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PDA Letter

December 2003

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

SciTech Summit™, page 18; 2003 PDA Awards, pages 30-31

PDA Comments on Two FDA Draft Guidances and a World Health Organization Guidance

PDA has submitted comments on two draft guidances released by FDA in September as part of its pharmaceutical/biotech quality initiative for the 21st Century. When final, these important guidances will help facilitate the industry-wide adoption of modern manufacturing technologies.

On Nov. 5, PDA submitted its comments on the FDA draft guidance on Process Analytical Technologies (PAT), "A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance." The document is intended to provide industry preliminary guidance on the implementation of modern, manufacturing control technologies and to clearly indicate the Agency's support for such technologies. While PDA is encouraged by the FDA guidance and the overall Agency PAT initiative, we believe there are a number of areas in this document that could be improved (*see p. 10 for the "cover letter" to the PDA comments*).

On Nov. 4, PDA submitted comments on the FDA draft Aseptic Processing guidance. Due to the intense interest in this document, PDA has made a substantial number of recommendations (*see p. 11 for the "cover letter" to the PDA comments*).

PDA also submitted comments on the World Health Organization "Supplementary Guideline on GMPs: Validation." PDA just recently received authorization from the WHO to comment on their guidelines. In our comments on the validation guideline, PDA asks if the document is redundant with the Pharmaceutical Inspection Convention Scheme (PIC/S) document on validation master plans (*see p. 12 for the "cover letter" to the PDA comments*). ■

Innovative Science & Manufacturing Technologies Discussed at the 2003 PDA Annual Meeting

• Former GlaxoSmithKline Official Paints Picture of Industry's Future

Microelectronic mechanical systems (MEMS)—a subset of nanotechnology—will open a "whole new world" to pharmaceutical and biopharmaceutical developers and manufacturers, according to Darren Dasburg, formerly with GlaxoSmithKline, now an industry consultant.

Addressing delegates at the closing session of the 2003 PDA Annual Meeting, Courses and Tabletop Exhibition at the Hilton Atlanta hotel, Nov. 10–14, Dasburg elaborated on the future look of medicinal products and pharmaceutical manufacturing.

Dasburg explained how MEMS can be used, for example, in patients with diabetes. He presented diagrams of an Integrated Microfluidic System for Bio-Chemical Assay ("BioFlips") which could be placed on a patient for real-time, continuous monitoring of blood glucose levels.

The ex-Glaxo official highlighted the use of MEMS in Japan where pharmaceutical scientists have engineered toilets that allow patients to collect continuous monitoring data from a certain period of time for their doctors. Eventually, patients could choose to allow the doctors real-time access to such data. "In the future," Dasburg said, "you may be at work at 12:00 when that…information is being fed to a hospital…and they pick you up at 4:30 for your bypass surgery" which they had just determined was necessary.

These anecdotes demonstrate how technologies like MEMS are now changing the industry. Dasburg explained that there exists a variety of "innovative technologies that will be fun" to work with and will have a "positive impact on the pharmaceutical industry."

continues on page 6

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Sartorius AG, Weender Landstrasse 94–108, 37075 Goettingen, Germany
Sartorius Corporation, 131 Heartland Blvd., Edgewood, NY 11717, USA
www.sartorius.com

PDA Global Headquarters
3 Bethesda Metro Center, Suite 1500
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900 Fax: +1 (301) 986-0296
E-mail: *info@pda.org*
Web site: www.pda.org

PDA European Headquarters
Gautam Maitra
Director, Europe
R-1059.747
Postfach
CH-4002 Basel
Switzerland
Tel: +41 61 321 56 30 (Fixnet)
Mobile: +41 79 439 59 56
Fax: +41 61 321 83 48
E-mail: *maitra@pda.org*

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

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Neal G. Koller
President

Matthew Clark
Director of Marketing Services

Walter Morris
Senior Editor

Janet Raysick
Production Manager

Virginia Ventura
Director, Membership and Chapters

Important Dates...

- **January 31, 2004—deadline for comment on EMEA Note for Guidance on Assessing the Risk for Virus Transmission, page 14**
- **February 16–20, 2004—2004 PDA International Congress, Courses and Tabletop Exhibition, page 19**
- **March 8, 2004—deadline for comment on FDA CDER Draft Guidance on Powder Blends and Finished Dosage Units, page 14**
- **March 8–12, 2004—SciTech Summit™, page 18**

IN THIS ISSUE...

Neal G. Koller
PDA President

Looking Forward to 2004 as PDA's Strategic Plan Continues to Unfold

PDA members have much to look forward to in 2004 as we work to build on the many successes of the past year.

PDA made great strides in 2003, establishing and building on many new structural and operational improvements, better positioning PDA to fulfill its Strategic Plan. In this, the last President's Message of 2003, I thought it would be valuable to present the more substantial enhancements made throughout the year. To help orient us to the Strategic Plan, many of the 2003 accomplishments are highlighted below in relation to each of the six strategies.

Strategy 1: Increase accessibility of services, education and training to the global membership

Improvements in the way PDA supports its chapters have been ongoing throughout the year. We have created a new system of support for our chapters, facilitating their ability to provide science comments on regulatory guidances from around the world. A new system was implemented to help chapters elicit involvement of health authority personnel from around the world in chapter events. A new staff position was added, the Chapter Coordinator, dedicated to work closely with and support our 20 chapters worldwide. PDA initiated a "Member Volunteer Program," which provides a cost-effective method for members to attend our events at a discount when they volunteer to work at PDA events. To increase the value of membership, we launched a new Career Center that includes searches by job location, storage of resumes and cover letters, and e-mail notifications of job matches and search agents. As the year closes, we expect new translations of Technical Reports will be available in Japanese and Chinese, and a new GMP handbook will be available in both Japanese and English.

Our programs and meetings—one of the key strengths of PDA—expanded globally in 2003, with a 50% increase in the total number of meetings planned and a 50% increase in the number of meetings held outside the U.S., as well as a 75% increase in audio and web-based offerings. In addition, PDA strengthened its ability to provide valuable and cost-effective events by co-sponsoring meetings with the EMEA, the Parenteral Society, FDA and PQRI. We also reached agreements for events in 2004, including: 1) PDA's new SciTech Summit™ which will be co-located to provide expanded facilities and capabilities with CleanRooms East's 2004 exhibition in Orlando, Florida, March 8–12, 2004 (*for more information, see p. 18*). This new and exciting event will bring unparalleled value to PDA members. 2) On the international front, PDA is continuing its always popular and successful collaboration with R³ Nordic, co-sponsoring a Science, Technology and Regulation Congress in Stockholm Sweden with them in June 2004. (*See p. 21.*)

Strategy 2: Build a stronger liaison with regulatory bodies

PDA worked very hard in 2003 to expand our relationships with regulatory bodies around the world. PDA and FDA considered the feasibility of expanding the Agency's participation in PDA's Science Advisory Board and discussed a speaker topic and speaker travel coordination system to better accommodate their needs. We established closer ties with EMEA, developing regular lines of communication and interaction, and most importantly, co-sponsored our first joint meeting with them. During the year, the World Health Organization (WHO) approved PDA to comment on their guidances and began discussions to sponsor joint meetings with us in WHO countries. Also in 2003, PDA established a working relationship with the International Conference on Harmonization (ICH), which granted PDA's request to comment on their guidances. Moreover, PDA held meetings with nearly a dozen national health authorities from around the world, conducted with the Italian Health Authority inspectorate training, and opened discussions on similar training in EU candidate countries and Taiwan. Equally significant, PDA instituted a new "deep discount government rate" for all events and publications to allow our health authority members to more easily participate in PDA.

Strategy 3: Continually improve the relevance of scientific information and programs

Throughout 2003 we achieved a number of enhancements in our efforts to advance this strategy. For the first time, PDA sponsored a meeting of the Editorial Advisory Board for the *PDA Journal of Pharmaceutical Science and Technology*. Additionally, the number of people on the Journal Board was increased to provide breadth of experience and improve scientific guidance and direction. A new Technical Book Editorial Board was formed in 2003 and held its first meeting. The Technical Book Editorial Board was established to provide scientific guidance and peer-review to this increasingly important benefit of PDA membership. PDA entered agreements with two science editors to edit and facilitate the completion of two Technical Reports improving our support to the PDA Science Advisory Board activities and task forces.

Strategy 4: Assure the financial resources are in place to support PDA's mission to be an international influence

Among the many improvements PDA made in 2003, systems were put in place for finance, accounting and forecasting to assure PDA has adequate methods to monitor its businesses. To better serve the membership, PDA established additional Swiss bank accounts permitting the use of multiple currencies. A new Web-based accounting system was introduced to support PDA chapter financial activity. Most importantly, PDA effected improvements that, as 2003 comes to a close, will considerably enhace our financial footing and ensure that PDA continues to be a strong organization in years to come.

Strategy 5: Continue to expand and market PDA

PDA completed a number of new initiatives in 2003 strengthening this critical strategy. The PDA Board approved member petitions to start two new chapters: The Prague and the France chapters. The Prague chapter, encompassing six of the European candidate countries, will afford PDA membership worldwide the opportunity to work with and benefit from the insight of colleagues in this important region of the world. The France chapter will bring PDA worldwide much closer to one of the world's largest and most important pharmaceutical and biopharmaceutical markets, and afford the PDA members in France a greater input and closer relationship with PDA worldwide initiatives. PDA launched a new chapter newsletter, an enhanced our press-release strategy and diversified our advertising across new mediums.

Strategy 6: Improve PDA's operating structure domestically and internationally

During 2003, the PDA "Membership Services" department was reorganized to better support our members and our chapters, and as such, was renamed "Membership & Chapters." Likewise, to better serve the membership, the "Marketing and Communications" department was reorganized and renamed "Marketing Services." To support these and other structural changes, new staff members and/or investments were approved in the following departments: Human Resources, the PDA Training & Research Institute, Science & Technology, Programs and Meetings, Finance and Strategic Planning, Membership and Chapters and Marketing Services.

As 2004 unfolds, PDA will remain focused on helping its membership perform better professionally and enrich their careers. We will work tirelessly to bring the PDA community closer together. And we will continue to focus on fulfilling our Strategic Plan, with a special emphasis on our unique capabilities and relationships in science, technology, regulation and training. For more information on improvements made at PDA in 2003, please see the 2003 "President's Report," delivered at the PDA 2003 Annual Meeting, available in the "Presentation Archive" in the member's section of pda.org. ■

Volunteer Needed For Audit Committee

PDA's Board of Directors is forming an Audit Committee to ensure that PDA maintains the highest level of integrity in its financial governance. Though associations are not subject to the requirements of the Sarbanes-Oxley Act, PDA has chosen to proactively conform with good audit oversight practices in anticipation of future regulation affecting not-for-profit organizations.

As part of this effort, the Audit Committee needs a PDA member with extensive accounting or related financial management experience. Ideally, the volunteer will have a certificate in accounting, i.e., a CPA or CFA . Preference will be given to those candidates with executive-level experience and profit and loss responsibilities, such as CEO, CFO or senior officer of a corporation or operating division.

For additional information or to express your interest in this volunteer opportunity, please contact Lance K. Hoboy, VP, Finance & Strategic Planning, at +1 301-656-5900 (ext. 114) or hoboy@pda.org. ■

Innovative Science & Manufacturing Technologies, from cover

Noting that GlaxoSmithKline is working with the University of California at Berkley Sensor and Actuator Center to explore pharmaceutical applications of MEMS, Dasburg stressed that this and other new technologies will challenge the "mindset" of QA/QC, production and other groups within the industry. To start preparing for this technological revolution, companies need to involve production, QA, engineering, finance, and industry vendors and groups with R&D, advised Dasburg.

Dasburg credited the U.S. FDA Center for Drug Evaluation and Research (CDER) for taking a "promising attitude" towards new technologies. He maintained that he had "never seen a more engaging group of people" working for CDER as those leading FDA's new drug product quality initiative. Considering the many opportunities for "very wonderful collaborations" with CDER, Dasburg insisted that the voice of an association like PDA will be an important one.

FDA-PDA Interactions Key To Agency Initiatives

CDER Acting Director Steven Galson, M.D., also recognized the value of PDA's voice as medical and manufacturing technology evolves.

Dr. Galson discussed FDA's "Five-Point Strategic Plan" unveiled by FDA earlier to create a better working environment between the Agency and industry. Folded into the five-point plan is CDER's effort to create risk-based, flexible manufacturing regulations to help facilitate the use of modern manufacturing technologies. To move these initiatives forward, "future interactions" between PDA and FDA will be "very important," stated Dr. Galson. FDA will not "be able to make progress consistently and in a forward direction unless we keep our relationship with you very close and very strong."

