Volume XXXIX, No. 1

PDA Letter

January 2003

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

PDA Meets with EMEA, page 10

FDA's Concept Paper on Sterile Drug Products Discussed at PDA Annual Meeting

On Monday, December 9, 2002 PDA held a special one-day session on the FDA's recently-released Concept Paper on Sterile Drug Products Produced by Aseptic Processing. This session was available to all attendees who had registered for the full Annual Meeting in New Orleans, Louisiana.

The session began with a review of PDA's presentation to the FDA's Advisory Committee on Pharmaceutical Science. Advisory committees are common for FDA, but unusual for a GMP guidance. The Advisory Committee was created by The Office of Pharmaceutical Sciences (OPS) in CDER to make scientific recommendations to the Agency. Members are primarily academics from colleges of pharmacy; some are consultants; all are USA-based. Vincent Lee, Ph.D., is the chairman of the committee.

Historical Notes:

- FDA's first Aseptic Processing (AP) Guideline was prepared in 1987. It involved CDER and Field Inspectors;
- EU GMP Annex 1 on sterile medicines was revised in 1995, with subsequent minor amendments;
- FDA began work on revision of AP Guide in the mid 1990s; and
- FDA Concept Paper (CP) was released on September 27, 2002.

A Concept Paper:

- Is not formally recognized in the FDA administrative process;
- Is a procedure which allows first public discussion without binding FDA or industry;

continues on page 7

Emer Cooke, Head of Inspections for EMEA, to Keynote PDA International Congress in Prague

Back to the Future—Ahead to the Past: Mastering the Fundamentals of GMPs to Manage the Challenges of Escalating Demands

Emer Cooke, who joined the European Medicines Evaluation Agency (EMEA) as the Head of the Sector for Inspections in July 2002, will discuss regulatory expectations for industry and will focus on regulatory issues for EU candidate countries.

Stephanie Gray, GlaxoSmithKline, will provide an overview of manufacturing issues from past to present.

Edmund M. Fry, IVAX Pharmaceuticals, will provide a history of GMPs and will identify strategies for meeting regulatory expectations.

Don't miss this unique opportunity to join PDA, industry colleagues from around the world, and representatives from various European Health Authorities to discuss *Mastering the Fundamentals of GMPs to Manage the Challenges of Escalating Demands*.

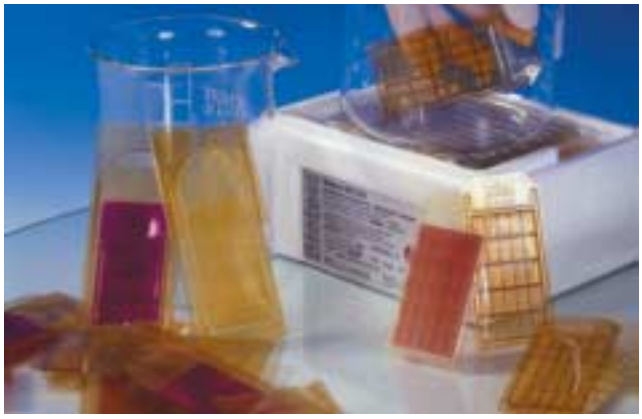
Congress Highlights:

- A multi-track format including sessions on aseptic processing, biotech issues and international regulatory issues;
- Keynote presentation by Stephanie Gray, GlaxoSmithKline, USA;

continues on page 17

Prague, Czech Republic

February 24–28, 2003



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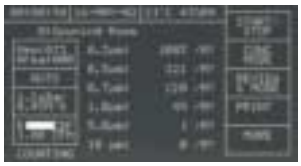

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Important Dates...

- **February 24–28—PDA International Congress, Prague—cover**
- **March 1–2—DUPHAT* 2003, page 20**
- **March 17–21—2003 PDA Spring Conference, page 16**

IN THIS ISSUE...

Russell E. Madsen, Acting President PDA

PDA Partners with the Hollis Group to Offer C3Q™ Methodology

PDA and The Hollis Group, Inc., have formed a strategic partnership to provide training and certification services for computer infrastructure assurance engineers and auditors working in regulated life sciences industries. PDA has accepted Hollis's Concurrent Computer Configuration Qualification Methodology (C3Q™) for inclusion in the PDA Training and Research Institute's (PDA-TRI) curriculum. The PDA-affiliated Audit Repository Center (ARC) will administer a C3Q™ certification program based upon ARC's current TR-32 auditor training and certification program.

This program allows PDA to extend its research collaboration services for life science to include qualification of computer and network infrastructures (CNI's) for regulatory compliance. Increasingly, regulatory agencies insist that information systems architectures provide for the confidentiality, integrity, availability, and authenticity of life science data. PDA now has the ability to train and verify the certification of practitioners to support this need.

Hollis and PDA have more than 10 years experience delivering Life Sciences IT training together, and this is a logical next step. Hollis will provide PDA with the training materials and Practitioner certifications for a methodology (C3Q™) specifically designed for CNI qualification. Working together, PDA and Hollis will be able to develop a Practitioner community that will substantially increase infrastructure assurance in the pharmaceutical, medical device, biotech, and associated services industries.

The Hollis Group, Inc., provides Infrastructure Assurance and Information Security (INFOSEC) products and services for computer and network infrastructure (CNI) qualification and operation, vendor evaluation, and software/systems integration projects. Hollis specializes in regulated industries, such as biotech, pharmaceuticals, medical devices, clinical/contract research, laboratories, and professional practices. Hollis has developed C3Q™, the Concurrent Computer Configuration Qualification Methodology, specifically for companies that need to demonstrate regulatory compliance of CNI's that support life-science information systems. ■

PDA BOOKS OF NOTE...

Laboratory Systems Validation Testing and Practice

by Paul Coombes

This book, based on more than 20 years of experience in the pharmaceutical industry, put the subject of systems validation in its rightful place in the quality assurance world from the author's perspective. First, the primary importance of valid analytical data is discussed together with a persuasive case study and novel definition. The term LSV (laboratory systems validation) is used to make a distinction from CSV (computer systems validation) and equipment qualification. The differences that exist in the world of laboratory systems are explored, followed by a mass of detailed advice and examples of the specific qualities of many types of laboratory system. This provides the reader (who could be from a computing, chemistry, engineering, or QA background) with proven approaches to the generation of requirements specifications, and thereby, the subsequent validation testing strategies and tactics for laboratory systems.

150 pp; $120 members/$149 nonmembers **Item 17196**

The 2003 PDA Board Members

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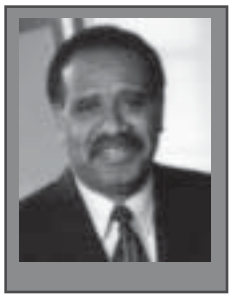

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Process Analytical Technology Initiative on Rapid Microbiology Methods

by Jeanne Moldenhauer, Vectech Pharmaceutical Consultants, Inc.

Rapid microbiology methods have been a goal of manufacturers because of the time required to perform conventional testing, which is dependent on microbial growth to make the microscopic become visible. New methods can reduce the time to obtain results from several days to a few hours. Under these circumstances, new methods may allow manufacturers to detect adverse trends early and make corrections before they endanger products or processes. By analogy, rapid methods in clinical microbiology identify microorganisms and allow physicians to begin treatment more quickly.

Implementation of new microbiological methods poses significant problems and risks. These include validation of methods that will not yield results equal to traditional methods. Additionally, comparative parallel testing is not always informative. Experimental designs for validating the methods can be developed, but may not be a perfect solution. Therefore, some risk is involved and there is a need to create a "safe harbor" for firms willing to undertake new microbiological tests.

The safe harbor concept for sterility testing using new/rapid microbiological test methods (a specification change using the ICDH definition of specification) may be limited because the test is qualitative and the established release test requirement is a critical parameter. For a critical parameter, the batch cannot be released if the parameter is not met. The safe harbor concept for sterility testing may not afford much latitude because a failed criterion prohibits retesting by the same method or even a compendial method. The batch must be rejected. Otherwise, the batch is "tested into compliance."

Quantitative (such as microbial limits tests for total counts or total fungi, or environmental monitoring) may be suitable for the safe harbor concept. Parallel testing and retesting might be considered since the counts and acceptance criteria may be based on different units of measure. Quantitative limits may be developed from parallel testing to establish reliability of a new test methods and correlation of the acceptance criteria. Experimental methods involving challenge and recovery studies may also be developed to validate new microbiological test procedures.

New/rapid microbiology methods seem least controversial for in-process tests. These tests measure the state of control of a process rather than the finished product. New baselines for process indicators may be established without a problem, but an awareness of such testing should expect the minimum delay when implementing these tests with adjusted acceptance criteria. Discussion of whether the safe harbor initiative should allow retests as part of an investigation of an in-process test result should be undertaken.

Rapid microbiology methods have been a goal of manufacturers because of the time required to perform conventional testing, which is dependent on microbial growth to make the microscopic become visible.

FDA's Rapid Microbiology Initiative

The Office of Pharmaceutical Sciences Advisory Committee met October 21–23, 2002 in Rockville Maryland. The last day of this meeting was devoted to issues on the Process Analytical Technologies (PAT) sub-committee.

In the morning, there were several presentations on the Part 11 issues and how they apply to PAT. Numerous draft guidance documents were provided for review. Additionally, there were presentations by Robert S. Chishelm, AstraZeneca International, Guy Wingate, GlaxoSmithKline, Deborah M. Thomas, Air Products and Chemicals, Inc. and John Murray, CDRH, FDA. The actual presentations can be obtained from www.FDALive.com, or may be downloaded from the FDA Web site (transcripts of Advisory Committee Meetings). One theme carried through the various presentations was the need to understand how much data is maintained with an automated system and the need to develop appropriate guidance. An interesting discussion occurred on the issue of whether all data generated electronically had to be maintained and for what time period. Sorry to say, there is no relief in immediate sight as there was no clear answer on this topic.

The afternoon included two breakout sessions, A Mock PAT Inspection and Rapid Microbiology Issues. In the rapid microbiology session, there were presentations by Silvano Lonardi, Ph.D., GlaxoSmithKline and a brief presentation on PDA Technical Report No. 33: *Evaluation, Validation and Implementation of Rapid Microbiology Technologies*. Lonardi's presentation described the program established for implementation of rapid microbiology and chemistry methods. An interesting point from his presentation was that implementation of rapid chemistry methods provides little help in the reduction of product release times unless one also concurrently develops rapid microbiology methods. He

also described the various types of equipment being evaluated and considered at his facility.

Peter Cooney, Ph.D., FDA introduced the session discussion questions. Due to limited time available, the questions were not discussed in detail.

1. Can validation of new methods employ laboratory models to demonstrate assay suitability? How can new acceptance criteria be established using different measures?
2. Should there be application of the "safe harbor" concept for sterility testing (something other than batch re-testing)?
3. If a failure situation develops in quantitative product tests (e.g., microbial limits), should the "safe harbor" concept include retesting by either the compendial method or by repeating the new/rapid method?
4. Should firms be permitted to return to traditional methods (without prior FDA approval) if the new method proves unsatisfactory?
5. To encourage implementation of rapid microbiological methods as part of the PAT initiative should FDA embark on specialized training of field and review staff, or establish a specialized team to address these techniques? How could this be accomplished?

