computer Products Supplier Auditing Process Model: Auditor Training* (PDA Training and Research Institute, Baltimore, MD)

7–8 2004 PDA/R3Nordic Conference—In collaboration with KTH—***Scientific, Industrial and Regulatory Aspects of Clean Products and Devices*** (Hilton Stockholm Slussen, Stockholm, Sweden)

14–18 PDA Training and Research Institute Laboratory Course *Aseptic Processing Training Program—Week 2* (PDA Training and Research Institute, Baltimore, MD)

15–17 PDA Training and Research Institute *Toronto Course Series* (The Westin Harbour Castle, Toronto, Canada)
June 15:
Sterile Manufacturing with Blow/Fill/Seal Technology
June 15–16:
Basic Concepts in Cleaning and Cleaning Validation
Cleanroom Management
Computer and Network Infrastructure (CNI) Qualification Using C3Q™
Preparing for an FDA Pre-Approval Inspection
June 16–17:
Qualification and Validation of API Manufacturing Operations

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Coming in June
New and improved department-specific calendars. **See p. 7 for more details**