To move these initiatives forward, "future interactions" between PDA and FDA will be "very important," stated Dr. Galson.

Dr. Galson was "encouraged" by PDA's goal of making it easier for FDA and other government employees to access PDA meetings and materials (*see "President's Message," pp. 4–5*). He highlighted PDA's plans to increase the number of activities "that bring folks in connection with FDA." Such interactions, he said, help advance manufacturing and QA/QC science and improve regulations—key elements of the Agency's five-point strategic plan.

Focusing FDA's manufacturing enforcement resources on risk to the patient "bodes very well" for the future of the overall enforcement program, said Dr. Galson. The eventual outcome will be a better "correlation between the Agency's strategic plan and where we want to see GMPs go."

Dr. Galson also discussed the "Innovation Initiative," meant to address the falling rates of new molecular entity (NME) applications being submitted to FDA and other regulatory agencies around the world. The "overall goal" of the initiative is to streamline the drug development process and conduct a "root cause analysis" into reasons for multiple review cycles for marketing applications which "result in longer development times," Galson explained. Part of this effort involves the application of quality principles to FDA's marketing application review function to ensure better "consistency across review divisions."

An "incredibly important" aspect of the Innovation Initiative, said Dr. Galson, is the recently released draft guidance on Pharmacogenomics data for investigational new drug application and new drug applications. He noted that the use of pharmacogenomics will be "linked with" the use of advanced diagnostic test kits, and told the PDA audience that "all must comment" on the document.

Contemporary Scientific Concerns Addressed

While Dasburg talked about future scientific issues, the focus of the 2003 PDA Annual Meeting was on contemporary manufacturing and QA/QC issues.

For example, NAMSA Senior Scientist David E. Albert, Ph.D., discussed the advantages of hypernated and hyphenated liquid chromatography in the evaluation of extractables and leachables for container/closure testing. The technique involves the coupling or linking of one (hyphenated) or more (hypernated) spectrometers to the chromatographic system to provide a better data set for extractables/leachables testing.

A variety of drug product stability issues were addressed during the meeting. For example, Paul Tsang, Associate Director, Amgen, outlined the strategies and challenges involved with building a sound and regulatory compliant stability program for biologicals and biotech products. AstraZeneca Pharmaceuticals, Senior QA Manager Larry Murphy shared with meeting attendees the strategies a large, international company like Astra uses to "globalize" a stability testing program. Aspects needing consideration to build a global stability testing program include product dosage form and packaging, test methods, data reporting/trending systems, sample handling, and expiration dating.

From the regulatory perspective, David Lin, Ph.D., Acting Deputy Director, Division of New Drug Chemistry, CDER, reported that the Agency's 1998 draft stability guidance is still under revision. The primary concern is to reduce redundancies with the International Conference on Harmonisation (ICH) stability guidances and with FDA's own manufacturing changes guidances, as well as to better organize the document and make it more user-friendly.

Speaking about the FDA's latest draft guidance for industry on aseptic processing, CDER compliance officer Brenda Uratani emphasized the overall need to change the regulations to better reflect sound science and risks to the consumer. She pointed out that the aseptic processing draft guidance exemplifies the type of scientifically-oriented, risk-based policies FDA wants to develop under its Five Point Strategic Plan and its 21st Century drug product quality initiative. Richard Johnson, Director, Abbott Laboratories, provided PDA's view of the draft aseptic guidance. A lively group discussion followed the two presentations.

A number of breakout sessions convened on a variety of important scientific and manufacturing issues, including 21 CFR Part 11 compliance, filtration, and computer systems validation. In addition, many of PDA's Interest Groups and Task Forces met to provide updates of their diverse projects. Drawing a large number of participants was the four PDA Cold Chain Management Task Force sessions, led by Rafik Bishara, Ph.D., Eli Lilly and Company. The group has completed a draft guideline for PDA members to review. The goal is to turn the document into a PDA Technical Report that could serve as the basis for a U.S. Pharmacopeia chapter or, perhaps, an FDA guidance. Companies joining Eli Lilly in lending experts to conduct this important work include Amgen, Human Genome Sciences, Abbott Diagnostics, Wyeth Pharmaceuticals, and Aventis Pasteur (see Oct. *PDA Letter*).

Last Autumn Annual Meeting a Resounding Success

The 2003 PDA Annual Meeting is the last to be held in the autumn/winter months. Starting in 2004, PDA will combine its Spring Conferences with the end-of-the-year annual meeting to form the new SciTech Summit™. See page 18 for more information.

Most of the slide presentations from the 2003 PDA Annual Meeting are available to members at pda.org. Photos from this year's meeting appear on pages 22 and 24. ■

Calendar of Events, from back cover

◆ May 24, 2004
PDA Presents
European Rotational Forums
Location TBA
Amsterdam, The Netherlands

May 24–28, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 1**
PDA Training and Research Institute, Baltimore, MD

June

◆ June 7–8, 2004
PDA/R3 Nordic
Scientific, Industrial, and Regulatory Aspects of Clean Products and Devices
Stockholm, Sweden

June 14–18, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 2**
PDA Training and Research Institute, Baltimore, MD

June 15–17, 2004
PDA Training and Research Institute
Toronto Course Series
The Westin Harbour Castle
Toronto, Canada

◆ June 28, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

August

August 16–20, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 1**
PDA Training and Research Institute, Baltimore, MD

◆ August 30, 2004
PDA Presents
European Rotational Forums
Location TBA
Berlin, Germany

September

September 2–3, 2004
PDA Training and Research Institute Laboratory Course
Advanced Environmental Mycology Identification Workshop
PDA Training and Research Institute, Baltimore, MD

September 13–17, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 2**
PDA Training and Research Institute, Baltimore, MD

◆ September 27, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

October

October 4–8, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 1**
PDA Training and Research Institute, Baltimore, MD

November

November 1–5, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 2**
PDA Training and Research Institute, Baltimore, MD

November 11–12, 2004
PDA Training and Research Institute Laboratory Course
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA Training and Research Institute, Baltimore, MD

Recent Sci-Tech Discussions

"Cleaning Validation (protein residue detection)"

The following, unedited remarks are taken from the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum held on the Internet 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

I am working on cleaning validation. We are looking for a method for the detection of allantoic liquid residues (or protein) on stainless steel tank surfaces. The main problem is that the allantoic liquid is very dry and it gets stuck on the surface and is not easy to swab (in order to detect). Which solvent could be used to recuperate the residue but would not interfere with TOC analysis?

Is there a way to detect the protein residues directly on the surface by application of a reagent into the tank? (ninhydrin or something else ?)

Response 1

Have you actually tried recovery studies with dried protein on surfaces? Don't assume they are difficult to swab until you have tried it. Make sure the amount of protein spiked is at or below your residue limit. In terms of solvents to assist in removal, do not use any organic solvents. Use only low TOC water, perhaps with a small amounts of sodium hydroxide or a small amount of phosphoric acid to adjust the pH, which may (or may not) result in better recoveries. If you use the higher pH and use a TOC analyzer that requires acidification of the sample for effective oxidation, you may have to adjust the acid feed in the TOC analyzer to assure sufficient neutralization of the alkalinity in the swabbing solution.

I would verify that you can't recover it by swabbing before I would consider other alternatives. However, I believe you should be able to get reasonable recoveries by swabbing and measuring TOC.

Response 2

1–I would go with TOC as your method.

2–I would vary the pH of the swabbing solution. This should reveal what pH is best for removing these residues. Look up the isoelectric point of your product. The isoelectric point of stainless steel is 8.3. Modify the pH of your swab solution so that both the product and stainless steel have the same charge. The product should come off more easily.

3–If your product is dried and stuck to the surface, it sounds like you need to revisit your cleaning procedure and modify it so that this does not happen. Based on #2 above you may find an aqueous cleaning at a certain pH which should give you the best results.

4–I would not recommend spraying anything "foreign" into your tank.

Response 3

The only diluents which can be used for TOC analysis is one not containing organic or inorganic carbon. This pretty much rules out most solvents except water. I'm not sure if non-carbonaceous acidified or alkaline aqueous solutions would work (e.g., dilute phosphoric, sulfuric, nitric acids, etc.). Perhaps someone could comment on this.
Also use of other reagents to detect residual protein by addition directly to surface walls is not advisable since you would need to prove recovery of added species (or at least down to a toxicologically or pharmacologically derived level). How would you quantify the level detected visually?

The best bet may be use of other organic solvents such as IPA, ETOH, MEOH (alone or mixed at different proportions with water) and analysis of the swab extracts or ruinates using HPLC or GC instead of TOC. ■

Biotechnology
Frank Matarrese
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608
Tel: +1 (510) 923-3128
Fax: +1 (510) 923-3375
E-mail: frank_matarrese@chiron.com

Computer Systems
Barbara L. Meserve
The Hollis Group Inc.
Station Square Two #109
Paoli, PA 19301
Tel: +1 (610) 889-7350
Fax: +1 (610) 296-2339
E-mail: bmeserve@hollisgroup.com

Contract Manufacturing
Thomas Handel
Meridian Medical Technology
10240 Old Columbia Road
Columbia, MD 21046
Tel: +1 (443) 259-7870
Fax: +1 (443) 259-7871
E-mail: Tom.Handel@meridianmt.com

Drug–Device Delivery Systems
Raymond A. Pritchard
Alkermes, Inc.
88 Sidney Street
Cambridge, MA 02139
Tel: +1 (617) 250-1621
Fax: +1 (617) 494-5504
E-mail: ray.pritchard@alkermes.com

Filtration
Jack Cole
Jack Cole Associates
115 Turtle Cove Lane
Huntington, NY 11743
Tel: +1 (631) 424-3658
Fax: +1 (631) 424-3658
E-mail: jvcole@aol.com

GMP Purchasing
Nancy M. Kochevar
Amgen, Inc.
MS 9-1-E
One Amgen Center
Thousand Oaks, CA 91320-1799
Tel: +1 (805) 447-4813
Fax: +1 (805) 447-1904
E-mail: nancyk@amgen.com

Inspection Trends/ Regulatory Affairs
Robert L. Dana
Elkhorn Associates Inc.
4828 Patrick Place
Liverpool, NY 13088
Tel: +1 (315) 457-3242
Fax: +1 (315) 451-7363
E-mail: elkhornassoc1@aol.com

Isolation Technology
Dimitri P. Wirchansky
Jacobs Engineering Group, Inc.
Three Tower Bridge
Two Ash Street, Ste. 3000
Conshohocken, PA 19428
Tel: +1 (610) 567-4452
Fax: +1 (610) 238-1100
E-mail: dimitri.wirchansky@jacobs.com

Lyophilization
Edward H. Trappler
Lyophilization Techology
30 Indian Drive
Ivyland, PA 18974
Tel: +1 (215) 396-8373
Fax: +1 (215) 396-8375
E-mail: frzdry@lyo-t.com

Microbiology/ Environmental Monitoring
Jeanne E. Moldenhauer, Ph.D.
Vectech Pharmaceutical Consulting, Inc.
16100 W. Port Clinton Rd.
Lincolnshire, IL 60069
Tel: +1 (847) 478-1439
Fax: +1 (847) 478-1745
E-mail: jeannemoldenhauer@yahoo.com

Ophthalmics
Chris Danford
Alcon Laboratories Inc.
Mail Code Q-108
6201 South Freeway
Ft. Worth, TX 76134
Tel: +1 (817) 551-4014
Fax: +1 (817) 568-7004
E-mail: chris.danford@alconlabs.com

Packaging Science
Edward J. Smith, Ph.D.
Wyeth Pharmaceuticals
2100 Renaissance Blvd.
King of Prussia, PA 19406
Tel: +1 (610) 313-4338
Fax: +1 (610) 313-4644
E-mail: smithej@wyeth.com

Pharmaceutical Water
Theodore H. Meltzer, Ph.D.
Capitola Consulting Co.
8103 Hampden Lane
Bethesda, MD 20814-1124
Tel: +1 (301) 986-8640
Fax: +1 (301) 986-9085
E-mail: theodorehmeltzer@hotmail.com

Production and Engineering
Frank Bing
Abbott Laboratories
D-968/AP4B
100 Abbott Park Road
Abbott Park, IL 60064-6076
Tel: +1 (847) 937-8191
Fax: +1 (847) 938-6569
E-mail: frank.bing@abbott.com