Implementation of new microbiological methods poses significant problems and risks.

One clear message from the FDA is that they encourage the use of rapid methods and are hoping that industry submits these methods for review and approval in their submissions. ■

FDA's Concept Paper on Sterile Drug Products from cover

- Allows for further public "notice and comment" (consultation);
- Is frequently used to start work in the EMEA.

General Reactions to the CP:

- A new guidance on aseptic processing is needed;
- Some problems with the draft need to be fixed;
- Industry needs a means of dispute resolution with FDA;
- Consistency between center, field, and industry is an ongoing issue;
- Industry is interested in providing input into next draft;
- Terminology was a general difficulty;
- The CP confused industry more than FDA expected;
- FDA sounded more reasonable in person than the document suggested;
- FDA is taking a 'risk-based' approach; and
- Each company should justify decisions based on risk analysis.

On Media Fills

On Media Fills (MF), there was discussion on the duration (length of time) for the media fill. It was stated that there is no data that duration is a significant factor. Is the room really dirtier at the end of a batch/shift? Not necessarily so, based on available data.

On interventions, does a firm have to do all interventions that would be probable in a batch? (This seems to be intent of the CP). If so, the size of the MF must usually be increased. Is this scientific, and is it what FDA really wants?

If FDA were to propose a number for media fill runs and pass/fail criteria for media fills it might be:

One positive unit in 10,000 would be a warning or alert; and two positive units in 10,000 would be a failure of the media fill. This suggests that Media Fills of 10,000 units could be routine in our future.

Incubation of units removed from media fill processing:

- Example, the first 50 units removed as a line flush;
- All removals have to be written into procedures and should be standard practice for all fills; and
- The procedures should have rationale for removing units from the MF.

On Environmental Monitoring

FDA said that Environmental Monitoring (EM) and critical surface testing is not a surrogate sterility test, i.e., a positive test on a critical surface test does not mean that the product is considered non-sterile.

On Isolators

The PDA presenters stated that isolators need to be better-embraced by FDA. CP wording suggests it is easier to run a standard filling room than an isolator. PDA presenters felt that this is not the right message.

On Inspectors

FDA must have a training program for inspectors on the new guidance. Inspectors are the industry concern, as written; the CP may give too much latitude for investigator interpretation.

The entire presentation to the FDA's Advisory Committee on Pharmaceutical Science, slides from the Aseptic Processing session at the Annual Meeting, and the Concept Paper on Sterile Drug Products Produced by Aseptic Processing, can be found on the PDA Web site, www.pda.org. ■

—William Stoedter

International Regulatory Briefs

The Australia Therapeutic Goods Administration has issued an updated Overseas Manufacturers GMP Preclearance Request Form and Checklist Many applications for listing or registration in the ARTG, of a therapeutic good, are either delayed or rejected due to a lack of acceptable evidence of the standard of manufacture of the therapeutic goods. To help ensure that applications for listing or registration will not be rejected or delayed sponsors may request assessment (pre-clearance) of the evidence of standard of manufacture prior to submitting an application. Sponsors should note that pre-clearance is mandatory for applications for listing of medicines using the Electronic Lodgement Facility (ELF). For other listing and registration applications pre-clearance is strongly recommended. The form can be found in the "What's New" section of the TGA Web site at: www.health.gov.au/tga.

The Canadian Therapeutic Products Directorate (TPD) has announced a new DRAFT GUIDANCE FOR INDUSTRY Release of Draft Guidance Document: Product Monograph. The revised Standard Product Monograph Template emphasizes the need for clinical relevance. The new format makes information easy to retrieve, provides consistency across different drugs and drug classes, and includes a new consumer information section. The draft guidance can be found at www.hc-sc.gc.ca. The draft guidance consists of the following Product Monographs:

- Draft Appendix E—Product Monograph Template—Standard
- Draft Appendix F—Product Monograph Template—Notice of Compliance with Conditions NOC/c
- Draft Appendix G—Product Monograph Template—Subsequent Entry Product (except for Schedule C and D products)
- Draft Appendix H—Product Monograph Template—Schedule C
- Draft Appendix I—Product Monograph Template—Schedule D ■

—William Stoedter

International Calendar

2003

February 24–28, 2003
2003 PDA International Congress, Courses and Exhibition
Back to the Future—Ahead to the Past: Mastering the Fundamentals of GMPs to Manage the Challenges of Escalating Demands
Congress: February 24–26
Courses: February 26–28
Exhibition: February 24–25
Hilton Prague, Prague
CZECH REPUBLIC
PDA-TRI Lecture Courses:
February 26–28
Requirements and Preparation of Pharmaceutical Grade Waters
February 27
GMP for Investigational Medicinal Products—Draft GMP Annex 13 and the European Clinical Trials Directive
Beyond the GMP/ISO Basics—Practical Strategies for Everyday Compliance
February 28
Aseptic Processing Validation—Trends and Issues

February 27–28, 2003
PDA/IABs Conference
Scientific Considerations for Comparability of Biopharmaceuticals
Hilton Prague, Prague
CZECH REPUBLIC

March 1–2, 2003
DUPHAT 2003
PDA International Pharmaceutical Manufacturing Issues Conference
Airport Expo Dubai, Dubai
UNITED ARAB EMIRATES

April 10–11, 2003
2003 Taormina International Conference and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry
Managing for Quality in a Cost-Focused Environment
Conference: April 10–11
Tabletop Exhibits: April 10
Grand Hotel Timeo & Villa Flora
Taormina, Sicily
ITALY

May 5–9, 2003
2003 PDA International Congress, Courses and Tabletop Exhibits
Congress: May 7–9
Courses: May 5–6
Tabletop Exhibits: May 7–8
The Ritz Carlton Millenia, Singapore
SINGAPORE

EMEA Issues Two Draft Guidances for Comment

1. Guidance on the Rapporteurs Meeting with Applicants on CPMP List of Questions

Background: The guidance is intended for the Centralized Procedure. The objective of the Centralized Procedure is to provide major innovative products with direct access to a Community wide market. Approval by this procedure leads to a Community authorization valid in all Member States. The procedure is compulsory for biotechnology products and veterinary products and optional for other high technology products and new chemical entities. It is a normal practice for applicants to meet with several Agencies to seek advice and canvass opinion during the development phase of a compound. This will help to develop a regulatory strategy for the marketing authorization. Advice may also be sought from the EMEA. The registration dossier is submitted to the EMEA (one copy to the EMEA and two full copies each for the rapportuer and co-rapportuer). The rapporteur and co-rapporteur evaluate the application and prepare a preliminary assessment report. This report is submitted to the CPMP for possible questions. A consolidated List of Questions is prepared by the rapporteur and co-rapportuer and is then considered by the CPMP and an approved List of Questions is transmitted to the applicant.

Objective of the guidance: The potential usefulness of clarification meetings between rapportuer and the applicant after the CPMP adoption of the List of Questions is recognized. The opportunity for clarification and transparent guidance on the List of Questions and the proposed strategy for the responses may potentially reduce the submission of incomplete responses. Moreover the timetable, needed for adequate documentation, can be discussed.

This guidance is issued in order to streamline the process and increase the transparency in this particular phase within the Centralized Procedure.

The Guidance is released for consultation in November 2002 with deadline for comments April 2003. You may access the guidance in the Web site: www.emea.eu.int. Responses should be sent to Soobhujhun.Susana@emea.eu.int.

2. Note for Guidance on the Non-clinical Documentation of Medicinal Products with Well-established Use (Draft)

A number of medicinal products marketed in the EU contain active substance(s) for which there is limited or no non-clinical information. In order to obtain a better understanding of the inherent risks with such products and to facilitate a continuous safety assessment, it is necessary to state the minimum requirements for non-clinical testing. Results of clinical trials as well as post-marketing experience gained by widespread clinical use in man contribute to the body of knowledge. A blind repetition of animal experiments should be avoided. The Guidance is released for consultation in November 2002 with deadline for comments May 2003. The draft guidance can be viewed in the Web site: www.emea.eu.int. Comments should be sent to the EMEA, SWP Secretariat via fax at +44 20 74 18 86 13. ■

—Gautam Maitra

PDA Meets with EMEA

In late November, Acting PDA President Russ Madsen, PDA Board Member Tim Marten, and a delegation of others met with the new Head of Inspections for the European Agency for the Evaluation of Medicinal Products (EMEA), Emer Cooke.

The purpose of the meeting was to promote closer relations between the two organizations, culminating in collaboration on a major international joint regulatory conference slated for 2003.

Cooke was accompanied by David Cockburn, Principal Scientific Administrator, Fergus Sweeney, Ph.D., Principal Scientific Administrator, and Gesine Bejeuhr, National Expert from Germany. Cooke explained in detail to the group how the various committees within EMEA function in order to coordinate site inspections, throughout Europe and of third parties outside Europe. Different committees exist to supervise human drug products and veterinary drug products, for example, and those committees contain working parties for quality, safety, efficacy and the like, for support.

The meeting concluded with the understanding that avenues will be identified for future cooperation between EMEA and PDA. David Cockburn expressed interest in seeking ways to have GMP and EU candidate countries work with PDA. Possibilities of having a high profile EMEA/PDA conference in London are being explored. ■

—Virginia Ventura

L–R: Emer Cooke, Head of Inspections, EMEA; Gesine Bejeuhr, National Expert, EMEA; David Cockburn, Principal Scientific Administrator, EMEA; Russell Madsen, PDA Acting President; PDA Board Member Tim Marten, AstraZeneca; Gautam Maitra, PDA Director, Europe Operations; Virginia Ventura, PDA Director, Member Services.

Pre-conference Visit to the Czech Republic

As the newly appointed Director of PDA Operations in Europe, I was asked by Zdenka Mrvova and Miroslav Janousek, active PDA members in the Czech Republic, to visit Prague. The objective was two-fold: to meet with key persons interested in promoting PDA activities in the Czech Republic and its neighboring countries; and to discuss the subject of extending invitations to select members of health authorities in the region to attend the PDA International Congress, Courses and Exhibition to be held in Prague February 24–28, 2003.

L–R: Zdenka Mrvova, Manager of Pharmaceutical R&D II, Léciva; Gautam Maitra, Europe Director, PDA; Jirí Michal, Chairman of the Board and CEO, Léciva; and Miroslav Janousek, QA & QC Director, Léciva.

Interestingly enough, a third objective evolved during my visit: there was an interest in starting a PDA chapter in the Eastern European Region. It was agreed that the chapter should include the following countries: Czech Republic, Slovakia, Slovenia, Croatia, Hungary and perhaps Poland. At a later stage, Estonia, Latvia, and Lithuania could join; however, the Czech Republic wanted to take the lead. Several chapter names were proposed including The New Europe Chapter or simply Prague Chapter. Other suggestions, including the Eastern Europe Chapter and the EU Candidates Chapter, were not favored.

It was decided that invitations to PDA's February meeting in Prague would be extended to about 20 members of the Region's health authorities. It was acknowledged that there was an interest in having forums in Prague since they would help to update the local health authorities with the latest trends in pharmaceutical and biopharmaceutical manufacturing.

Jirí Michal, Chairman of the Board and CEO of Léciva, the largest pharmaceutical company in the Czech Republic, mentioned that it was in the interest of pharmaceutical companies that local health authorities have cutting-edge regulatory knowledge; a gap that PDA can be very instrumental in filling. Michal also mentioned that training local pharmaceutical companies with regard to EU regulations was also desired. A further meeting on this subject is planned in Prague on February 26, 2003. ■

—Gautam Maitra

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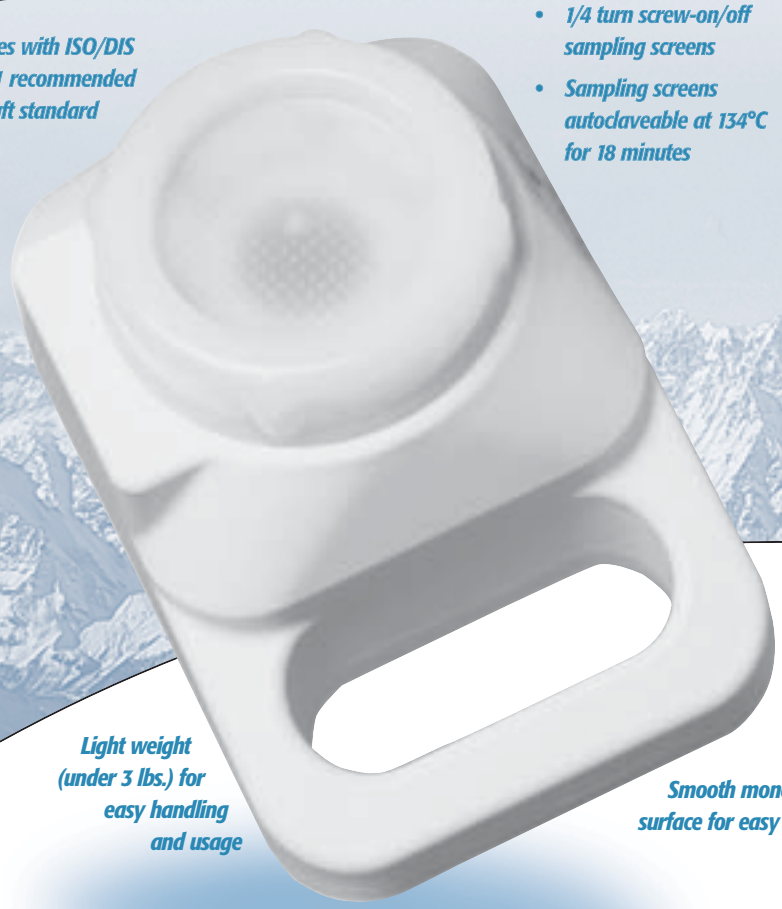

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To insure that you receive details about PDA Exhibit shows, contact Nahid Kiani at PDA, kiani@pda.org, Tel: (301) 986-0293 ext. 128, Fax: (301) 986-0296. Details on these events are posted to www.pda.org as they become available. ■

—Linda Williams

2003 PDA Exhibit Opportunities

February 24–28, 2003
2003 PDA International Congress, Courses and Exhibition
Back to the Future—Ahead to the Past: Mastering the Fundamentals of GMPs to Manage the Challenges of Escalating Demands
Congress: February 24–26
Courses: February 26–28
Exhibition: February 24–25
Hilton Prague, Prague, CZECH REPUBLIC

March 17–21, 2003
2003 PDA Spring Conference, Courses and Tabletop Exhibits
Bridging the Gap between Science and Compliance: The Impact of Today's Regulatory Environment on Biopharmaceutical Development and Approval
Conference: March 17–19
Courses: March 20–21
Tabletop Exhibits: March 17–18
Paradise Point Resort, San Diego, CA

April 10–11, 2003
2003 Taormina Conference and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry Managing for Quality in a Cost-Focused Environment
Conference: April 10–11
Tabletop Exhibits: April 10
Grand Hotel Timeo & Villa Flora, Taormina, Sicily ITALY
[Only 10 tabletops available; conference is limited to 100 participants]

May 5–9, 2003
2003 PDA International Congress, Courses and Tabletop Exhibits
Congress: May 7–9
Courses: May 5–7
Tabletop Exhibits: May 7–8
The Ritz Carlton Millenia, Singapore, SINGAPORE

September 8–12, 2003
2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits
Conference: September 8–10
Courses: September 11–12
Tabletop Exhibits: September 8–9
Omni Shoreham Hotel, Washington, DC

November 10–14, 2003
2003 PDA Annual Meeting, Courses and Exhibition
Annual Meeting: November 10–12
Courses: November 13–14
Exhibition: November 10–11
Hilton Atlanta, Atlanta, GA

Who is in Charge of Validation?

The following remarks are taken from an exchange in 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

I want your advice regarding a not-yet defined issue. What department of a company should be in charge of validation? I know that there must be a validation committee formed by Quality Assurance, Production, Engineering, and R&D, but who should lead this team? It is clearly defined that all departments in a plant are responsible for validation and everybody should be involved in it, but it is [also] true that validation [generally] should be part of [i.e. the responsibility of] one department of the company; which one is the more adequate? Is it R&D (as it is in my company)? Is it Quality Assurance? Or Production?

Response 1

Usually the Engineering Department, with final Quality Assurance, signs-off on all validation docs.

Response 2

I carried out a US industry-wide survey, of PDA and ISPE members on this exact topic several months ago. The results from 400 respondents to the question, to which department in your company does validation report to, were:

Production/Operations	28%
Quality	45%
Engineering	3%
Development	3%
Regulatory	2%
Other	19%

And [among] the [19% of the] responses to "Other" [included/] stated [the following]: Every conceivable other function in the company, including three [who reported] directly to the President, and even one person who reported to marketing!

Response 3

In my company, Engineering qualifies all equipment plus validates sterilization processes; autoclave loads and SIP of all vessels. Individual manufacturing departments do all process validations ("validation batches") and cleaning validations. Regardless of who is the responsible lead for any given project, QA and Regulatory Affairs are also involved with approvals. We do not have such a thing as a validation "committee"; however, the "stakeholders" involved with each specific validation project meet as necessary. The stakeholders always include the owning department and QA. Usually they also include Process Engineering and Regulatory Affairs. Facilities Engineering, Technical Services, and QC are often needed as well.

Response 4

I have been involved with different organizations where validation reported to Production, Quality and sometimes R&D. Every company is different when it comes to department definitions and responsibilities. From my experience, when it comes to areas such as process/product/cleaning validation, the Process Development [PD] area seems to be a good fit; especially for new product validations. There's carryover from PD establishing critical process parameters into the validation protocol which makes sense. Cleaning issues are also more likely to be fresh in the minds of professionals when PD is involved/provides input into the cleaning validation methods.

Computer validation and equipment qualification/validation often find a different domain within IT or Pharma Engineering.

Although one can make an argument for or against having validation as a function of any one of these departments, PD seems to be the one with the very few "cons".

I'm curious to read other feedback on this topic.

Response 5

There's no requirement for any specific area for leading validations activities...in fact the validation committee is not a requirement for every country.

continues on page 14

Join this lively online discussion group, where more than 2,000 of your colleagues from around the globe meet and find solutions to complex issues. Access is open to both PDA members and nonmembers, and discussions may be accessed via e-mail or the Web.

See the PDA Web site at **www.pda.org** to sign up via the Web or send an e-mail to *requests@www2.pharmweb.net* if you don't have Web access, with one of the following commands placed in the body of the message: "subscribe PharmTech" (to receive individual messages daily), or "subscribe digest PharmTech" (to receive one daily digest). Replace "subscribe" with "unsubscribe" to leave the list. For help topics, type "help PharmTech" in the body of the message and send.

Sci-Tech Discussion from page 13

Anyway, in my experience, the committee and one member leading it, is a good organization (the leader used to be QA or PTS, but again it's not a requirement).

The issue is that with this organization the "rest" used-to-forget their responsibilities regarding validation, so the validation committee needs to work hard with them advising, training (and documenting!!) their responsibilities.

Some things to consider regarding other responsibilities (in addition to those of the validation committee):

- Owner (e.g. lab manager, manufacturing manager) is responsible for assuring that resources are available which only use validated systems and processes (this is "major"), but they are also responsible for designing the URS.
- QA is responsible for assuring that validations meet regulatory requirements (QA needs to approve all documentation).

Remember that technical resources is the best approach for designing a specific validation (for MRP II systems don't forget include IT and EMU for HVACs) even if, in your organization, R&D is leading these activities.

Response 6

There are no rules concerning who should be in charge of validation, providing it is completed correctly. The important points are that the manager of each department should ensure that his/her department is fully validated. The Head of Quality and Head of Production have a joint responsibility for process validation. Protocol approval should include the relevant Head of Department and Head of Quality. Approval from other functions, e.g. engineering for IQ, may be required. Final reports should be approved by the same functions that approved the protocol.

Response 7

Most pharmaceutical companies in Mexico, have a "Validation Department" in each facility, or, at least, one person in charge of Validation Regards.

Response 8

Validation should be done by the people responsible for doing the work. Who better than the person who develops the formulation, is responsible for the scale-up, packaging, etc. to know what parameters are important and should be monitored? That's why the diversity of the survey.

In a small firm it might be the Vice-President.

Response 9

I would like to respond to the idea that validation should be performed by those responsible for the work being validated. It could be considered a conflict of interest to allow the person (or group) responsible for developing and/or implementing a system or process to prove that it works as intended. Isn't this why GMP requires us to have independent QA departments? Subject matter experts must be thoroughly consulted, but an objective outsider can be invaluable to the process.

Response 10

Regulatory authorities expect QA to sign/approve the validation study. In any given pharmaceutical forum, Distinguished Pharmaceutical Experts (DPE) convey that QA is the heart of the pharmaceutical industry, as though nothing should move in the industry without the express consent of QA; including validation. These very same DPEs in reality practice exactly the opposite. When it comes to designing or procuring new equipment or facilities, they don't even bother to consult QA; but go ahead in finalizing planning/procurements. And when it comes to qualifying their finalized plans/procurements, they pressure QA for validation completion. This scenario is widely practiced in most pharmaceutical companies without mentioning/documenting the actual procedure followed in planning/procurements.

Now let's move on to actual question "Who is in charge of validation?" Theoretically, the person who clears the plan for execution, [the one] who procures should also be responsible to demonstrate its qualifications status without expecting others to qualify what they have put in place/procured. With regard to signing the validation protocols and approving the validation study, these matters could be done in consultation with QA for regulatory compliance.