Quality Assurance/ Quality Control
Don E. Elinski
Johnson & Johnson Merck
1734 Valette Drive
Lancaster, PA 17602
Tel: +1 (717) 207-3858
Fax: +1 (717) 207-3556
E-mail: elinski@aol.com

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly & Company
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: +1 (317) 277-3618
Fax: +1 (317) 276-3618
E-mail: jimenez_pedro_j@lilly.com

Stability
Rafik H. Bishara, Ph.D
Eli Lilly & Company
DC 2623 Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: +1 (317) 276-4116
Fax: +1 (317) 276-1838
E-mail: rhb@lilly.com

Sterilization/ Aseptic Processing
James P. Agalloco
Agalloco & Associates
2162 US Highway 206
Belle Mead, NJ 08502
Tel: +1 (908) 874-7558
Fax: +1 (908) 874-8161
E-mail: jagalloco@aol.com

Training
Thomas W. Wilkin, Ed.D.
Schering-Plough Corp.
M/S R-40
2000 Galloping Hill Road
Kenilworth, NJ 07083-1328
Tel: +1 (908) 298-5213
Fax: +1 (908) 298-5120
E-mail: thomas.wilkin@spcorp.com

Vaccines
Frank S. Kohn, Ph.D.
FSK Associate
1899 North Twins Lake Rd.
Manson, IA 50563
Tel: +1 (712) 297-8074
Fax: +1 (712) 297-8074
E-mail: fsk@lowatelecom.net

Validation
Bohdan M. Ferenc
Qualification Services
116 Route 10
Succasunna, NJ 07876
Tel: +1 (973) 927-9823
Fax: +1 (973) 927-9823
E-mail: biferenc@aol.com

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pfizer Inc.
7171 Portage Road
MS 2043-41-104
Kalamazoo, MI 49001-0199
Tel: +1 (269) 833-8906
Fax: +1 (616) 833-9987
E-mail: john.g.shabushnig@pfizer.com

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

Docket No. 2003D-0380

Re: Guidance for Industry PAT - A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance (Draft Guidance, August 2003)

PDA is pleased to provide comments on the recently issued Guidance for Industry entitled PAT - A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance. PDA is an international professional association of more than 10,500 individual member scientists having interest and expertise in pharmaceutical manufacturing and quality. A committee of experts in this field prepared the comments that follow.

We are encouraged by the initiative of the FDA to clarify their position on process analytical technology (PAT) and appreciate the rapid pace with which this guidance was prepared. We believe this action will speed the adoption of this beneficial technology in our industry. The PDA supports the development and implementation of PAT for use in the manufacture of pharmaceutical products and offers these comments in a constructive manner.

General Comments:

1. We recommend that the section on the background of PAT *(Section III, lines 82–169)* and other general information regarding the use and benefits of PAT be removed from the body of the guidance. This information may be more appropriate in an appendix or a separate concept paper. Greater emphasis on regulatory expectations is desired in the guidance.
2. The footnotes included in the document provide useful reference to related FDA documents. We recommend further references of this nature. Specifically, reference to applicable sections of the Guideline on General Principles of Process Validation (USFDA, May 1987), Hazard Analysis and Critical Control Point Principles and Application Guidelines (USFDA, USDA, August 14, 1997) and other relevant existing documents would help clarify how this new guidance supports or modifies the agency's positions in these areas.

Additional Information and Clarification Requested:

1. Safe Harbor and Research Exemption. During preliminary and more advanced discussions over the past 18 months on the subject of PAT implementation, the terms "Safe Harbor" and "Research Exemption" were used to convey a concise and central definition to a concept critical to broad use of these technologies. *Lines 632–633 and 635–647* imply these concepts, but the reader is forced to rely on a tangential interpretation with respect to measurement devices and data quality rather than a direct discussion of the impact of PAT data to a product's compliance with registered specifications. This has been one of the most contentious areas of the PAT initiative and has the potential to slow experimentation with and implementation of these technologies. Further clarification that products will be assessed with current methods and against current specifications is desired.
2. Specifications. It is imperative that the agency re-evaluates the current definition of specification limits to ensure that processes that have historically produced acceptable product are not unduly penalized by the increased amount of data available with PAT methods. It is unclear what the status of previously registered methods and specifications will be once a PAT method is initiated. Product release specifications should be set to meet patient safety and efficacy requirements, not process capability as stated in *lines 451–455*. Internal process control limits should be set and re-evaluated periodically as additional process experience is gained and process improvements made as stated in *lines 490–496*.
3. Validation. It is expected that the development and implementation of PAT will drive changes in the way equipment and processes are validated. It would be helpful if this guidance provided validation expectations for PAT methods and equipment. *Lines 519–520* state "An emphasis on process knowledge can provide less burdensome approaches for validating new technologies for their intended use". An example would help demonstrate this point. Further explanation on what is meant by "continuous quality verification" or "continuous real time quality assurance" is desired. A comparison with the current prospective three-batch process validation strategy would be helpful.
4. Chemometrics. The section entitled Multivariate Data Acquisition and Analysis *(Section IV.A.1.a, lines 326–401)* would benefit from a specific discussion on chemometrics and some of the common modeling tools such as Principle Component Analysis (PCA) and Partial Least Squares (PLS). An example or examples, including validation, registration strategy and data retention guidelines would be helpful. Alternatively, such information could be developed with a third party such as PQRI or ASTM and placed in a separate guide or standard.
5. Process Signature. The concept of a "process signature" as discussed in *lines 389–392* should be clarified. If documenting such a signature becomes a regulatory expectation, deviation from this signature should not be treated the same as current process deviations or OOS results. It can be difficult to correlate non-specific changes in process signature with specific changes in product quality. As a result, this approach may be extremely prone to false positives, frustrating the ruggedness of PAT methodology.

continues on page 13

November 4, 2003

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

Re Docket No. 2003D-0382

Draft Guidance for Industry on Sterile Drug Products Produced by Aseptic Processing

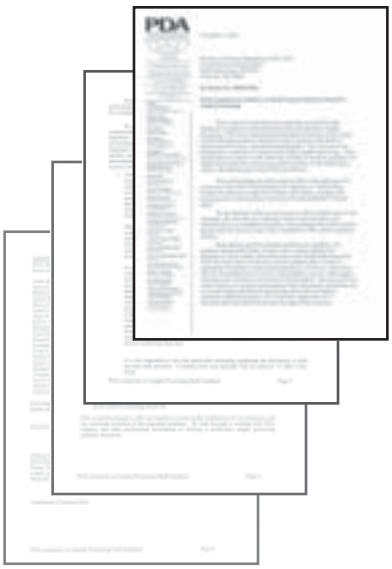
PDA is pleased to provide these comments on the FDA Draft Guidance for Industry on Sterile Drug Products Produced by Aseptic Processing. PDA is an international professional association of more than 10,500 individual member scientists having an interest in the fields of pharmaceutical science, manufacturing and quality. Our comments were prepared by a committee of experts in the field of aseptic processing. These stakeholders are ready to work with FDA via PDA to develop a guidance for aseptic processing that would ensure quality products in the market place, which is the ultimate goal of both FDA and industry.

PDA acknowledges the effort made by FDA in the publication for comments of the FDA's Draft Guidance for Industry on "Sterile Drug Products Produced by Aseptic Processing" and wishes to recognize the improvements in this document from the previously published "Concept Paper."

We are pleased to offer our comments in order to further improve the document. We trust that our comments will be received as they were intended; that is, to strengthen the utility of the guidance that will be used by people with very diverse needs: ORA, Compliance, OPS, and the regulated industry.

Both industry and FDA urgently need this new guidance. The guidance should enable firms to know what to expect during FDA inspections of their aseptic processing areas and it should help ensure that FDA 483 observations are based on current guidance that is rooted in appropriate technology, science and best practices. However, some of the items in this guidance are covered in other guidance, and we would suggest that these items should be removed from this document. This document also makes reference to products and processes other than aseptic processing, and we would suggest clarification that this document does not apply to terminally sterilized products. We would also suggest the use of Internationally Standardized (SI) units throughout the document.

Several recommendations may be unnecessarily specific and may prevent future technological advances because the solution is already prescribed in a FDA Guidance document. For example, specifics mentioned on lines 313, 373, 1510, 1042, and 1305



We welcome the concept described in line 1171 that reads, "Detection of microbial contamination on a critical site should not necessarily result in batch rejection." This concept is important and recognizes that individual values over the alert and action levels during environmental monitoring are not necessarily an indication of an out of control condition. It is important to note that environmental sampling of any surface is a test that neither confirms sterility nor indicates a lack of sterility assurance. Sampling activities themselves are aseptic interventions and the results of these activities are themselves uncertain. We ask that the Agency incorporate this concept in other sections of the document, such as:

1. Text in the Draft FDA aseptic processing guideline (see lines 132–137) suggests that cleanrooms used for aseptic processing should be evaluated under both as-built and static conditions, but that classification of the cleanroom should be conducted under dynamic conditions "with personnel present, equipment in place and operations ongoing." PDA recognizes that in part this does not reflect new policy from FDA. However, we believe that the position taken in the draft guideline has the potential to both require unnecessary cleanroom evaluation and to further blur the distinction between classification of cleanrooms and monitoring of their contamination control performance.

   PDA believes that classification of cleanrooms should be done primarily under static or as-built conditions as defined in ISO 14644 and that evaluation of the dynamic performance of a cleanroom should be left to the monitoring program. PDA suggests that recertification of the cleanroom on an annual or biannual basis is sufficient and that an assessment of clean room classification under "dynamic conditions on a routine basis" is unwarranted.

   It is inevitable that production operations will release relatively low levels of particulate contamination into the surrounding environment. The supply of components on conveyor systems, loading of component supply hoppers, vibratory bowl operations, and personnel movement can all result in intermittent or continuous particle generation or release. It is quite possible for there to be locations within a well controlled and carefully operated aseptic processing area that regularly exceed a particulate classification rating. The only way to prevent low level particulate generation of this kind would be to turn off the processing equipment, and completely eliminate personnel and their movement, neither of which are practical in a working manufacturing environment. PDA agrees that should changes to the operation of process equipment result in particulate counts that statistically exceed the process norm, investigation and possibly corrective action should occur. However, the observation of spikes during routine monitoring is not atypical and does not mean that the facility is operating

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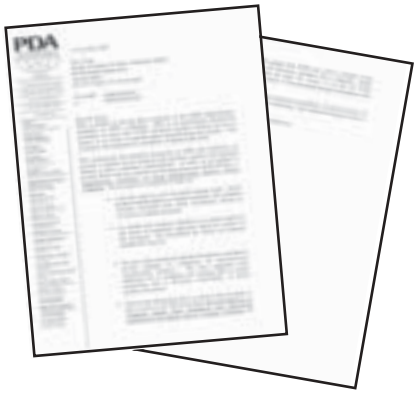


15 November 2003

Dr S. Kopp
Quality Assurance & Safety: Medicines (QSM)
World Health Organization
Avenue Appia
CH-1211 Geneva 27, Switzerland

Via e-mail, kopps@who.int
cc bonnyw@who.int

Dear Dr. Kopp:

PDA is pleased to provide these comments on the WHO Supplementary Guideline on GMPs: Validation. PDA is an international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical manufacturing and quality. Our comments were prepared by a committee of experts in this field.

PDA understands that guideline documents on GMP and Validation can provide a valuable role in assisting both regulatory agencies and regulated industry in their compliance responsibilities. As such, we are pleased to provide WHO with our comments on Working document QS/03.055/Rev. 1, Supplementary Guidelines on Good Manufacturing Practice (GMP): Validation. The key points we would like to make are:

- Limit the scope to cover non-sterile dosage forms. Sterile product manufacturing is a complex operation. The validation activities associated with sterile manufacture should be covered in a separate document.
- In a similar vein, computer validation is a complex operation that cannot be adequately addressed within the confines of this document. We recommend the section on computer validation be removed.
- We note in the Introduction that this document is intended to provide guidance to "inspectors of pharmaceutical manufacturing facilities". We have suggested some additional text to strengthen this message and to include terminology that is becoming commonplace in global guidance documents.
- Much of the information that is covered in this document is also covered in the PIC/S document Recommendations on Validation Master Plans Installation and Operational Qualification Non-Sterile Process Cleaning Validation, PI 006-1, 3 August 2001. We suggest that WHO may wish to consider if this document already provides the necessary guidance that is required. PIC/S document PI 006-1 provided the basis for Annex 15 of the EU GMP Qualification and Validation. Annex 15 was developed through consultation with industry.