In practice, most companies nominate a group with members from Engineering, Production, R & D and QA/QC, with QA/QC as head of the group. Most of the time, the Engineering Department is made responsible for equipment/facility validation, with process validation being given to R & D. Cleaning Validation is shared jointly by the production and development teams. In all these functions QA/QC is made responsible for directing the work as required. The protocols and data is assessed by this group, while final approval/rejection to the study is given by the senior member group within the organization; with site head as the chairman and QA/QC chief as secretary signing the final validation study. Though this practice/procedure works well, the actual procedures and practices differ from organization to organization.
Best of luck in your validation studies.

Response 11

In my organization QA is solely responsible for all validation activities. Each validation team was constituted comprising experts from Engineering, Instrumentation, QC and Production. The team is also described in each validation protocol.

Response 12

Surely it is precisely the independent QA that allows you to have the rest of the work carried out

by people who do indeed have an interest in the results—otherwise we can all go home—manufacturing is interested in manufacturing and QC is interested in the samples passing.

Response 13

It is exactly this approach that has gotten many companies in trouble. The 483 list is full of them.

Does anyone actually believe that just because you have an outline, anyone can do the job? Who will do the job after the validation is done? The purpose of validation is to prove that your people know what they are doing and can do it reproducibly. That the process, people and all, are under control.

Response 14

The quick answer is that there is no straight answer.

I have worked for several large pharmaceutical and biotech companies and "validation" is/was handled differently in each of them, and even differently at different times.

I worked in a biotech facility where there was a Validation department that was responsible for all validation, and did everything.

I worked at a pharmaceutical facility where there was no Validation department. Engineering did equipment qualifications, Microbiology did their own cleaning validations (micro only), R&D did some process and cleaning validations, and other internal companies did some process and cleaning validations for their products (3rd party). It was very "scattered about." Then they created a Validation department in QA. Later, they dissolved the Validation department and spread the responsibility around again. Next they recreated a Validation department but as part of operations…

I worked in another pharmaceutical facility where the Validation department was in Technical Operations and another where it was split between Operations and Engineering.

It very much varies from company to company and seems to be based on the particular company's culture. In companies with a strong engineering bent, validation will probably be in Engineering, most specialists will be engineers and the efforts may be strongly equipment related and may be weak in areas like cleaning and process validation. Other companies with a strong research bent will focus on process validation and may be weak in equipment qualification. Some companies with a strong focus on business may be weak in all validation aspects.

Also, considering the wide scope of validation, I think it's hard to find a Validation Department that is strong in all areas. With the high level of turnover these days, a Validation Department that is strong in all areas one day may not be the next. So expertise/resources will almost certainly need to be drawn from other groups. Cleaning validation is a great example of where input from many areas is best. You certainly need the resources and guidance of Medical Services, Toxicology, Microbiology, and Analytical as well as support from Operations to get a program in place. The only regulatory requirement for "who does what" is that Quality must approve the validations.

Response 15

In this discussion, it seems that the words "responsibility" and "in-charge" have thrown us up to different places. I believe the FINAL responsibility of validation is the Quality Unit—the QA/QC breeds. The three responsibility functions that I heard somewhere and sometime ago of the Quality Unit (QU) are:

1. RELEASE/REJECT—it is QU's sole responsibility to perform and conclude, and [this responsibility] cannot be delegated.
2. REVIEW & APPROVE—it is other units' responsibility to perform and make the conclusion, but the conclusion is not official until QU approves for taking further actions.
3. ASSURE—it is other units' responsibility to perform, conclude, and complete the action, and QU audits the process and outcome.

I believe validation belongs to #2 above. ■

—compiled by Russell E. Madsen

2003 PDA Spring Conference, Courses and Tabletop Exhibits

Bridging the Gap between Science and Compliance: The Impact of Today's Regulatory Environment on Biopharmaceutical Development and Approval

March 17–21, 2003 • Paradise Point Resort, San Diego, CA

Where is the Compliance Environment Going?

Conference:
March 17–19

Courses:
March 20–21

Tabletop Exhibits:
March 17–18

Mark A. Elengold, Deputy Director, Operations of the FDA's Center for Biologics Evaluation and Research (CBER) will address "Where is the Compliance Environment Going?" at the PDA 2003 Spring Conference, Courses and Tabletop Exhibits in San Diego, March 17–21.

Concluding two days of topical sessions on issues such as quality oversight during clinical development, and manufacturing process controls, Mr. Elengold's presentation will focus on the recently-proposed organizational changes at CBER, how this might impact inspections of biologics manufacturers, and the recently-announced GMP initiative.

Elengold will discuss the impacts of bioterrorism on CGMP and plant and transportation security, as well as other issues that are new and important to biologics development and manufacture.

The session will conclude with a panel comprised of FDA and industry speakers, from the various sessions during the conference, who will wrap-up discussion with Q&A from conference attendees.

Elengold joined FDA as an investigator in the New York District Office. After transferring to the White Plains Resident Post, he was selected for an FDA Management Development Program. He began his career at CBER in 1988 as the Director of CBER's Office of Communications, Training and Manufacturers Assistance. He was responsible for coordinating CBER's external affairs, training, and document control functions.

Prior to joining CBER, Elengold held various positions in the Center for Drug Evaluation and Research, (CDER) the Bureau of Veterinary Medicine, and the Office of the Commissioner.

Check PDA's Web site to register or to obtain additional information (www.pda.org) as details for the Spring Conference are finalized. ■

—Lisa Wade

PDA-TRI Lecture Courses

March 20

Achieving CGMP Compliance during Development of a Biotechnology Product

Good Documentation Practices in the Pharmaceutical Industry

March 20–21

A Practical Approach to Aseptic Processing and Contamination Control

Assessing Packaging and Processing Extractables/Leachables

Preparing for an FDA Pre-Approval Inspection

Validation: An Introduction

March 21

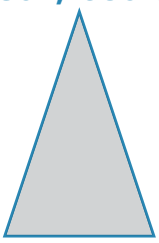
Conducting Compliant Deviation Investigations for Pharmaceutical Industry

For Exhibiting Information, contact Nahid Kiani—

E-mail: kiani@pda.org

Phone: (301) 986-0293 ext. 128

Fax: (301) 986-0296



February 27–28, 2003

PDA and IABs Conference

Scientific Considerations for Comparability of Biopharmaceuticals

Hilton Prague, Czech Republic

Following the PDA International Congress in Prague, PDA, in collaboration with the International Association for Biologics (IABs), will host an important conference on ***Scientific Considerations for Comparability of Biopharmaceuticals***. Participants in the conference will review policies and experiences pertaining to establishing comparability of biotech-derived therapeutics subject to changes in their manufacturing process.

Leading industry and regulatory experts will provide case studies of experiences and summarize the current regulatory policies, state of knowledge regarding process/product changes, and principles of comparability and therapeutic equivalence. The impressive list of presenters includes:

- Huub Schellekens, Central Laboratory Animal Institute, Utrecht University, who will deliver the keynote presentation on Immunogenic Issues in Biotech Comparability;
- Anthony Mire-Sluis, CBER, FDA, who will present on Immunogenicity of Recombinant Proteins;
- Anthony Ridgway, Bureau of Biologics and Radiopharmaceuticals, Health Canada, who will present Canadian regulatory perspectives; and
- Toru Kawanishi, Division of Biological Chemistry and Biologicals of the National Institute of Health Sciences, Japan, who will present Japanese regulatory perspectives.

This symposium is timely as the ICH Expert Working Group for Quality begins its deliberations on Comparability with the goal of developing a harmonized guidance document on this subject.

Plan now to attend this important two-day conference at the Hilton Hotel, Prague in February. For registration information, visit PDA's Web site at www.pda.org. ■

—Leslie Zeck

Prague International Congress from cover

- A Gala Banquet at the Municipal House—Smetana Hall, one of the most prominent buildings of Prague Art Nouveau-style on the site of the former King's Court—will enhance the networking opportunities for participants in the Congress;
- More than 40 exhibit booths featuring the latest in science and technology;
- A special session on the FDA Preliminary Concept Paper on Sterile Drug Products Produced by Aseptic Processing with a confirmed FDA representative and industry experts discussing each section of the concept paper; and
- Special presentations on issues for EU candidate countries.

Visit PDA's Web site at www.pda.org to register and for additional details. ■

—Leslie Zeck

Prague, Czech Republic

Hilton Prague
Congress: February 24–26
Courses: February 26–28
Exhibition: February 24–25

For Exhibiting Information, contact Nahid Kiani—
E-mail: kiani@pda.org
Phone: (301) 986-0293 ext. 128
Fax: (301) 986-0296

See Registration Form on page 28

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- ✔ Unit dose reduces handling of material
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PDA to Launch 2003 Audio Conference Series and Regional Conferences

PDA recognizes that the increasing costs of airfare, lodging, and lost productivity when traveling have made frequent in-person meetings an expensive option. Fortunately, competitive and cost-effective communication technologies are available, allowing quick and easy exchange of the most critical and complex information—regardless of physical distance. Audio conferences help thousands of businesses save money and improve productivity. PDA is pleased to initiate a series of audio conferences on the most updated scientific and technical information in the industry.

Think of it like "talk radio." Listeners can be anywhere and still call in to participate. One speaker phone in a central location will allow for as many listeners as the room can accommodate for one low registration fee. Most importantly, information on rapidly advancing technology, regulations, products, markets and events can be delivered rapidly and affordably in real-time, and interactive question-and-answer discussions can be facilitated.

PDA began offering audio conferences in April 2002 and continues the series this year. Upcoming topics include: Guidance on Aseptic Processing; Rapid Microbial Methods; Writing OOS Reports; Contracts; Internal Audits. All PDA audio conference registrants will be e-mailed speaker presentation materials in advance or will be able to access these materials from a Web site. Check www.pda.org for the full schedule and list of presenters. Won't you consider participating in an audio conference this year?

Audio Conferences are promoted through www.pda.org, e-mail and fax.

Due to the short lead time, individual event promotion through snail mail or the *PDA Letter* is not practical.

Taking the Meeting to the Membership

PDA continues to reach out to its members and will begin to hold two-day conferences with a regional focus. The programming topics will emphasize issues germane to the specific region/country. PDA will work closely with Chapters to ensure PDA does not conflict with critical chapter meetings and to assist in identifying the "hot topics" for their regions.

Still in the planning phase, look for PDA's first "regional conferences" scheduled for spring 2003 in Puerto Rico and Canada. If you are interested in serving on the program planning committee for these conferences, please contact PDA at info@pda.org. ■

—Lisa Wade

SAVE THE DATE!

PDA International Pharmaceutical Manufacturing Issues Conference at DUPHAT* 2003

Airport Expo Dubai • United Arab Emirates • March 1–2, 2003

As a premier international association for pharmaceutical science and technology, PDA is pleased to present an International Pharmaceutical Manufacturing Issues Conference at the 2003 DUPHAT exposition. Interactive sessions and presentations will focus on topics such as:

- ICH Q7A Guidance Document and APIs;
- Global Pharmaceutical Manufacturing Issues;
- Regulatory Procedure in the EU;
- Regulatory Inspection and Compliance;
- Challenges for a European Multinational Company doing Business in the Middle East;
- QC/QA Protocols;
- GMP Compliance Issues;
- Update on the Middle East Regulatory Conference held in Cairo in October 2002;
- EU GMP Annex 1;
- Compilation of IND/CTX; and
- Validation Techniques.

Stuart R. Heir, Head Global Quality Assurance, Novartis Pharma AG, will present the keynote address, "Doing Business in a Global Economy: Experiences From a Multinational Company."

International professionals and scientists in the parenteral, sterile products, biotechnology, and related fields are invited to attend this cutting-edge event and witness high-level education and dialogue among industry and regulatory experts. All individuals interested in the future of pharmaceutical science and technology, including those engaged in manufacturing, production, quality assurance/quality control, engineering and maintenance operations, facility design, product and process development, scale up, validation, compliance and regulatory affairs, and research and development, will derive significant value from participation.

The agenda and information is currently in development.

Please register your interest by e-mailing your full contact information to zeck@pda.org.

Visit PDA's Web site www.pda.org for details as they become available.

*DUPHAT is supported by the UAE Ministry of Health, Dubai Chamber of Commerce and Industry, and organized by INDEX Conferences and Exhibitions Organization Est. ■

—Leslie Zeck

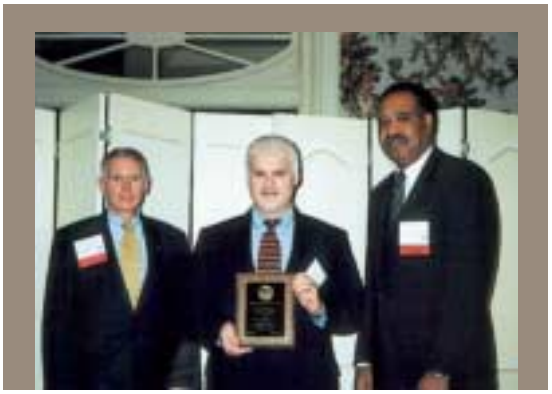
2002 PDA Award Photos

(*Some photos not available at time of publication*)

Honorary Membership, Joseph R. Robinson, Ph.D.

Frederick J. Carlton Award, Robert B. Myers

Agalloco Award, Göran Bringert



Frederick D. Simon Award, Robert A. Bellantone

PDA Chapter Award, Randy Liebowitz, Capital Area Chapter

PDA Chapter Award, Mitch Garber, Delaware Valley Chapter

Editor's Note:

In each photo, with the award recipient PDA Chair Floyd Benjamin is pictured on the right and PDA Acting President Russell E. Madsen is pictured on the left.

▪▪▪

continues on next page

...More 2002 PDA Award Photos

(*Some photos not available at time of publication*)

PDA Chapter Award, Marco Budini, Italy Chapter, with PDA Chair Floyd Benjamin on the right and PDA Acting President Russell E. Madsen on the left.

Michael S. Korczynski Lecture, Bill Whyte, D.Sc., left, with Russell E. Madsen, PDA Acting President.

Plan to attend the 2003 PDA Annual Meeting, Courses and Exhibition—November 10–14
Hilton Atlanta
Atlanta, Georgia

Scenes from the 2002 PDA Annual Meeting, Courses and Exhibition

Laura Thoma, Pharm. D., University of Tennessee-Memphis, Annual Meeting Program Chair

Conference attendees parade from a General Session at the Ritz Carlton Hotel, to the opening of the Exhibit Session at the New Orleans Marriott.

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Quality
On-Line

PDA Will Offer the ICH Q7A Training Conference in Singapore

2003 PDA International Congress, Courses and Tabletop Exhibits

The Ritz Carlton Millenia Singapore • May 5–9, 2003

Congress: May 7–9 • Courses: May 5–7 • Tabletop Exhibits: May 7–8

The Q7A Workshop at the Singapore Conference will provide training of regulatory personnel alongside industry participants. The faculty is comprised of both regulators and industry representatives who served as members of the ICH Expert Working Group that developed the document. Substantial time has been allotted for question-and-answer sessions.

Highlights:

- This Q7A Training is being conducted by members of the Expert Working Group that developed the guidance; and
- The joint industry/regulatory/faculty participation will facilitate a mutual exchange of discussion issues on the Q7A document.

Training will be presented by members of the International Conference on Harmonization (ICH) Q7A Expert Working Group, including Dr. Gordon Munro, Medicines and Healthcare Products Regulatory Agency, UK.

The Q7A Guidance Document can be found on the following Web sites:

1. http://www.fda.gov/cder/guidance/index.htm;
2. http://www.emea.eu.int/pdfs/human/ich/410600en.pdf; and
3. www.ifpma.org/ich5q.html#gmp.

A searchable database of frequently asked questions from recently-held ICH Q7A Training Conferences can be found on PDA's homepage (www.pda.org).

Who Should Attend

This document covers all aspects of the manufacturing, controlling and regulating of APIs. The following professionals will benefit from this training:

- Auditors of API Manufacturing Operations;
- Agents, Brokers, Traders, Distributors, Repackers and Relabellers of APIs;
- GMP Compliance Officials;
- Process Engineers;
- Production Engineers;
- Regulatory Investigators and Compliance Officers;
- Reviewing Chemists;
- Quality Assurance/Quality Control and Regulatory Affairs Professionals; and
- Consultants to the Pharmaceutical Industry.

Learning Objectives

- Understand the intent of the Expert Working Group that developed the Q7A Guidance Document;
- Minimize variation in interpretation among industry and regulatory bodies worldwide;
- Address how the concepts of the Q7A guidance should be applied;
- Understand inspectional issues through side-by-side training of industry and regulators; and
- Understand how to interpret all 19 chapters of Q7A guidance, including special sections on APIs manufactured by cell culture/fermentation, and APIs for use in clinical trials.

An important multi-track format for the conference on pharmaceutical manufacturing issues will provide participants with the opportunity to focus on the most cutting-edge topics of importance to industry, including:

- Regulatory Compliance Issues;
- Biotechnology Issues;
- Environmental Monitoring and Aseptic Processing;
- Important Update on the FDA Preliminary Concept Paper for Sterile Drug Products Produced by Aseptic Processing;
- FDA Guidelines (BACPAC, Post Approval Changes, Drug Substance Guidance);
- Pharmacopeial Issues;
- Process Analytical Technologies;
- ICH Harmonization Issues; and
- Drug Development/Pharmaceutics.

The conference invites international professionals and scientists in the parenteral, sterile products, biotechnology, and related fields for high-level education and dialogue among industry and regulatory experts. All individuals interested in the future of pharmaceutical science and technology, including those engaged in manufacturing, production, quality assurance/quality control, engineering and maintenance operations, facility design, product and process development, scale up, validation, compliance and regulatory affairs, and research and development, will derive significant value from participation.

Additional information is forthcoming and will be available on PDA's Web site, www.pda.org. ■

—Leslie Zeck

April 10–11, 2003

2003 Taormina International Conference and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry

Managing for Quality in a Cost-Focused Environment

Conference: April 10–11 • Tabletop Exhibits: April 10

Grand Hotel Timeo & Villa Flora, Taormina, Sicily ITALY

Senior level pharmaceutical company representatives are encouraged to plan for this important international conference which will embrace a variety of important topics:

- Development, Implementation and Execution of a New Quality Management System;
- Quality Metrics;
- Key Elements of Building an Effective Quality System;
- The Complexity of Managing Quality: Outside Views;
- Legal Strategies for Consent Decree; and
- Supply Chain Management-Strategic Contracting.

The following speakers are scheduled to present:

Michael Beatrice, Vice President, Corporate Regulatory and Quality Science, Abbott Laboratories, USA—*The Cost of Managing a Consent Decree: Rebuilding Quality*

Eric M. Blumberg, Deputy Associate General Counsel, FDA, USA—*Development of Quality from the Regulatory Perspective*

Douglas Dean, Consultant, PriceWaterhouse Coopers Consulting, Switzerland—*Cost Trade Offs and How to Manage Quality*

Rob Hughes, Director, Operations, QA, and Dossier Management, Astra Zeneca, UK—*Quality Metrics*

Brian R. Matthews, Ph.D., Senior Director, EC Registration, Alcon Laboratories, UK—*Regulatory Perspectives on Managing for Quality*

David Miner, Ph.D., Compliance Leader, Corporate Quality Assurance, Eli Lilly and Company, USA—*Building Quality*

Ronald F. Tetzlaff, Ph.D., President, KMI/Parexel, USA—*A Consultant's Perspective on Managing Quality*

Paolo Verardi, Director of Quality, GlaxoSmithKline, Parma, Italy—*Development, Implementation and Execution of a New Quality Management System*

PDA members are encouraged to share information about this important conference with industry management. Roundtable and panel discussions will provide attendees with opportunities for high-level interaction and information exchange.

The official brochure and registration information for this conference are forthcoming. Watch PDA's Web site for updated information and new speaker confirmations. ■

—Leslie Zeck

September 8–12, 2003

2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits

Conference: September 8–10
Courses: September 11–12
Tabletop Exhibits: September 8–9
Omni Shoreham Hotel, Washington, DC

Save the date and plan to attend the 2003 PDA/FDA Joint Regulatory Conference in Washington, DC this September. Now at a larger venue, this years conference will offer unique opportunities to interact with all levels of FDA staff including division directors, local investigators and scientists. Prepare in advance by submitting your request for topics or technical and regulatory questions for the FDA and industry panelists and your colleagues. You may e-mail these requests to zeck@pda.org.

Keynote presentations by both FDA and industry representatives will provide a comprehensive overview of the most important issues impacting the industry, including the Revisions to the GMPs, the CDER/CBER reorganization, and the Draft Concept Paper on the Aseptic Processing Guidance Document.

Tabletop exhibits will feature the latest technologies, products, and services.

This highly interactive conference will be of professional value to all individuals involved in pharmaceutical, biopharmaceutical product development, regulatory approval, production and quality assurance including those associated with drug product manufacture, service providers, contract services and USA and international regulatory authorities.

Registration information and a detailed brochure will be available May/June. ■

—Leslie Zeck

New this year, PDA plans to offer interactive networking luncheons with CDER, CBER and ORA representatives, offering you even more opportunities to discuss issues with the FDA and international health authorities.

Registration Form

2003 PDA International Congress, Courses and Exhibition
Prague, Czech Republic ■ 24-28 February 2003

1. Please type or clearly print your contact information.

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

Job Title | Membership Number

Company (indicate full company name)

Business Address

City | State/Province | Zip + 4/Postal Code | Country

Business Phone | Fax | E-mail

☐ Substituting for

(Check here only if you are substituting for a previously enrolled colleague. If you are a nonmember substituting for a member, the additional nonmember fee must be paid.)

2. Fees If you are not currently a PDA member, you must add the nonmember fee. Nonmembers will receive one year of full membership in PDA. Membership dues are non-refundable and non-transferable. ***All fees include VAT***.