PDA has reviewed the document in detail and our comments are attached. For ease of review we have included a copy of the Guideline with line numbering. Our comment document refers to the guideline by line number.

If I can be of further assistance, please feel free to contact me.

Sincerely,

William Stoedter, RAC
PDA Director of Regulatory Affairs
E-mail: Stoedter@pda.org
Web Site: www.pda.org
Attachment: PDA Validation Comment Grid ■

Go to www.pda.org to see the full comment grid.

PDA Comments: PAT Guidance, from page 10

6. Life-Cycle. An example showing the use of PAT during product/process development and subsequent deployment at production scale would be instructive. It appears likely that data collected during development could lead to simplified measurement and control strategies in production. Further, with increased production experience, it may be justified to remove a PAT device. Following the regulatory expectations of this evolutionary process would be helpful.
7. Risk Assessment. The guidance refers on several occasions to "risk" and "risk-based" methods and decisions *(e.g. lines 27, 124, 406, 476, 481, 544, and 547)*. There is confusion as to the nature of the risk being managed. Risk associated with product safety and quality and that with resource conservation appear to be used interchangeably. Clarification is needed on how to assess risk. Information such as that provided in ISO 14971: 2000, Application of Risk Management to Medical Devices (February 12, 2002) would eliminate this confusion.
8. Dosage Forms. The guidance appears to focus on the application of PAT to drug products, and primarily solid oral dosage forms. PAT is also applicable to liquid and semi-solid products. Furthermore, the chemical industry has a long history of successful use of these technologies and use in the production of active pharmaceutical ingredients (API) or drug substances by traditional chemical synthesis or fermentation should also be encouraged. These points could be made through selection of examples in the guidance, or a broader scope statement.
9. Regulatory Filing Process. While the regulatory filing process is mentioned in this guidance, the document would benefit from a flow chart showing the different types of filings expected (new or existing product), the desired timing of contact with the agency, who to contact and the information expected at each stage.

PDA appreciates the opportunity to support the FDA in the preparation of sound and science based guidance. Please contact me if you have any questions on this matter.

Sincerely,

William Stoedter, RAC
PDA Director of Regulatory Affairs
301-656-5900 ext. 121
Stoedter@pda.org
www.pda.org ■

Regulatory Briefs

Key Regulatory Dates

Jan. 31—Deadline for public comment on **EMEA** Note for Guidance on Assessing the Risk for Virus Transmission—New Chapter 6 of the Note for Guidance on Plasma-Derived Medicinal Products (CPMP/BWP/269/95)

March 8—Deadline for public comment on **FDA** CDER Draft Guidance on Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment.

U.S. FDA

CDER Releases Draft Guidance on Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment This guidance is intended to assist manufacturers of human drug products demonstrate the adequacy of mixing to ensure uniformity of in-process powder blends and finished dosage units per the GMPs. This guidance describes the procedures for assessing powder mix adequacy, correlating in-process dosage unit test results with powder mix test results, and establishing the initial criteria for control procedures used in routine manufacturing.

The Product Quality Research Institute (PQRI) formed the Blend Uniformity Working Group to develop a draft recommendation for FDA. The draft recommendation received examination and peer review in multiple scientific and public venues, including the Advisory Committee for Pharmaceutical Science, and it was revised to incorporate public comments and was presented to the Agency in December. The recommendation was subsequently published in the *PDA Journal of Pharmaceutical Science and Technology*. The draft guidance incorporates PQRI's recommendation. PDA is hosting a 1½-day PQRI workshop on the recommendations in early December. The draft guidance can be found at: http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0493-gdl0001.doc. Comments are due to FDA by March 8, 2004.

CBER and CDER Issue International Conference on Harmonization Q3C Tables and List of Residual Solvents This is the companion document for the International Conference on Harmonization (ICH) guidance for industry Q3C Impurities: Residual Solvents (1997), which makes recommendations as to what amounts of residual solvents are considered safe in pharmaceuticals. This document contains a list of solvents included in the Q3C Guidance and tables of solvents grouped by class.

Solvents in Class 1 (Table 1) should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity or their deleterious environmental effect. However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, their levels should be restricted as shown in Table 1, unless otherwise justified. Solvents in Class 2 (Table 2) should be limited in pharmaceutical products because of their inherent toxicity. Class 3 (Table 3) encompasses no solvent known as a human health hazard at levels normally accepted in pharmaceuticals. However, there are no long-term toxicity or carcinogenicity studies for many of the solvents in Class 3. Available data indicate that they are less toxic in acute or short-term studies and negative in genotoxicity studies. It is considered that amounts of these residual solvents of 50 mg per day or less (corresponding to 5,000 ppm or 0.5 percent under Option 1) would be acceptable without justification. Q3C Tables and list can be found at: http://www.fda.gov/cber/gdlns/ichq3ctablist.htm.

CDER and CBER Issue ICH Guidance Q3B(R) Impurities in New Drug Products This guidance provides recommendations for registration applications on the content and qualification of impurities in new drug products produced from chemically synthesized new drug substances not previously registered in a region or member state. This guidance revises the ICH guidance of the same title, which was issued in May 1997. The revised guidance clarifies the 1997 guidance and makes some changes. The revision also provides consistency with more recently published ICH guidances (e.g., Q3A(R) Impurities in New Drug Substances, Q3C Impurities: Residual Solvents, and Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances). This guidance complements the ICH Q3A(R) guidance, which should be consulted for basic principles along with ICH Q3C when appropriate. The Guidance can be found at: http://www.fda.gov/cber/gdlns/ichq3br.htm.

CDER Proposes Rule on Requirements for Submission of In Vivo BE Data CDER is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies that the applicant conducts on a drug product formulation submitted for approval.

In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets bioequivalence criteria for FDA to approve the ANDA, but have not typically submitted additional BE studies conducted on the same drug product formulation, such as studies that do not show that the product meets these criteria. FDA is proposing this change because they now believe that data from additional BE studies may be

important in the determination of whether the proposed formulation is bioequivalent to the reference listed drug and are relevant to the evaluation of ANDAs in general. In addition, such data will increase the FDAs understanding of how changes in components, composition, and methods of manufacture may affect formulation performance. The proposed rule can be found at: www.fda.gov/cder/guidance/index.htm.

Japan MHLW

A Delegation of the European Federation of Pharmaceutical Industries and Association (EFPIA) met Nov. 14 with Japanese authorities to address: the situation of the research-based pharmaceutical industry in Japan; the alarming loss of competitiveness (both Japan and Europe are lagging behind the U.S.); and the urgent need to provide an adequate environment for pharmaceutical innovation so that new medicines can be developed, benefit Japanese patients and improve public health.

EFPIA welcomes the commitment of the Japanese authorities to improve the competitiveness of the pharmaceutical industry. Recent accomplishments include the launch of the Ministry of Health, Labour and Welfare 'Vision' for the pharmaceutical industry, which offers specific business and market-based measures to attract R&D investment. The EFPIA delegates, however, believe more needs to be done in order to implement all actions included in the 'Vision' and to improve the competitiveness of the Japanese pharmaceutical sector in the global marketplace. For example, the Japanese authorities could set in place pricing rules for medicines that truly reward pharmaceutical innovation. In addition, more progress could be made on the regulatory side to achieve a world-class regulatory system.

EU EMEA

New Chapter 6 on Plasma-Derived Medicinal Products of the Committee for Proprietary Medicinal Products "Note for Guidance on Assessing the Risk for Virus Transmission" was released in October for "consultation." The goal of the chapter is to outline the general principles that manufacturers should follow when performing risk assessment with respect to potential virus transmission from plasma-derived medicinal products. The chapter addresses general principles of risk assessments, including: potential virus input; overall virus inactivation/removal capacity; contribution from specific antibodies to virus safety; and estimation of virus particles per dose. It also makes recommendations on how to evaluate the clinical experience and how to apply the guidance. The chapter is available at: http://www.emea.eu.int/htms/human/bwp/bwpdraft.htm. The deadline for comments is the end of January 2004.

WHO

The World Health Organization (WHO) Expanding Efforts to Combat Substandard and Counterfeit Medicines WHO will launch an action plan against substandard and counterfeit medicines with six countries from the Greater Mekong sub-region this week. The plan follows similar initiatives begun in Africa and will continue to expand in response to countries' increasing calls for assistance to improve the quality of their medicines. Counterfeit and substandard medicines are frequently detected in Cambodia, China, the Lao People's Democratic Republic, Myanmar, Thailand and Viet Nam, and the problem seems to be increasing. Products most commonly counterfeited in this region include antibiotics and those used in the treatment of tuberculosis, malaria and HIV/AIDS.

At a Nov. 11–13 meeting in Hanoi, Viet Nam, WHO and the six countries met to kick-start joint activities to combat counterfeiting of medicines in the region, to promote advocacy activities directed at key decision-makers, health professionals and the general public, and to strengthen inspection and post-marketing surveillance. For more information contact: Ms Daniela Bagozzi, Telephone: +41 22 791 4544, Mobile phone: +41 79 4755490, Email: bagozzid@who.int.

PIC/S

Latvia Invited to join PIC/S at a Joint Meeting of Committee Officials in Geneva, Switzerland, Nov. 11–12, 2003 Latvia's State Pharmaceutical Inspection first applied for PIC/S membership in 1996. During the Nov. meeting, PIC/S also identified the need for closer co-operation with the EU, EMEA, and the European Directorate for the Quality of Medicines (EDQM).

Reports on the reassessment of Australia's Therapeutic Goods Administration, Greece's National Organization for Medicines and Romania's National Medicines Agency were presented at the meeting. Joint reassessments of Italy's Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza and the Norwegian Medicines Agency are currently ongoing. The Committee decided to wait until early 2004 before starting with the planned reassessment of Germany. With regard to the planned reassessment of the Slovak State Institute for Drug Control, PIC/S decided to give priority to the Commission's pre-MRA visit to the Slovak Republic and to check whether it could be combined with the joint reassessment.

For more information on these and other issues discussed at the conference, go to the PIC/S Web site: www.picscheme.org. ■

—compiled by Gautam Maitra, Bill Stoedter and Walter Morris

PDA Comments: Aseptic Processing Guidance, from page 11

outside of its classification nor does it imply that process control has been lost.

It is also important to note that particulate measuring equipment has limitations in both accuracy and precision. Counting error may typically vary as much as +/- 20% of the mean.

FDA should take measurement limitations into account as well as the operational realities of processes and not expect or require industry to consider occasional excursions beyond the classification level to warrant investigation or corrective action. Rigorous control of aseptic processing environments is a goal both industry and FDA share, however standards and/or guidance that does not pragmatically consider both measurement error and actual manufacturing conditions is not helpful and only serves to create dissonance between guideline objectives and actual capability.

The wording in this section also implies that there can be a microbiological classification of cleanrooms. PDA agrees that it is normal industry practice to expect the incidence rate at which contamination is observed in cleanrooms to be well controlled and relatively constant. However, personnel release the vast majority of cleanroom contamination into the environment. Therefore, the areas of increased risk within a cleanroom will be those in which personnel are present and active. PDA realizes that scientists have published a correlation between particulate levels and microbial contamination (Reinmüller and Ljungqvist). However, in their studies the source of both total particulate and microbiological contamination was personnel. Therefore, PDA asserts that there is no value to requiring microbiological assessment of cleanrooms using the principles of total particulate classification. Microbiological assessment of cleanrooms is, in the view of PDA, strictly a monitoring exercise distinct and technically different from the assessment of the facility air supply, which is in fact an insignificant contributor of viable contamination.

2. The interpretation that single alert or action level excursions may constitute OOS may be an unintended consequence of Table 1. These are not absolute values. The document should clarify that microbial values have inherent variability. Sources of this variability include media, incubation time, incubation temperature, and adventitious contamination from personnel since samples are generally taken manually and aseptically.
3. PDA has stated in many previous responses to FDA policy on aseptic processing that actions including placing product on hold or rejection are not appropriate based upon single point excursions beyond suggested levels such as those in Table 1. We reiterate our view that it is inappropriate to require action as a result of tenuous and uncertain data. PDA does not believe that actions are appropriate unless the overall incidence of microbial recovery exceeds a firm's norm over a sampling period of sufficient time to conclude that a change in the state of control may have occurred. Investigations on single point excursions will result in reports that can draw no clear conclusion and which will not be useful in assessing actual risk

PDA would be pleased to offer our expertise to assist in the clarification of our comments, and the continued evolution of this important guidance. We look forward to working with FDA, industry and other professional associations to develop a world-class aseptic processing guidance document.