LTR 01/03

CONFERENCE REGISTRATION	Member Fee	Nonmember Fee	Government/ Health Fee*
☐ Full Registration	☐ € 895	☐ € 1,090	☐ € 350
☐ Monday only (includes Gala Banquet)	☐ € 550	☐ € 745	☐ € 250
☐ Tuesday only	☐ € 525	☐ € 720	☐ € 250
☐ Wednesday only	☐ € 525	☐ € 720	☐ € 200
☐ Gala Banquet Ticket (The banquet is included as part of your full conference registration. Check here if you would like to purchase extra tickets for guests.) €85 each X (# of Tickets) = ☐ €			
PDA and IABs Conference on Scientific Considerations for Comparability of Biopharmaceuticals: 27-28 February 2003. ***This discounted fee is only ifyou register for the 2003 International Congress.***			
☐ Full Registration	☐ € 895	☐ € 1,090	☐ € 300
☐ Thursday only	☐ € 525	☐ € 720	☐ € 250
☐ Friday only	☐ € 525	☐ € 720	☐ € 250
OPTIONAL TOURS			
☐ Half day tour Prague castle (pp) : €45 each X (# of Tickets) = ☐ €			
☐ Half day tour Old Town (pp): €35 each X (# of Tickets) = ☐ €			
☐ Half day tour Jewish Town (pp): €45 each X (# of Tickets) = ☐ €			
☐ Full day tour Cesky Krumlov or Kutna hora (pp) *(includes bus, guide, entrance fee, lunch):* €100 each X (# of Tickets) = ☐ €			

** You must be an employee of an official government agency to qualify for this discounted rate.*

PDA-TRI COURSES	Member Fee	Nonmember Fee	Gov./Health Member Fee*	Gov./Health Nonmember Fee*
☐ Requirements and Preparation of Pharmaceutical Grade Waters (PDA #394) *26-28 February 2003*	☐ € 2,050	☐ € 2,245	☐ € 1,560	☐ € 1,640
☐ Beyond the GMP/ISO Basics – Practical Strategies for Everyday Compliance (PDA #123) *27 February 2003*	☐ € 900	☐ € 1,095	☐ € 675	☐ € 755
☐ GMP for Investigational Medicinal Products – Draft GMP Annex 13 and the European Clinical Trials Directive (PDA #287) *27 February 2003*	☐ € 900	☐ € 1,095	☐ € 675	☐ € 755
☐ Aseptic Processing Validation–Trends & Issues (PDA #185) *28 February 2003*	☐ € 900	☐ € 1,095	☐ € 675	☐ € 755
Course Sub Total	€	€	€	€
Sub Total Conference, Course & Optional Fees	€	€	€	€
TOTAL FEES	€	€	€	€

3. Payment Options:

A) *By bank-to-bank transfer* to the Raiffeisen Bank on account number 107 100 2796; Bank code 5500, Swift Code: RZBCCZPT; Ref. "PDA-Registration";
Bank Address: Vodickova 38, 111 21 Prague 1 Account number: Important: When making a bank transfer it is most important that the name of the delegate is clearly stated!
Please note: All banking fees have to be settled by the remitter.
B) *By a bankers' draft* forwarded together with the registration form payable to AIMS International Congress Services, c/o PDA
C) *By credit card* (Visa, Eurocard/MasterCard, American Express), clearly indicating account number and expiration date.

4. Please check the appropriate box.

☐ Check Enclosed *Charge to:* ☐ MasterCard/EuroCard ☐ VISA ☐ AMEX

Account Number _____ Exp. Date _____

Name Exactly as on Card _____

Signature _____ Date _____

5. Return completed form with payment (payment must be included to be considered registered) made to:

Mail or FAX to
AIMS International Congress Services
Na Zderaze 15
CZ-12000
Prague, Czech Republic
Tel: +420 2 2492 1180 • Fax: +420 2 2491 6226
E-mail: Helena@aims.cz, elena@aims.cz

Wire Transfer Payments:
Raiffeisen Bank
Address: Vodickova 38, 111 21 Prague 1
Account number: 107 100 2796; Bank code 5500, Swift Code: RZBCCZPT
Ref. "PDA-Registration"

LIABILITY: *AIMS International act as agents only and cannot be held responsible for any loss, injury or damage to any person or property, whatever the cause may be. Liability of persons and enterprises providing means of transportation, or other services, however, remains unaffected. The customer takes part in all tours and trips at his own risk. Only written arrangements are binding. We kindly ask you to authorise AIMS with your signature to use all registration data given by this form for a computerised handling on the congress.* ***SEE PAGE 16 FOR CANCELLATION/REFUND/SUBSTITUTION INFORMATION.***

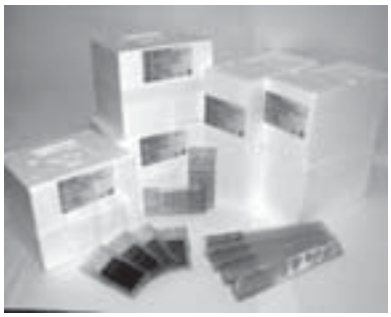
Company, Colleague & Product Announcements

KMI, a division of PAREXEL International, LLC, has announced the formation of its European Operations Group to better serve clients in Europe and worldwide. **James Lyda** has been appointed the Managing Director of the group, having previously worked for PDA and the US FDA. Lyda joined KMI in early 2002 and will continue to work out of Basel, Switzerland. **Ron Kraus** has been named Director of Consulting and will relocate from KMI's Waltham, MA headquarters to Uxbridge, UK (near London) in January of 2003. Kraus has been with KMI since 1995. To create the European Operations Group, KMI has combined their existing compliance consultants, validation staff, and information technology consultants into one group in order to better respond to client needs. KMI now has experts based across Europe with offices in UK, France, Italy, and Switzerland. For further information contact KMI at Europe@kminc.com or visit the KMI Web site at www.kminc.com.


James Lyda

Document Control Systems, Inc. now offers a new, cost-effective solution for FDA-regulated companies that addresses the full cycle of validation, including Performance Qualification (PQ); the final stage in the sequence of a software system's validation that science manufacturers must complete to achieve compliance with FDA requirements, including 21 CFR Part 11. This new service addresses PQ validation for life science manufacturers that implement DCS' quality management software, MASTERControl FDA Edition™. Performed onsite by document control Systems' Validation Services Team, the PQ validation service ensures compliance consistent with FDA industry standard methods and according to the customer's specific policies and procedures. Since the Validation Team is intimately familiar with the software, PQ testing is completed at a much faster rate. For more information, contact Jason Clegg at (801) 942-4000 or jclegg@mastercontrol.com.

Biotest Diagnostics Corporation, USA recently introduced new media for agar strips and contact slides specific for cleanrooms and isolators. For the air, two new agar strip media: TCI-g, the Total Count Isolator agar strip neutralizes H_2O_2, up to 100 ppm and can be used immediately after short isolator ventilation times; and SDX-g, modified Sabouraud Dextrose Agar for determination of yeasts and molds, is now available gamma-irradiated in a sterile double-wrapped package. For surfaces, three new HYCON contact slide media: DE-g, modified D/E Agar for the determination of the total microbial count on disinfected surfaces (The D/E media neutralizes: H_2O_2, chlorine compounds, formaldehyde, gluteraldehyde, iodide, merthiolate, phenol and quaternary ammonia agents.); and SDX and SDX-g, modified Sabouraud Dextrose Agar for fungal monitoring of surfaces; gamma-irradiated sterile double-wrapped version available. For additional information, contact Carol Julich at (973) 625-1300 or visit www.BiotestUSA.com.



Berger Instruments, Inc., a Mettler-Toledo Company, has been awarded an *R&D Magazine* 100 Award for Technological Innovation for its Berger PrepSFC Preparative Purification System. PrepSFC™ combines the advantages of high throughput with low cost to help speed the pharmaceutical drug discovery process. Pharmaceutical companies using this system have estimated a net 40-fold decrease in the cost of purifying each sample in the 100 to 200 mg range. For more information, visit www.bergersfc.com. ■

—compiled by Joseph G. Bury

Send us your news . . .

. . . address news releases to Joe Bury via e-mail at bury@pda.org or mail hard copy to PDA headquarters in Bethesda, MD.

Upcoming PDA-TRI Education Courses

Courses listed in alphabetical order

Aseptic Processing 2003 Training Program—Lab Option 1: SOLD OUT 31, 2003 and March 3–7, 2003; Option 2: SOLD OUT 2003 and May 5–9, 2003; **Option 3**: August 25–29, 2003 and September 22–26, 2003; **Option 4**: October 27–31, 2003 and November 17–21, 2003; $7,500 members/$7,695 nonmembers; *Faculty:* John Lindsay and David Matsuhiro

Baltimore Course Series May 14–16, 2003, Baltimore, MD

Boston Course Series October 20–22, 2003, Boston, MA

Cleaning Validation—Lab February 19–21, 2003; May 19–21, 2003; October 13–15, 2003; $3,000 members/$3,195 nonmembers; *Faculty:* Jon Voss and Bob O'Brien

These courses will be held at PDA-TRI in Baltimore, MD unless otherwise noted.

- **For course content information**, call PDA-TRI directly at **(410) 455-5800**.
- **For registration information**, call PDA headquarters in Bethesda, MD at **(301) 986-0293**.

Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance—Lab February 12–14, 2003; $2,500 members/$2,695 nonmembers; *Faculty:* Bob Livingston and Gilbert J. Paul

Ensuring Measurement Integrity in the Validation of Thermal Processes—Lab April 28–29, 2003; November 6–7, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* Göran Bringert

Environmental Mycology Identification Workshop March 13–14, 2003; May 15–16, 2003; October 2–3, 2003; December 4–5, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* John Brecker

Puerto Rico Course Series February 5–7, 2003, San Juan, Puerto Rico—*including* A Comprehensive Guide to OOS Regulations; Auditing Techniques for CGMP Compliance; Current Good Manufacturing, Quality and Compliance; Active Pharmaceutical Ingredients: Manufacture & Validation; Introduction to Competency Based Training; Change Control and Documentation; Risk Assessment Training; Validation by Design; Annual Product Reviews: How to Comply with FDA & ICH Requirements

Toronto Course Series June 23–25, 2003, Toronto, Ontario, Canada ■

New Release

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002, Sixth Edition (The "Orange Guide")

This book, commonly known as the "Orange Guide," brings together the main pharmaceutical Regulations, Directives and Guidance, including GMP and GDP, which manufacturers and wholesalers are expected to follow when making and distributing medicinal products in the European Union and European Economic Area.

Key features:

This 2002 edition has been substantially updated to include the following:

- New annexes 15, 16, 17 and 18 to the EU guidelines in Good Manufacturing Practice including the ICH GMP for active pharmaceutical ingredients.
- Revised annexes in the Guide to GMP on the manufacture of sterile products (annex 1), medicinal gases (annex 6) and on products derived from human blood or plasma (annex 14)
- The updated version of the UK's Code of Practice for Qualified Persons
- A new section on the Inspection and Enforcement Division of the Medicines Control Agency including notes on mutual recognition agreements for manufacture, supply of unlicensed products and the services of the Division.