Acknowledgements:

PDA thanks the members of the Aseptic Processing Task Force for their input in developing these comments.

Anita Albrechtsen, Ferring Pharmaceuticals A/S
James E. Akers, Akers Kennedy & Associates
Martyn Becker, Merck & Co.
Gunter Bruckschlegel, ZLB Bioplasma AG
Doris Conrad, GlaxoSmithKline
John G. Grazal, AstraZeneca Pharmaceuticals
Nigel A. Halls, NHC-Nigel Halls Consulting
Karl L. Hoffmann, Bristol-Myers Squibb Co.
Richard M. Johnson, Abbott Laboratories, Co-chair
Carol M. Lampe, Baxter Healthcare Corporation
Russell E. Madsen, The Williamsburg Group
Leonard Mestrandrea, Pfizer Inc.
Terry E. Munson, KMI/PAREXEL, Inc.
Rainer F. Newman, Johnson & Johnson
Jean I. Olsen, GlaxoSmithKline
Richard Prince, RPA, Inc.
Norman Rabin, Eli Lilly
Ian D. Symonds, GlaxoSmithKline
Martin VanTrieste, VanTrieste &Associates, Co-chair
Glenn E. Wright, Eli Lilly & Company

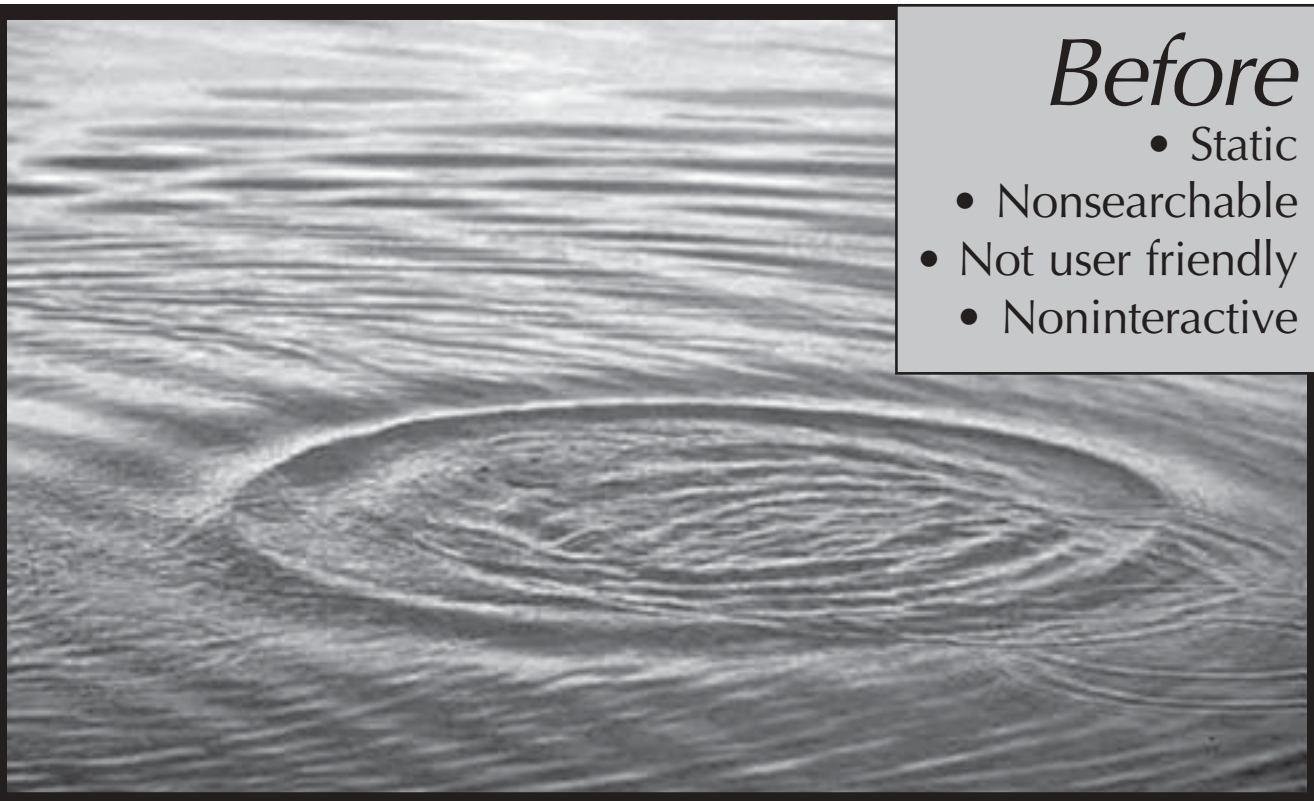
PDA thanks you again for the opportunity to comment on this draft guidance. If you require further information, please feel free to contact me via the information below.

Sincerely,

William Stoedter, RAC
PDA Director of Regulatory Affairs
Phone: 301-656-5900 ext. 121
e-mail: stoedter@pda.org
Web site: www.pda.org

Attachment: Comment Grid ■

Go to www.pda.org to see the full comment grid.



Before

- Static
- Nonsearchable
- Not user friendly
- Noninteractive

The New PDA Online Career Center

After

- Job searches
- Interactive (store resumes/cover letters)
- E-mail notifications

Make Waves!

http://careers.pda.org

PDA
An International Association For Pharmaceutical Science And Technology

2004 PDA SciTech Summit™—Orlando, Florida, March 8–12

That excited buzz you're hearing in the pharmaceutical and biopharmaceutical communities is about the 2004 PDA SciTech Summit™.

SciTech Summit will be PDA's "new" annual meeting—a combination of the best of both the traditional PDA Annual Meeting and Spring Conference.

What is new about this conference? • Expanded discussion time with scientific experts and regulatory representatives • Focus on new science and new technologies such as nanotechnology • More opportunities for discovery, discussion and networking are being offered.

Whether you are a seasoned industry veteran or new to the pharmaceutical manufacturing community, the 2004 SciTech Summit will provide you with key information on the most critical issues facing you today. The week-long series of scientific sessions and training courses will provide pharmaceutical and biopharmaceutical professionals with a "one-stop-shop" for all training and education needs in areas like:

- MEMs and Nanotechnologies: Technologies of the Future
- ICH 6: Update for Industry
- Blow Fill Seal Technology: Extruder Challenge Testing and BFS Aseptic Survey Results
- Case Studies in Biopharmaceutical Cold Chain Management
- Combination Products
- Visual Inspections: Survey Results
- New Filling Technologies
- New Regulatory Guidances

Plus, take advantage of these great social and networking activities:

- PDA Members Only Networking Reception
- Reception at Universal Studios
- Expanded Exhibit Hall: Chance to Win the Grand Prize—a Harley Davidson motorcycle!
- Interest Group and Task Force Discussions

This event will be co-located with CleanRooms East 2004. This coming year, CleanRooms East 2004 conference will offer the perfect complement to the PDA SciTech Summit, offering three days of sessions geared toward facility design and construction, cleanroom ISO standards, HVAC and air filtration engineering issues, proper gowning techniques as well as panel discussions aimed to help end users find proper retrofit and construction solutions.

Exhibitors: Take advantage of this exciting event in Orlando, Florida, and increase your brand recognition along with unbeatable visibility for your products and services.

Delegates: Take advantage of all that Orlando has to offer—including a fun filled reception at Universal Studios—part of your full conference registration. Special discounts will apply to three or more individuals registering from the same corporate site. Chances to win a free conference registration are being offered to each chapter.

Join the pharmaceutical and biopharmaceutical manufacturing community in warm and sunny Orlando, Florida, in March 2004. This is one conference you won't want to miss!

Contact PDA if you are interested in exhibit or speaking opportunities. Check the PDA Web site at www.pda.org for updated information on the PDA 2004 SciTech Summit. ■

The Pharmaceutical Blow Fill Seal International Operators Association to hold Annual General Meeting—March 6–8, 2004 in Orlando

BFS International has announced that it will host its Annual General Meeting in conjunction with the PDA SciTech Summit™ in Orlando, Florida. In addition to the general business of the association, comprehensive scientific presentations highlighting new "extruder challenge testing" and new data on the BFS aseptic survey results will be presented as part of PDA's SciTech Summit™. PDA members will receive a discounted registration fee to attend the BFS meeting, and BFS members will be eligible for a discount to the SciTech Summit™.

Additional information is available at www.pda.org or on the BFS web site: www.bfsinternational.com.

Emerging European Regulations and Impact on Clinical Supplies at the 2004 PDA SciTech Summit March 9–10, 2004

Global Supply Chain Managers: Get updated on how to interpret and implement the Annex 13: Clinical Trials Directive!

European Industry and Regulatory Experts have been invited to discuss:

- The New Guidance Document on Phases II and III for Clinical Trials
- The GMP Regulatory Environment for IMPs in Europe: Legal Framework and Implementation Strategies
- The GCP Regulatory Environment for IMPs in Europe: Legal Framework and Implementation Strategies
- Current Implementation Status of Directive 2001/20/EC across EU Member States: A Regulatory Perspective
- Current Implementation Status of Directive 2001/20/EC across EU Member States: An Industry Perspective
- The new "IMP QP"
- Implementing Directive 2001/20/EC – A CRO's perspective
- Creating Effective Supply Chains for European Clinical Trials

Make your plans now to attend!

2004 PDA International Congress, Courses and Tabletop Exhibition Rapidly Approaching

Make your air and room reservations now for the 2004 PDA International Congress at the Messe Basel Convention Center in Switzerland. The Congress and Exhibition begin February 16 and the Training Courses start on February 19, and the skiing, sightseeing and fun lasts all week long!

This unique event will bring together senior industry experts and regulators from around the world. The Plenary Session includes two must-see presentations from Frank Hallinan, Ph.D., Chief Executive, Wyeth Medica (Ireland) and Anders Vinther, Ph.D., Chief Quality Officer, CMC Biopharmaceuticals.

Afterwards, the meeting will break into concurrent sessions covering a host of topics, including: Information Technology, Manufacturing, Innovation and Regulation, Filtration, Cold Chain Management, Aseptic Processing, Quality, and Biotechnology. Participants in these sessions will hear:

- Experts from leading pharmaceutical and biopharmaceutical companies like AstraZeneca, Eli Lilly, Genentech, GlaxoSmithKline, Novartis and MedImmune;
- Seasoned regulators from the U.S. FDA Center for Drug Evaluation and Research and the EU EMEA; and
- Leading academics from universities like the Tehran University of Medical Science, the University of Connecticut (Storrs), and the University of Calabria.

For more information on this event and to view the brochure, go to pda.org/PDF/Meetings/04Basel-Bro.pdf. ■

2004 PDA Pharmaceutical and Biopharmaceutical Manufacturing Science and Technology Congress, Training Courses and Exhibition

The Ritz-Carlton Millenia Singapore

May 17–19, 2004 Courses: May 19–21, 2004

Join experts from international health authorities and the pharmaceutical manufacturing industry for the first PDA Congress in the Pacific Rim. This two and a half day conference will include sessions on biotechnology, outsourcing, aseptic processing, regulatory, pharmacopeial and ICH harmonization issues. Industry experts and representatives from international regulatory agencies, and the U.S. Pharmacopeia, Japanese Pharmaceopeia and European Pharmacopei are confirmed to participate. **Dr. Chor Hiang Tan, CEO, Health Sciences Authority of Singapore**, will deliver the regulatory keynote address and **Kenneth A. Bradley, Managing Director, Pfizer Asia Pacific** Pte Ltd., is slated to present the industry keynote.

Q7A Workshop

As an optional track at the conference, attendees can attend one or all sessions of the ICH Q7A Workshop, conducted by members of the Expert Working Group that developed the Guidance. The ICH Q7A document, the first GMP guidance jointly developed between regulators and industry, is intended for use worldwide. It impacts any manufacturer who manufactures in, or intends to export to, the ICH regions (U.S., Europe, Japan). The ICH Q7A workshop has sold out in eight locations in North America and Europe; this is the first time it has been offered in Asia.

Educational Courses

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

- A Practical Approach to Aseptic Processing and Contamination Control
- Basic Concepts in Cleaning and Cleaning Validation
- Qualification and Validation of API Manufacturing Operations
- Requirements and Preparation of Pharmaceutical Grade Waters
- Computer Products Supplier Auditing Process Model: Auditor Training

Exhibits

The exhibition will include information on the latest advances in pharmaceutical science and technology. A limited number of tabletop exhibits are being offered. Please contact Nahid Kiani at +1 (301) 656-5900 or via email at Kiani@pda.org for more details. ■

2004 PDA/R3 Nordic Conference—Scientific, Industrial and Regulatory Aspects of Clean Products and Devices

June 7–8, 2004, Stockholm, Sweden

This important two-day conference is being offered by PDA in cooperation with R3 Nordic, the Nordic Association for Contamination Control & Clean Rooms. The focus of the conference will be the scientific, industrial and regulatory aspects of sterile product manufacturing.