Published by the Medicines Control Agency (MCA), ISBN 011-322559-8, 343 pages
Price: $45 member (*Exclusive for PDA members only*) **Item No: 12001**

PDA-TRI **PUERTO RICO COURSES** | **REGISTRATION FORM**

February 5-7, 2003

Inter-Continental San Juan Resort & Casino, 5961 Isla Verde Avenue, Puerto Rico 00979

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

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

Membership Number

Job Title Company

Business Address

City State/Province Zip + 4/Postal Code Country

Business Phone Fax E-mail

☐ Substituting for

(check here only if you are substituting for a previously enrolled colleague. If you are a nonmember substituting for a member, the additional nonmember fee must be paid.)

2. Courses & Fees: Individuals registering at the nonmember rate receive one full year of PDA membership. (If you DO NOT want to become a PDA member, please check this box ☐). Membership dues are non-refundable and non-transferable.

LTR 01/03

		Member	Government
Auditing Techniques for CGMP Compliance (*February 5, 2003*)	PDA #496	$ 900 ☐	$ 675 ☐
A Comprehensive Guide to OOS Regulations (*February 5, 2003*)	PDA #500	$ 900 ☐	$ 675 ☐
Current Good Manufacturing Practices, Quality and Compliance (*February 5, 2003*)	PDA #270	$ 900 ☐	$ 675 ☐
Active Pharmaceutical Ingredients: Manufacture & Validation (*February 5-7, 2003*)	PDA #154	$ 1,950 ☐	$ 1,460 ☐
Introduction to Competency Based Training (*February 5-7, 2003*)	PDA #403	$ 1,950 ☐	$ 1,460 ☐
Risk Assessment Training (*February 6, 2003*)	PDA #291	$ 900 ☐	$ 675 ☐
Change Control and Documentation (*February 6, 2003*)	PDA #115	$ 900 ☐	$ 675 ☐
Validation By Design® (*February 6-7, 2003*)	PDA #373	$ 1,350 ☐	$ 1,000 ☐
Annual Product Reviews: How to Comply with FDA & ICH Requirements (*February 7, 2003*)	PDA #269	$ 900 ☐	$ 675 ☐
Nonmembers Add This Fee*		$ 195 ☐	$ 80 ☐
	Total	$ $	

** Nonmembers must check the nonmember fee box and include the additional fees.*

3. Please check the appropriate box.

☐ Check Enclosed Charge to: ☐ MasterCard/EuroCard ☐ VISA ☐ AMEX

Account Number _____ Exp. Date _____

Name Exactly as on Card _____

Signature _____ Date _____

Payments must be made to PDA in US dollars by check drawn on a US bank or by MasterCard, VISA or American Express.

4. Return completed form with payment (payment must be included to be considered registered) made to:

PDA
P.O. Box 79465
Baltimore, MD 21279-0465 USA
Fax: (301) 986-1093 (Credit Cards Only)

Federal Tax I.D. #52-1906152

Confirmation: Written confirmation will be sent to you once payment is received. You must have written confirmation to be considered enrolled in a PDA event. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time. If you are preregistering as a substitute attendee, indicate this on the registration form. A nonmember substituting for a member must pay the additional fee. **Refunds:** Registrants whose written requests for refunds are received at PDA **on or before January 8, 2003** will receive a full refund less a $55 processing fee. Registrants whose written requests for refunds are received **after January 8, 2003 and on or before January 22, 2003** will receive 50% of the registration fee. No refunds will be issued for cancellations received **after January 22, 2003**. Substitutions may be made at any time. **Event Cancellation:** PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA cannot be responsible for discount airfare penalties or other costs incurred due to a cancellation. Course enrollment is limited for the benefit of all attendees; this necessitates early registration.

Please tell us how you learned about this event

- ☐ I'm a PDA member
- ☐ Advertisement
- ☐ Direct Mail
- ☐ Fax
- ☐ Internet
- ☐ Colleague
- ☐ Other_____

Business Environment
(check one)

- ☐ Academic
- ☐ Consultant
- ☐ Engineering and Construction
- ☐ Government Regulatory Agency
- ☐ Industry Supplier
- ☐ Medical Device Manufacturing
- ☐ Pharmaceutical Manufacturing
- ☐ Pharmacy
- ☐ Recruiter
- ☐ Other_____

Professional Interest
(check all that apply)

- ☐ Aerosols
- ☐ Analytical Chemistry
- ☐ Biologicals
- ☐ Biotechnology
- ☐ Computers
- ☐ Engineering
- ☐ Formulation Development
- ☐ GMP Compliance/ Inspection Trends
- ☐ Liquids
- ☐ Maintenance
- ☐ Manufacturing/Production
- ☐ Microbiology
- ☐ Ointments
- ☐ Ophthalmics
- ☐ Packaging
- ☐ Parenterals
- ☐ Quality Assurance/ Quality Control
- ☐ Regulatory Affairs
- ☐ Research
- ☐ Solid Dosage Forms
- ☐ Sterilization/ Aseptic Processing
- ☐ Training
- ☐ Validation

PDA Use: Date:_____ Check #:_____ Amount:_____ Account:_____

PDA-TRI Location/Lodging Information

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

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

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

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

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

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

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

Holiday Inn Inner Harbor**
(*Special Rates for our courses Attendees*)
(410) 685-3500
(410) 727-6169 – fax

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

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

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

Holiday Inn—BWI***
(410) 859-8400
(410) 684-6778 – 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 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 ww.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site.

Transportation to PDA-TRI: 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.

PDA-TRI Thanks the Following...

Sponsors

Abbott Laboratories
Allegiance Healthcare Corporation
Alma, Inc.
Becton Dickinson Microbiology Systems
Berkshire Corporation
bioMerieux Vitek, Inc.
Bioscience International
Biotest Diagnostics Corporation
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Kaye Instruments, Inc.
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Neslo, Inc.
Perfex Corporation
Pharmacia
Sievers Instruments, Inc.
Technovation

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

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

Membership Number

Job Title Company

Business Address

City State/Province ZIP/Postal Code

Tel Fax E-mail

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

LTR 01/03

2. Indicate the course(s) you'd like to attend (please print). Individuals registering at the nonmember rate receive one full year of PDA membership. Nonmembers registering for multiple events need only pay the nonmember fee once. (If you do **NOT** want to become a PDA member, please check here ❑).

COURSE TITLE	COURSE #	DATE	LOCATION	PRICE (member or nonmember)
			TOTAL :	$

3. Please check the appropriate box:

❑ **Check** enclosed ***Charge:*** ❑ MC/EuroCard ❑ VISA ❑ AMEX

Account Number_____ Exp. Date _____

Name _____
(exactly as on card)

Signature_____ Date _____

Payments must be made to PDA in US dollars by check drawn on a US bank, or by American Express, MasterCard, or VISA.

4. Return completed form with payment made to:

PDA
P.O. Box 79465
Baltimore, MD 21279-0465 USA
USA Fax: (301) 986-1093 (credit cards only)

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

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.*
Substitutions*: If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site. 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 start of an event (course series, conference, etc.), a full refund, minus a $55.00 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 the 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.*

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

PDA Books

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 What you need to know about positioning regulated establishments for achieving electronic information assurance—the concepts and principles that need to be considered when building, maintaining, managing and transitioning electronic environments—can be found in Good Electronic Records Management (GERM), Part 1 of the PDA–ISPE series on Good Practice and Compliance for Electronic Records and Electronic Signatures. Focusing on requirements and concepts rather than technical implementation details, this resource document is a valuable tool for the architects of electronic records environments. Whether your mission is to define the requirements, policies and procedures or to construct the physical environment, you will find that Good Electronic Records Management (GERM) is a must for your bookshelf. Key elements of the document include: prerequisites; electronic records; organizational controls; operations and infrastructure; transactions; records retention; personnel qualification and training; hybrid systems and controls; legal; glossary; and further reading.

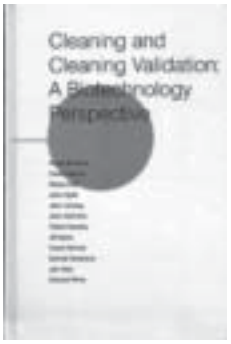
This document was produced through the collaboration of several industry groups (FDA regulated companies, system suppliers, legal experts, and consultants). It represents a compendium of current thinking on good electronic record management from an FDA regulated industry perspective. GERM attempts to present these practices at an abstraction level that is descriptive. The stated practices and concepts are meant to educate the reader when considering options for electronic records management. No endorsement of specific technologies is made, nor are there any specifics that direct a standard for the implementation of concepts. Current thinking on the topics presented means that this compendium is intended to evolve as experience with electronic recordkeeping grows. Application of concepts may require a paradigm shift in some organizations with regard to the treatment of electronic records. Such changes are a conscious business decision and not an intentional prerequisite for implementation of any of the concepts presented. 2002; 104 pages; $95 PDA members/$190 nonmembers **Item No. 19003**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures This document has been produced by a Special Interest Group of the GAMP Forum (pharmaceutical companies, suppliers, consultants and the Medicines Control Agency in the UK) in order to promote a better understanding of 21 CFR Part 11. It aims to provide industry and its suppliers with practical guidance on how to comply with the rule, while highlighting and addressing common issues of concern. The manuscript provides a management process for achieving and maintaining compliance with 21 CFR Part 11 in manufacturing environments. Specific guidance is provided for both new and existing systems in addition to the role of suppliers in supporting this approach. Appendices provide information, examples, templates, checklists, and a lifecycle for the management of electronic documents that are useful when implementing 21 CFR Part 11 compliance programs. A Glossary and References List are also included.