Confirmed FDA speakers presenting at the conference are: David Hussong, CDER; Christopher Joneckis, Ph.D., CBER; Anthony Mire-Sluis, Ph.D., CDER; Dan Schultz, CDRH; and Ajaz Hussain, Ph.D., CDER. Speakers also have been invited from EMEA, MCA, MPA and industry.

Technical/scientific personnel, manufacturing personnel, laboratory technicians, QA/QC, regulatory affairs and validation personnel, cleanroom design technicians, who must have an understanding and appreciation for international guidelines for aseptic processing and environmental monitoring requirements and related regulations will benefit from participation in this important conference.

Stockholm is a city rich with history and culture, yet also a modern metropolitan destination. The city spans 14 islands, so visitors are never far from the water. The architecture includes and interesting mix of well-preserved medieval structures and modern buildings. Stockholm is a beautiful city to visit anytime of the year, but June is a particularly pleasant month of long days with temperatures averaging 70 degrees.

Watch www.pda.org for more details and registration information. ■

PDA Web Seminars

Check www.pda.org for new PDA Web Seminars regularly. We have selected some of our most popular presentations from recent conferences and made them available to you on-demand. View the slides and listen to the synchronized audio presentation at your convenience and from your desk.

The following Web Seminars are currently available for purchase:

- How to Build an Effective CAPA Program
- Designing a Cleaning and Disinfection Program in GMP Controlled Environments
- Rapid Microbiology Methods: A Regulatory Viewpoint
- Opportunities to Employ Rapid Microbiological Methods in the Pharmaceutical Industry: Examples from Compendial Applications
- GMP Training Overview and Job Skills Training Requirements in an Aseptic Environment: or What Does the FDA Have to Say About That?
- Navigating Legal Waters & Compliance Currents & Riding the Changing Compliance Tides: Global Industry Perspective
- Biopharmaceutical Process Validation Issues
- PDA/FDA Joint Regulatory Conference Closing Plenary Session ■

Registration Fee per Web Seminar

…$150 for PDA Members
…$300 Nonmembers
…$60 for Government Member (must be an employee of an official government agency).

Pictures from the PDA 2003 Annual Meeting

The PDA Strategic Planning Committee Convenes

Delegates listen to keynote address

Cold Chain Management Interest Group

Delegates visit the exhibits

New PDA Members

First meeting of the *PDA Journal of Pharmaceutical Science and Technology* Editorial Advisory Committee

CDER Acting Director Steven Galson, M.D., visits the PDA booth

photos continue on page 24

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Kathleen Greene, Russell Madsen, and Janis Olson

Glenn Wright gives the PDA Annual Meeting the "thumbs up"!

Caricature artist at the "Midnight Train to Georgia" reception

PDA Training and Research Institute Director's Message

Classic Movies, Record Attendance and Member Service

Bob Mello, Ph.D.

I love movies. New, old, comedy, drama, action film or chick flick, I see them all (except "slasher" movies. I'll never understand the allure of those films). Two of my favorite classics, *The Wizard of Oz* and *Gone With the Wind*, were on television recently and I had to watch them, again. This time, though, there seemed to be a few additional parallels with my travel schedule. While in Oz, Dorothy said, "there's no place like home." She clicked the heels of her ruby slippers three times and was transported back home to Kansas. Although I have been in the Baltimore, Maryland, area for a long time, I was born in Rhode Island. So I clicked the heels of my black wing tips and lo and behold I was transported (via my VW Passat) back to my native New England in late October to oversee the three-day TRI Boston course series. It was great to be back in New England in the Fall. The foliage was spectacular this year (and my New England relatives were in rare form!). Even greater, though, was the response of our membership to the Boston course offerings.

The 11 courses set an all time attendance record at PDA for a stand-alone course series. At TRI we strive to serve our membership by providing the best, professionally relevant and practical training courses both domestically and internationally. The Boston series covered topics for both the beginner and the more experienced pharmaceutical and biopharmaceutical professional, such as general assay validation and bioassay development. Practical aspects such as understanding packaging materials (glass, rubber, plastic) and contamination control in aseptic areas were discussed. Training issues and training techniques, sampling statistics, and annual product reviews also were covered. Contributing to the success of the event was the PDA New England Chapter's sponsorship of a networking reception for the students, faculty and TRI staff. It was a great way to meet other PDA members from the world over. That is no exaggeration. The Boston course attendees were from no less than 25 states in the U.S. as well as eight other countries representing Europe (Germany, France, Denmark, Belgium), The Americas (Canada, Puerto Rico), and Asia-Pacific (South Korea and Australia). It was gratifying to see the interactions among them, and to know that we played a part in bringing them together.

Students listen attentively in Boston.

I returned home from Boston excited, refreshed and focused, which was a good thing considering the Institute was gearing up for its very popular (and sold out) Aseptic Processing Course. It wasn't long, however, before my luggage, laptop and person were back on another plane. Which brings me to the second classic movie I recently saw (G.W.T.W., see above). This time I was headed to Atlanta for the 2003 PDA Annual Meeting and Courses held at the Atlanta Hilton. Unlike Sherman's March through Georgia, however, there was no plan to burn and pillage. Rather, PDA-TRI sought once again to provide the highest quality in training to its membership. Attendees for the Atlanta courses traveled from 19 states and nine countries (Canada, Croatia, Denmark, Switzerland, India, Japan, New Zealand, South Korea and Taiwan) to attend courses on CGMP auditing, aseptic processing/ contamination control, cleaning and cleaning validation, computer validation, and change control documentation.

Service to the membership. That's what it is all about for us at PDA. It is what we strive for and why we are always asking for your input (you know, those pesky little surveys I hand out in the last minute of your class as you are rushing off to catch your plane). It's why we try to schedule courses nearer to you. It's why we will be offering courses—not just at TRI in Baltimore, Maryland—but the world over next year in Lake Tahoe, Nevada; Basel, Switzerland; Orlando, Florida; Puerto Rico; Singapore; San Diego, California; Toronto, Canada; Chicago, Illinois; and (yes) Boston, Massachusetts.

I am truly grateful to all—faculty, staff, and sponsors—who helped make these recent events successful. And I have to agree with Dorothy, there really is no place like home. Nevertheless, the upcoming course schedule promises to keep me sharp as the PDA Training and Research Institute will be looking to make more history in 2004. Therefore, I guess I'll just click my heels three times and be on a plane to the next course series (Lake Tahoe, February 4–6, 2004). With your continued support of our course offerings, I'm sure I will see you there! ■

—Bob Mello

Registration Form

PDA Training and Research Institute Courses

R

LTR 12/03

1. **Please type or print your name, address and affiliation.**

Preferred Address: ❑ **Business** ❑ **Home**

❑ Mr. ❑ Ms. ❑ Dr. First Name Middle Initial Last Name

Job Title Membership Number

Company/Organization

Address

City State/Province ZIP+4/Postal Code

Business Phone Fax E-mail

❑ Substituting for _____
(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the additional fee.)

Not a current PDA member?
Join today and save up to 50% on training courses!

Plus…

- ✓ Save on PDA meetings, conferences and publications
- ✓ Gain access to expert, peer-reviewed information relevant to your career
- ✓ Connect to global and regional science and regulatory expertise
- ✓ Become a part of the world's leading international network of pharmaceutical and biopharmaceutical professionals.

Check below to become a PDA member:

❑ **Individual membership fee: $195 U.S.** (one year)

❑ **Special discounted government/health authority fee: $80 U.S.** (one year)*

* Must be an employee of an official government agency or health authority

For more details on PDA and the benefits of becoming a member, visit www.pda.org today.

2.

Course Title/Course No.	Date	Current Member	Join PDA and Attend Course	Attend Course Only; Do Not Join PDA	Government/Health Authority Employee *

* *You must be an employee of an official government agency or health authority to qualify for this rate.* TOTAL

3. **Payment Options** (please check one).

❑ A. By **Credit Card** (VISA, MasterCard/EuroCard, American Express), clearly indicating account number and expiration date. **Proceed to Item 4 below.**

❑ B. By **Bankers' Draft** forwarded together with the registration form PAYABLE IN US DOLLARS ONLY to:

PDA, Inc., P.O. Box 79465, Baltimore MD 21279-0465

Please mark here to request a **PROFORMA INVOICE** from PDA to process your company payment.[1] ❑

❑ C. **Wire Transfer Payments**/By bank-to-bank transfer to: (required if paying in foreign currency; prevailing exchange rates at date of submission will apply.)

UBS AG Basel Swift Code: **UBSWCHZH40M**

Account number (please specify correct account number for currency being remitted):

- ❑ CHF: Account No. 292-568-280-02T
- ❑ EUR: Account No. 292-568-280-64B
- ❑ GBP: Account No. 292-568-280-65E
- ❑ USD: Account No. 292-568-280-66M
- ❑ YEN: Account No. 292-568-280-67C

Please reference code: **2-2-2000**

Bank Address:
UBS AG Basel
Postfach
Aeschenplatz 6
4002 Basel, Switzerland

[1] You are not considered registered for a PDA course until payment is received and a confirmation letter is issued by PDA. Should you attend a course without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment at the time of the course.

4. **Please check the appropriate box:** ❑ Check Enclosed ❑ Wire Transfer Charge: ❑ MastercardCard/EuroCard ❑ VISA ❑ AmEx

Account Number: _____ Exp. Date: _____

Name *(exactly as on card)*: _____

Signature: _____ Date: _____

Wire Transfer Confirmation: _____
(insert your confirmation of receipt by UBS Bank here.)

Federal Tax I.D. #52-1906152

5. **Return completed form with payment made to:** PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA **FAX:** +1 (301) 986-1093 (credit cards only)

Deadline: Enrollment is limited for the benefit of all attendees; this necessitates early registration. Paid registrations must be received one week prior to the event. **Confirmation:** Written confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site up to the time of the course. If you are pre-registering as a substitute attendee, indicate this on the registration form. **Refunds:** Refund requests must be in writing. If received one month prior to the start of an event (course series, conference, etc.), a full refund, minus a $55 handling fee, will be made. If received two weeks prior to the event, one-half of the registration fee will be refunded. After that time, no refunds will be made. **Event Cancellation:** PDA reserves the right to modify the material or instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **For more details, call PDA at (301) 656-5900.**

PDA USE:
Date: _____ Check: _____ Amount: _____ Account: _____

2004 Aseptic Processing Training Program Dates

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 date to this series in 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.

The 2004 dates are as follows:

Session I
Week 1 January 26–30
Week 2 February 23–27

Session II
Week 1 March 22–26
Week 2 April 26–30

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 ■

—Bob Mello, Ph.D.

PDA Training and Research Institute Thanks the Following...

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Technovation

Upcoming PDA Training and Research Institute Education Courses

Courses listed in chronological order

Environmental Mycology Identification Workshop—Lab February 12–13, 2004; May 13–14, 2004; December 2–3, 2004; $2,000 members/$2,195 nonmembers; *Faculty:* John Brecker

Cleaning Validation—Lab April 19–21, 2004

Advanced Environmental Mycology Identification Workshop September 2–3, 2004

Ensuring Measurement Integrity in the Validation of Thermal Processes November 11–12, 2004

Aseptic Processing 2004 Training Program—Lab **Session 1**: January 26–30, 2004 and February 23–27, 2004; **Session 2**: March 22–26, 2004 and April 26–30, 2004; **Session 3**: May 24–28, 2004 and June 14–18, 2004; **Session 4**: August 16–20, 2004 and September 13–17, 2004; **Session 5**: October 4–8, 2004 and November 1–5, 2004; $7,800 members/$9,300 nonmembers; *Faculty:* John Lindsay and David Matsuhiro ■

These courses will be held at the PDA Training and Research Institute (PDA-TRI) in Baltimore, MD, unless otherwise noted. **For course content information,** call PDA-TRI directly at +1 (410) 455-5800.

For registration information, call PDA's world headquarters in Bethesda, MD at +1 (301) 656-5900.

PDA Training and Research Institute Location/Lodging Information

Unless otherwise noted, PDA Training & Research Institute courses are held at: PDA Training & Research Institute, UMBC Technology Center, 1450 South Rolling Road, Baltimore, MD 21227, Tel: +1 (410) 455-5800; Fax: +1 (410) 455-5802.

PDA has not secured any specific room blocks for participants attending courses at the Training & Research Institute. There are several hotels in the Inner Harbor (downtown Baltimore) and Baltimore/Washington International (BWI) airport areas. These include, but are not limited to:

Baltimore Hilton & Towers Inner Harbor
+1 (410) 539-8400
+1 (410) 625-1060 - fax

Baltimore Marriott Inner Harbor
+1 (410) 962-0202
+1 (410) 625-7892 - fax

Courtyard Baltimore Downtown/Inner Harbor
+1 (443) 923-4000
+1 (443) 923-9970 – fax

Courtyard by Marriott–BWI
+1 (410) 859-8855
+1 (410) 859-5068 – fax

Embassy Suites BWI
+1 (410) 850-0747
+1 (410) 850-0816 – fax

Holiday Inn—BWI ***
+1 (410) 859-8400
+1 (410) 684-6778 – fax

Holiday Inn Inner Harbor **
(*Special Rates for our course attendees*)
+1 (410) 685-3500
+1 (410) 727-6169 – fax

Homewood Suites BWI*
+1 (410) 684-6100
+1 (410) 684-6810 – fax

Hyatt Regency Baltimore Inner Harbor
+1 (410) 528-1234
+1 (410) 605-2870 – fax

Sheraton International Hotel BWI
+1 (410) 859-3300
+1 (410) 859-0565 - fax

* no on-site restaurant

**** A discounted rate** is available for **Holiday Inn Inner Harbor of $99.** To receive this rate call the number above and mention the PDA-TRI Corporate Rate (ID #100196574) when making your reservations. **Rooms are based on availability.**

***** A discounted room rate** is also available from the **Holiday Inn—BWI.** You must call the number above and mention the PDA Corporate Rate (3-PDA) when making your reservations.

For additional hotel information, please visit www.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site.

Transportation to the PDA Training and Research Institute:
All listed hotels are no more than a 15–20 minute taxi ride to the Training and Research Institute. All hotels can assist you with taxi arrangements. Registrants may prefer to rent a car for easier access to and from the Institute.

Chapter Focus: The PDA Japan Chapter

Founded in 1991, the Japan Chapter has become one of PDA's most active. With 725 members, the chapter has been instrumental in the establishment of a strong PDA presence in Japan.

The chapter currently is guided by an outstanding group of officers: President Katsutoshi Mise, Senior Advisor, R&D promotion, the Organization for Pharmaceutical Safety and Research; Vice President Katsuhide Terada, Pharmaceutics Department, Toho University; Secretary Hisao Kyogoku, Executive Director of Sales, Nihon Pall; Secretariat Hiroshi Harada, Business Center for Academic Societies; Treasurer Yoshihisa Matsuda, Department of Pharmaceutical Technology, Kobe Pharmaceutical; and Chapter Liaison Kunio Kawamura, Executive Advisor, OtsukaPharmaceutical.

The Japan Chapter regularly participates in the regulatory and pharmacopeial processes in Japan, and it hosts multiple events for its members each year. The chapter also serves as an academic association approved by the Japan government and as such, took part in the election of officials in the Japan Academic Association this year.

In keeping with the chapter's pioneering spirit and support for the PDA mission, it regularly holds meetings and courses that typically attract 100 attendees or more. Most recently, the Japan Chapter held a "Symposium on Water for Pharmaceutical Use in Japan—For International Harmonization" which boasted over 150 participants. With Japan participating in the Pharmacopeial Discussion Group under the International Conference on Harmonization, the goal of this Nov. 17 symposium was to help accelerate the harmonization of standards for pharmaceutical water.

Presentations were made by experts from the U.S., EU and Japan. The U.S. was represented by Anthony Bevilacqua, Ph.D., and Frank Barletta, Ph.D., both from the U.S. Pharmacopeia Water Specifications Committee and Alex Konopka, Eli Lilly and Company. Dr. Emmanuel Charton spoke for the European Pharmacopeia. Presenting the Japanese viewpoint were: Japan Chapter President Mise, Dr. Tuguo Sasaki from the Japanese National Institute of Infectious Diseases, Kunio Kawamura (Otsuka Pharmaceutical), and Tsutomu Kamikutika (Cuno Co.).

Next on the Chapter's agenda is the Chapter's API-GMP Symposium, scheduled for Nov. 27. This meeting is focused on the ICH "Q7A" GMPs for active pharmaceutical ingredients.

At the end of October, the Chapter held its 11th Annual Meeting in Tokyo. The featured speaker was James Cohen, Associate Director, Center for Biologics Evaluation and Research (CBER) Office of Compliance and Biologics Quality, who gave three separate talks on recent CBER initiatives, recent CBER compliance activities, and comparability protocols.

Prior to that, an important event called "Japan PDA GMP-Related Engineering Two Days Course" drew an audience of 110 members. The course covered a variety of fundamental engineering issues relating to GMP and was planned in response to the good evaluation of last year's course of the same name. The chapter also sponsored a course titled "FDA Inspection Actual Examples and How to Prepare and Receive It" by Sadayoshi Tomita of Japan PDA.

Future events currently in the planning phase include a March meeting and the chapter's 2004 Annual Meeting.

...the goal of this Nov. 17 symposium was to help accelerate the harmonization of standards for pharmaceutical water.

The Japan Chapter also publishes translated technical reports, and recent translations of reports on validation have become very popular texts on the topic in Japan. In the summer, the Chapter published the biannual *PDA Journal of GMP and Validation* in Japan, Vol. 5, No. 1. The Journal contained: the Organization of the Ministry of Health, Labour and Welfare's (MHLW) most recent regulation revisions; an article stating recent issues concerning risk management, compliance, regulations and the responsibility of pharmaceutical industries; Virus Validation; GMP-Grade Aseptic Cell Therapy and Re-generation Medicine; Temperature Development of Multiplication Accumulation Chemical Indicators; and other scientific papers.

PDA President Neal Koller recently met with the Japan Chapter as part of PDA's focused and ongoing dialogue concerning science and technology-based partnerships with health authorities and industry worldwide (see "President's Message" October *PDA Letter*). The meeting was considered a success and a positive step for PDA's global mission. ■

—KiKi Coffman and Walter Morris

For more information about the PDA Japan Chapter, please visit its Web site at **www.j-pda.jp.**

More information on this and other PDA chapters, including PDA Chapter News (the association's monthly, Web-based communication for members specifically targeted towards those active in our chapters) can be found at: www.pda.org.

2003 PDA Award Winners and 2004 Officers and Board of Directors

The 2003 PDA Awards were announced at the Annual Meeting and handed out during the Board of Directors Dinner (*see p. 31 for pictures of the awards presentation*). The 2003 winners are:

Honorary Membership—PDA's most prestigious award, conferring lifetime membership benefits to the recipient: **Fred Gustafson**, Retired (formerly Abbott).

Gordon Personeus Award—Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member, other than a Board member, for long-term acts or contributions: **Julius Knapp**, Principle, Research & Development Association.

Frederick J. Carleton Award—Presented as a tribute to lifetime contributor, past President, past Executive Director, and Honorary Member Frederick J. Carleton: **Henry Kwan**, Ph.D., Kwan Consulting.

Distinguished Service Award—Given for special acts or services that have contributed to the success and strength of PDA: **Don Elinski**, Validation Manager PWC, Eli Lilly & Company; **Taiichi Mizuta**, Ph.D., Shinogi & Co., Ltd.; and **Thomas Wilkin**, Director, Technical Operations Training, Schering-Plough.

Service Appreciation Award—Given for special acts or services that have contributed to the success and strength of PDA's Exhibit Advisory Board: **Thomas Handel**, VP–Homeland Security, Meridian Medical Technology.

Agalloco Award—Presented to the PDA faculty member each year who exemplifies outstanding performance in education. Named for James P. Agalloco in honor of his work in developing the PDA education program: **Joerg Neuhaus**, Bezirksregierung Koln. PDA extends condolences to Mr. Neuhaus who could not be in attendance to receive his award due to the death of a family member.

Frederick D. Simon Award—Presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology*: "Theoretical Analysis of the Condensation of Hydrogen Peroxide Gas and Water Vapor as Used in Surface Decontamination" (Nov/Dec 2002), **David Watling**, Ph.D., Technical Director, Bioquell Pharma and Co-authors: **Cian Ryle**, Brandon Biopharm Engineering, **Matthew Parks**, RBDS Manager, Bioquell Pharma, and **Matthew Christopher**, Project Manager, Pilot Process Systems. Dr. Watling and Mr. Parks were in attendance to receive the award.

Korczynski Award—A grant awarded in the name of Michael S. Korczynski, Ph.D., that funds travel expenses for an international guest to deliver the "Korczynski Paper" at a PDA meeting: **Anders Vinther**, Chief Quality Officer, CMC Biotech.

PDA Chapter Award—Recognizes the contributions of PDA members who participate at the chapter level. **Susan Moore**, Application Specialist, Millipore (Southeast Chapter); **Robert Pazzano**, Director, Business Development, VTS Consultants (New England Chapter); **Oh Jong Hwa** (Korea Chapter); and **Anthony Rowland**, Director, Seer Pharma (Australia Chapter). Ms. Moore was in attendance to receive her award. ■

At a PDA Board of Directors dinner during the Annual Meeting, 2002–2003 Chair Floyd Benjamin, Keystone Pharmaceuticals, passed the gavel to Nikki V. Mehringer, Eli Lilly, who was elected the 2004 Chair.

The 2004 PDA officers are:

Chair, **Nikki V. Mehringer**,
Eli Lilly and Company

Chair-Elect, **Richard V. Levy**, Ph.D.
KMI, a division of PAREXEL, Intl.

Secretary, **Stephanie R. Gray**
GlaxoSmithKline

Treasurer, **Georg L. Roessling**, Ph.D.
Schering AG

The 2004 Directors are:

Jennie K. H. Allewell, Cell Therapeutics
Vince H. Anicetti, Genentech
Floyd Benjamin, Immediate Past Chair
Robert L. Dana, Elkhorn Associates
Rebecca A. Devine, Ph.D., Consultant
Kathleen S. Greene, Novartis Pharmaceuticals
Yoshihito Hashimoto, Chiyoda Corp.
Maik W. Jornitz, Sartorius
Suzanne Levesque, Sabex
Tim R. Marten, Ph.D., AstraZeneca
John G. Shabushnig, Ph.D., Pfizer
Lisa M. Skeens, Ph.D., Baxter Healthcare

PDA 2003 Awards Ceremony at the Annual Meeting

The 2003 PDA Award Recipients with outgoing Chair Floyd Benjamin.

Honorary Membership Award:
Fred Gustafson

Gordon Personeus Award:
Julius Knapp

Distinguished Service Award:
Don Elinski

Distinguished Service Award:
Thomas Wilkin

Frederick J. Carleton Award:
Henry Kwan, Ph.D.

Korczynski Award:
Anders Vinther

Service Appreciation Award:
Thomas Handel

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David Watling, Ph.D.

Frederick Simon Award:
Matthew Parks

PDA Chapter Award:
Susan Moore

For more information on the awards, see page 7; for more pictures from the 2003 PDA Annual Meeting, see pages 22–24.

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International Chapters

Australia Chapter
Contact: Ken Dibble
Millipore Australia
Tel: +61-4-1835-0455
Fax: +61-3-9563-2605
E-mail: ken_dibble@millipore.com

Canada Chapter
Contact: Grace Chin
Pellemon, Inc.
Tel: +1 (416) 422-4056 x230
Fax: +1 (416) 422-4638
E-mail: grace.chin@snclavalin.com

Central Europe Chapter
Contact: Erich Sturzenegger, Ph.D.
Novartis Pharma AG
Tel: +41-61-324-5572
Fax: +41-61-324-2089
E-mail: erich.sturzenegger@pharma.novartis.com

Israel Chapter
Contact: Karen S. Ginsbury
PCI-Pharmaceutical Consulting Israel Ltd.
Tel: +972-3-921-4261
Fax: +972-3-921-5127
E-mail: kstaylor@netvision.net.il

Italy Chapter
Contact: Vincenzo Baselli
Pall Italia
Tel: +39-02-477-961
Fax: +39-02-423-6908
E-mail: vincenzo_baselli@europe.pall.com
Web site: http://www.pda-it.org

Japan Chapter
Contact: Hiroshi Harada
Tel: +81-3-3815-1681
Fax: +81-3-3815-1691
E-mail: van@bcasj.or.jp
Web site: http://www.j-pda.jp/index.html

Korea Chapter
Contact: Jun Yeon Park
Tel: +82-2-560-7833
Fax: +82-2-560-7822
E-mail: jun_yeon_park@pall.com

Southeast Asia Chapter
Contact: K. P. P. Prasad
Wyeth Pharmaceuticals
Tel: +65-6415-2000
Fax: +65-6415-2008
E-mail: Prasadk@labs.wyeth.com

Taiwan Chapter
Contact: Tuan-Tuan Su
Tel: +8862-2550-9301
Fax: +8862-2555-4707
E-mail: pdatc@ms17.hinet.net

United Kingdom and Ireland Chapter
Contact: John Moys
Sartorius
Tel: +44-1372-737-140
Fax: +44-1372-726-171
E-mail: john.moys@sartorius.com

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Areas Served: MD, DC, VA, WV
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Tel: +1 (410) 804-2284
Fax: +1 (410) 455-5802
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E-mail: mary_carver@eisai.com
Web site: www.pdase.org

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Allergan
Tel: +1 (714) 246-5834
Fax: +1 (714) 246-4272
E-mail: spoden_john@allergan.com
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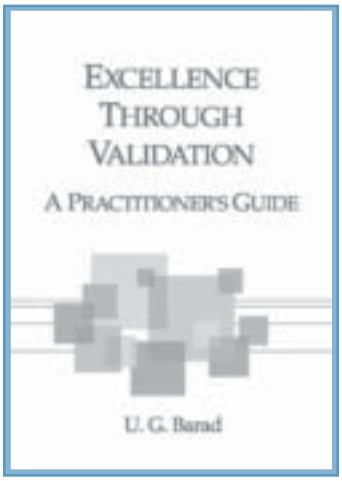

U.G. Barad

Written for a global pharmaceutical manufacturing audience, this book provides well-researched guidance in useful validation practices and standards that were developed by comparing

- Various US regulations from the FDA, EU, EMEA, MCA, Swissmedic, TGA, WHO, the gulf countries MOH, and the Indian FDA
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New managers and executives will find the help they need in this guide to quickly gain access to what is expected from demanding and growing validation topics worldwide. Intermediate users will find the book a practical reference for every day use, and beginners will use this book as a prescription and guide as they prepare for their career.

This concise book is a compilation of the author's practical experience from over 20 years of close interaction with leading multinational pharmaceutical companies and with various regulatory authorities' requirements. Divided into 14 logical sections, it covers all the requirements for achieving total excellence through validation. Hardcover; 336 pages; 2003; ISBN#1-930114-58-3

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Commercial Off-The-Shelf Software Validation for 21 CFR Part 11 David Nettleton and Janet Gough; Validation clearly is a requirement for regulatory compliance. Every indication is that the regulations will focus more and more on the electronic generation of data, data control, and data transfer. The goal of this book is to provide guidance for validating commercial, off-the-shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. This book provides the practical information needed to ensure an understanding of the FDA-issued guidance as they develop systems that will enable them to go partially or fully electronic; hardcover; 118 pp; $185 members/$229 nonmembers **Item No. 17200**

The Essence of GMPs: A Concise Practitioner's Guide U.G. Barad; This book is a compilation of more than 20 years of experience working with multinational pharmaceutical manufacturing companies and with various regulatory authorities. It incorporates and addresses the essence of GMPs prevailing around the world. It is organized in four sections. The principal section, entitled "Essentials", covers policies that are expected to prevail in any pharmaceutical industry. The second section covers policies (prevention of contamination) that are the requirements of non-sterile pharmaceuticals. This section is followed by complete coverage of sterile products, and the book culminates with a complete glossary in part four.

The purpose of the book is to enable novices, busy executives, and hard-pressed colleagues to quickly gain access to excellent global GMP practice and expectations. Beginners will find that it provides a solid prescription in preparation for the constantly expanding global GMPs. Experienced readers will find this book invaluable as a tool for assistance in the preparation and design of common practices worldwide by enabling them to speak on common quality language regardless of location. 280 pp; $185 members/$229 nonmembers; hardcover **Item No. 17203**

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, 3rd edition James Vesper; A quick guide to GMP, designed to simplify and enhance the understanding of most of the current GMP expectations and how they apply to ongoing tasks in any given pharmaceutical manufacturing situation. 252 pp; $105 members/$129 nonmembers **Item No. 17199**

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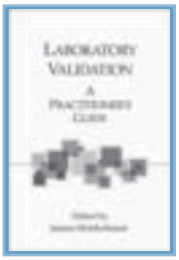

Laboratory Validation: A Practitioner's Guide Edited by Jeanne Moldenhauer; In recent years, regulatory inspections have focused on laboratory testing performed to assess the quality attributes of a product. In many cases, the testing is so specialized or complex, that the entire responsibility for validation has been transferred to the laboratory personnel. This excellent guide and reference provides an overview of validation from a laboratory perspective.

Divided into three parts, Part 1 includes an overview of many of the laboratory support systems and equipment common to both microbiology and chemistry laboratories. Part 2 is dedicated to systems applicable specifically to the chemistry laboratory, and Part 3 covers the systems applicable to microbiology laboratories. Where the laboratory predominantly performs the test, for example, cleaning and disinfection, requirements are included within the text. While the book offer validation details representative of the most common types of laboratory systems, should you have a system that is not included, the information in these 38 chapters will likely be of great assistance in providing resources for compilation of requirements for other systems. 1,224 pp; hardcover; $250 member/ $309 nonmember **Item No. 17201**

Microbiology in Pharmaceutical Manufacturing Richard Prince, Editor; 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. It is hoped that this book will demystify the field of microbiology by describing it plainly and systematically from various scientific, technical, and functional perspectives. 900 pp; $240 members/$299 nonmembers; hardcover **Item No. 17185**

Rapid Analytical Microbiology: The Chemistry and Physics of Microbial Identification Wayne P. Olson, Editor; The old, dendritic methods of identifying microbes can be found in the most recent edition of *Bergey's Manual* (Holt 1993). The issues with this approach to microbial identification (ID) include the time required to make a critical ID and the accuracy and reliability of IDs. Hence, the introduction and success of automated, rapid methods. This book focuses on the numerous new, efficient, and effective methods currently available and serves as both guide and reference to readers interested in improving performance and accuracy in a timely manner. 2003; 354 pp; ISBN 1-930114-36-2; $195 members/ $239 nonmembers; hardcover **Item No. 17184**

Steam Sterilization—A Practitioner's Guide Jeanne Moldenhauer, Editor; Contains pragmatic details on how to accomplish the tasks necessary for a sterility assurance program for steam sterilization processes. Each chapter author is a subject matter expert and has a minimum of 10 years of hands-on experience in the topics discussed. The authors use this experience to identify practical ways to perform research, development, validation, and production activities associated with steam sterilization. Many of the chapters include sample standard procedures or protocols that may be used as templates to generate documents for your facility. Other chapters outline and explain the requirements. The book also provides guidance for those individuals who are responsible for the oversight of these processes or those who wish to update their knowledge. While written primarily for the pharmaceutical industry, much of the content may be applicable to the food and cosmetic industries as well. While this book does not specifically address the bulk drug industry, certain information may be applicable to bulk drug manufacturers. Whether your organization is small or large, this book contains insights and techniques that will prove invaluable in your effort to develop and maintain a sterility assurance program for steam sterilization processes. 740 pp; $215 members/$269 nonmembers; hardcover **Item No. 17183**

Good Practice and Compliance for Electronic Records

Published jointly with ISPE

Part 1—Good Electronic Records Management (GERM): Electronic Information Assurance for the Regulated Industry—Guide to Current Good Practice for Electronic Records and Signatures 2002; 104 pages; $95 PDA members/$190 nonmembers **Item No. 19003**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures 80 pages; $95 members/$190 nonmembers (English) **Item No. 19001**

Also available in German and Spanish. For more information, visit www.pda.org.

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. 1 Validation of Steam Sterilization Cycles This is a comprehensive, straightforward approach toward validation procedures for steam sterilization cycles. There is no known similar treatise. This report was produced by a Task Force of the PDA Research Committee and is primarily the work of R. Michael Enzinger. 1978; 36 pp; $75 member/$550 nonmember **Item No.01001**

Technical Report No. 13 (REVISED 2001) Fundamentals of a Microbiological Environmental Monitoring Program The purpose of this document is to identify 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. While this publication cannot possibly supplant the wealth of information published on this subject, it provides summary information and appropriate references for the reader to consult, if necessary. The objective was to contemporize the first edition through the utilization of current definitions, recognition of improved environmental monitoring procedures, and equipment. 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 concepts for sterile product manufacturing are the most stringent application, but these concepts can also be applied to non-sterile product manufacture. 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. 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**

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The Archive is updated each year, adding six issues of the *PDA Journal*, all PDA Technical Reports and Monographs, and selected PDA Meeting Proceedings. The archive is a 4-CD set. Archive (contains data through the year 2002); $395 member/$1,200 nonmember **Item No. 01101**

2002 Update (only for those who already have an earlier version of the PDA Archive); $95 member $725 nonmember **Item No. 01002**

Pocket Code of Federal Regulations GMP Guide—2003 Edition 21 CFR Part 210-CGMP in Manufacturing, Processing, Packing, or holding of drugs; general. 21 CFR Part 211—CGMP for Finished Pharmaceuticals. Reproduced in pocket size by PDA. April, 2003. 56 pp; $4 members/$10 nonmembers **Item No. 13004**

PDA Proceedings

2003 PDA Proceedings PDA/FDA Joint Regulatory Conference: Navigating Current GMPS: Catch the Compliance Wave, Washington, DC, September 2003

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PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 1**
PDA Training and Research Institute, Baltimore, MD

February

February 4–6, 2004
PDA Training and Research Institute
Lake Tahoe Course Series
Hyatt Regency Lake Tahoe
Incline Village, NV
PDA Training and Research Institute Lecture Courses:
February 4
A Comprehensive Guide to OOS Regulations
Failures/Deviations and Change Control
Training for Performance
February 4–5
Preparing for an FDA Pre-Approval Inspection
February 4–6
Introduction to Competency-Based Training
February 5
Documentation Systems and Practices
Z1.4 Attribute Inspection Sampling In a CGMP Environment
February 5–6
Design and Implementations of a World-Class Quality System
February 6
Achieving CGMP Compliance During Development of a Biotechnology Product
A Practical Guide to Change Control
Biopharmaceutical QA/QC Strategy For Senior Management

February 12–13, 2004
PDA Training and Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA Training and Research Institute, Baltimore, MD

◆ February 16–20, 2004
2004 PDA International Congress—Basel
Science, Technology and Regulations in the Global Pharmaceutical Industry
Congress: February 16–18
Courses: February 19–20
Tabletop Exhibits: February 16–18
Messe Basel Convention Center
Basel, Switzerland
PDA Training and Research Institute Lecture Courses:
February 19
Clinical Trials Directive & MP for Investigational Medicinal Products
Risk Estimation in Aseptic Processing
February 19–20
CGMPs for Bioprocesses
Ventilation & Airborne Contamination in Cleanrooms
Pragmatic Cleaning Validation

February 23–27, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 2**
PDA Training and Research Institute, Baltimore, MD

March

◆ March 1, 2004
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Location TBA
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March 4–5, 2004
PDA Training and Research Institute Laboratory Course
Ensuring Measurement Integrity in the Validation of Thermal"Processes
PDA Training and Research Institute, Baltimore, MD

March 8–12, 2004
PDA SciTech Summit™
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Orlando County Convention Center
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◆ March 29, 2004
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April

April 19–21, 2004
PDA Training and Research Institute Laboratory Course
Cleaning Validation
PDA Training and Research Institute, Baltimore, MD

April 26–30, 2004
PDA Training and Research Institute Laboratory Course
***Aseptic Processing Training Program*—Week 2**
PDA Training and Research Institute, Baltimore, MD

May

May 13–14, 2004
PDA Training and Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA Training and Research Institute, Baltimore, MD

May 17–21, 2004
2004 PDA Biennial Training Conference, Courses and Vendor Exhibit
The Westin Rio Mar Beach Resort & Golf Club, Puerto Rico

■ May 17–21, 2004
PDA 2004 Pharmaceutical & Biopharmaceutical Manufacturing Science & Technology Congress, Training Courses, and Exhibition
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia
Singapore

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◆ Denotes European program/meeting

■ Denotes Pacific Rim program/meeting

Be sure to check **www.pda.org** for conference and course updates!