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages; $95 members/$190 nonmembers
Item 19001 (English)

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages, $95 PDA members/$190 nonmembers
Item 19002 (German)

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages, $95 PDA members/$190 nonmembers
(Spanish)—*The Spanish version must be ordered directly from:* Ediciones VR, Av. Belgrano 3786, Of. #2, (1210) Buenos Aires, Argentina, Attn: Ms. Florencia Viscaino; E-mail: subscripciones@edicionesvr.com; Fax: 54 11 4931 4861 ext. 36



Cleaning & Cleaning Validation: A Biotechnology Perspective Authors: Roger Brunkow, David DeLucia, George Green, Shane Haft, John Hyde, John Lindsay, Jill Myers, Robert Murphy, John McEntire, Karen Nichols, Ray Prasad, Brenda Terranova, Jon Voss, Caroline Weil, Edward White; This book is intended to serve as a source of practical technical information for those persons in the biotechnology industry. Case studies and/or actual industry examples are used to support the text wherever possible. While much of the material contained within this text is equally applicable to non-biopharmaceutical processes, the emphasis has been focused directly upon biopharmaceutical manufacturing. Section I provides an in-depth analysis of the design concepts that lead to cleanable equipment. Also covered are cleaning mechanisms and cleaning systems. The first section is particularly useful to those persons faced with the task of designing systems that will be cleaned and also provides the biochemical background of the mechanisms associated with the removal of common biotechnology soils. Section II focuses on cleaning validation concepts. While the material is equally useful for single product cleaning, emphasis is placed upon multi-product cleaning validation. Included are general validation principles as they apply to cleaning validation, detailed analysis of cleaning process validation, sampling techniques, analytical methods and acceptance criteria. The material in Section II will be useful to anyone responsible for the development of a cleaning validation program. Section III provides an overview of multi-product biotechnology manufacturing procedures. Included an analysis of the risk to benefit scenarios associated with the various forms of product manufacturing, analysis of changeover programs, equipment considerations and material transport as they are affected by multi-product manufacturing strategies. 1995; 190 pages; $125 members/$145 nonmembers **Item 13002**

Books from PDA-DHI Press

Change Control Soren Schwartz; This manual provides a well-organized, practical process for the management of changes to the Information and Control Systems used in GxP-related operations. 25 pp; $90members/$109 nonmembers **Item 17189**

Electronic Records and Electronic Signatures Compliance Assessment Chris Reid and Barbara Mullendore; *ERES* provides practical guidance on the interpretation of 21CFR Part 11 and the steps you need to take to address current and future compliance issues. 58 pp; $90 members/$109 nonmembers **Item 17177**

External Quality Audit, The Janet Gough and Monica Grimaldi; Will help you to effectively evaluate suppliers to determine reliability, quality and value. 100 pp; $120 members/$149 nonmembers **Item 17180**

Filtration Handbook—Integrity Testing Maik W. Jornitz and Theodore H. Meltzer; This complete guide explains the proper performance of filter integrity testing by clarifying its relationship to bioburden concerns and assessing its role in filter validation. It offers practical approaches to appropriate use of integrity testing, wetting and temperature requirements, the Bubble Point test, diffusive airflow testing and much more. Numerous regulatory citations and references complete this invaluable book. 160 pp; $185 members/$229 nonmembers **Item 17197**

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, 3rd edition James Vesper; A quick guide to GMP, designed to simplify and enhance understanding of most of the current GMP expectations and how they apply to ongoing tasks in any given pharmaceutical manufacturing situation. 224 pp; $100 members/$125 nonmembers **Item 17199**

Hosting a Compliance Inspection Janet Gough; This is the guidance you need to host a compliance inspection. 106 pp; $120 members/$149 nonmembers **Item 17192**

Internal Quality Audit, The Janet Gough and Monica Grimaldi; This book provides guidance for performing a systematic internal quality audit with guidelines and a common sense approach to an often difficult task. 100 pp; $120 members/$149 nonmembers **Item 17179**

Introduction to Environmental Monitoring in Pharmaceutical Areas Michael Jahnke; Topics discussed include all aspects of cleanrooms, air handling systems, HAACP and risk analysis along with numerous useful charts, tables and figures. 104 pages; $90 members/$109 nonmembers **Item 17182**

Laboratory Systems Validation Testing and Practice Paul Coombes; This book, based on more than 20 years of experience in the pharmaceutical industry, put the subject of systems validation in its rightful place in the quality assurance world from the author's perspective. First, the primary importance of valid analytical data is discussed together with a persuasive case study and novel definition. The term LSV (laboratory systems validation) is used to make a distinction from CSV (computer systems validation) and equipment qualification. The differences that exist in the world of laboratory systems are explored, followed by a mass of detailed advice and examples of the specific qualities of many types of laboratory system. This provides the reader (who could be from a computing, chemistry, engineering, or QA background) with proven approaches to the generation of requirements specifications, and thereby, the subsequent validation testing strategies and tactics for laboratory systems. 113 pp; $120 members/$149 nonmembers **Item 17196**

Media Fill Validation Environmental Monitoring During Aseptic Processing Michael Jahnke; The second in this series of four books. Provides current, practical techniques that focus on considerations in the preparation and monitoring of aseptic manufacturing, taking into account the national and international requirements, and guidelines concerning the validation of aseptic processing. Topics include: Risk analysis, HAACP, Documentation and qualification; Qualification and training of personnel; Scope of validation; Overall requirements; Release requirements; Documentation; Authorization. The guide also includes an excellent Manufacturing and Testing Master Batch Record, and 25 extremely valuable charts, graphs, and figures. 108 pp; $90 members/$109 nonmembers **Item 17181**

Microbiological Monitoring of Pharmaceutical Process Water Michael Jahnke; Following a discussion of the regulations to be followed in the microbiological control of water processing and distribution systems, this work focuses on practical aspects in the pharmaceutical environment and gives advice on the methodology to be used, e.g., for sampling, the selection of nutrient media, incubation conditions, and identification of contaminants. It also describes trend analysis strategies and quality assurance to help you ensure consistent validation of water processing and distribution systems. The practices here were developed in a pharmaceutical manufacturing facility that produces drugs for parenteral use. The design, installation, and operation of a system to produce Purified Water and Water for Injection is presented and the practical aspects of microbiological monitoring is discussed. 70 pp; $90 members/$109 nonmembers **Item 17193**

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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 thought leaders, have invested their considerable talents and prestige in developing this comprehensive collection of timely information on this critically important subject. This book encapsulates current

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Books from PDA-DHI Press *(continued)*

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 **Item 17185**

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Understanding Active Pharmaceutical Ingredients Seigfried Schmitt; Written by a Chartered Chemist and Member of the Royal Society of Chemistry, and edited by Trevor Deeks, this succinct document provides an overview of API use, including regulatory and validation details. 44 pp; $80 members/$109 nonmembers **Item 17188**

Understanding GMP: A Practical Guide Martyn Becker; This ex-MCA inspector, now at Merck, shares his expertise and perspectives on GMP regulations, legislation, applications, and practical challenges and solutions to applying GMP to the manufacturing environment. 237 pp; $120 member/$149 nonmember **Item 17174**

Selected PDA Technical Reports

TR 36 Current Practices in the Validation of Aseptic Processing—2001; The validation of aseptic processing continues to be a major area of interest within the pharmaceutical industry. Five years have passed since the last PDA survey on this subject. While there have been no new broadly applicable regulations or regulatory guidance since that time, there has been continued controversy over the details of aseptic processing and process simulation practice. Industry practices largely adhere to current regulations and guidelines on aseptic processing by the European Union, ISO, and FDA. The impact of PDA's TR 22: Process Simulation Testing for Aseptically Filled Products, is also apparent. Over time industry methods, practices and limits have been modified to adapt to the changing circumstances. The Pharmaceutical Manufacturers Association (now PhRMA) in 1979 and PDA in 1986, 1992 and 1996 conducted surveys on this subject that have provided a clearer understanding of contemporary industry practice. This survey addresses the continuing need to track industry practice in the validation of aseptic processing as it evolves. Questionnaires were sent to 88 firms that specifically agreed to participate with PDA in this effort. Forty-three responses were received representing both US and overseas locations. The results were tabulated to provide both raw numerical and percentage of total respondents. Where the respondents provided comments, whether solicited or voluntarily, these are provided after the question. Where more than one respondent provided essentially the same response selection and comment, they have been consolidated and a number appears next to the response indicating the number of comments of that type. The nature and extent of the comments received were extensive, and for this reason the authors have chosen to combine similar responses. One of the major benefits of surveying on a regular basis is the opportunity to follow the evolution of concepts and practices over time. To that end, this survey instrument used many questions that were nearly identical to those asked in 1992 and 1996. 2001; 34 pages; $75 members/$125 nonmembers. **Item No. 01036**

TR 35 A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry; Many firms today have separate departments with different training requirements. Employees associated with the Microbiological Function do not always receive consistent training. This can lead to varying microbiological control practices within a manufacturing facility. This Technical Report was produced by the PDA Subcommittee on Microbiology Training, formed in January 2001, to develop an industry vision and guidance for instituting a step-wise, competency-based training program for microbiologi-

Selected PDA Technical Reports *(continued)*

cal training of individuals engaged in work activities connected to contamination control and microbiological testing of pharmaceutical articles. 2001; 24 pages; $75 members/$125 nonmembers. **Item No. 01035**

TR 34 Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products; This technical report addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. It covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials. 2001; 25 pages; $75 member/$125 nonmember. **Item No. 01034**

TR 13 Revised Fundamentals of an 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 (Revised), *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 clean room 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 pages; $75 member/$125 nonmember. **Item No. 01013**

TR 33 Evaluation, Validation and Implementation of New Microbiological Testing Methods; This report is intended to provide a general approach to the introduction of new microbiology methods in a government-regulated environment. It is also intended to provide guidance for the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed. 2000; 37 pp; $75 members/$125 nonmembers. **Item No. 01033**

TR 32 Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; 277 pp; $90 members/$140 nonmembers (paper copy; **Item No. 01032**); **CD**—$50 members/$75 nonmembers (CD-ROM format; **Item No. 01132**).

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Managing for Quality in a Cost-Focused Environment
Conference: April 10–11
Tabletop Exhibits: April 10
Grand Hotel Timeo & Villa Flora
Taormina, Sicily ITALY

April 17, 2003
PDA Southeast Chapter Spring Meeting
Sheraton Imperial, Research Triangle Park, NC

April 28–29, 2003
PDA-TRI Laboratory Course:
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

May

May 5–9, 2003
2003 PDA International Congress, Courses and Tabletop Exhibits
Congress: May 7–9
Courses: May 5–7
Tabletop Exhibits: May 7–8
The Ritz Carlton Millenia, Singapore, SINGAPORE

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PDA-TRI Baltimore, MD

May 14–16, 2003
PDA-TRI Baltimore Course Series
Wyndham Inner Harbor, Baltimore, MD

May 15–16, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

May 19–21, 2003
PDA-TRI Laboratory Course:
Cleaning Validation
PDA-TRI Baltimore, MD

May 22, 2003
UK & Ireland Chapter Meeting
Directive 2001//20/EC and Annex 13
Britannia International, Canary Wharf, London, UK

June

June 6, 2003
PDA Southeast Chapter Golf Outing
Location TBA

June 23–25, 2003
PDA-TRI Toronto Course Series
Westin Harbour Castle, Toronto, CANADA

August

August 19–21, 2003
PDA-TRI San Francisco Course Series
The Fairmont, San Francisco, CA

August 25–29, 2003
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

September

September 3, 2003
UK & Ireland Chapter Meeting
Training Strategies
Royal Pharmaceutical Society, UK

September 8–12, 2003
2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits
Conference: September 8–10
Courses: September 11–12
Tabletop Exhibits: September 8–9
Omni Shoreham Hotel, Washington, DC

September 22–26, 2003
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

September 24–25, 2003
UK & Ireland Chapter Meeting
What to Do When Things Go Wrong
Britannia International, Canary Wharf, London, UK

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November 10–14, 2003
2003 PDA Annual Meeting, Courses and Exhibition
Annual Meeting: November 10–12
Courses: November 13–14
Exhibition: November 10–11
Hilton Atlanta, Atlanta, GA

November 17–21, 2003
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

November 20, 2003
UK & Ireland Chapter Meeting
Impact of FDA's Revised Guidelines on Aseptic Manufacture
Keele University Management Centre, UK

December

December 4–5, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

Information on these conferences and courses will be posted on the PDA Web site as they become available.

Visit often to get the latest information!

www.pda.org

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An International Association For Pharmaceutical Science And Technology

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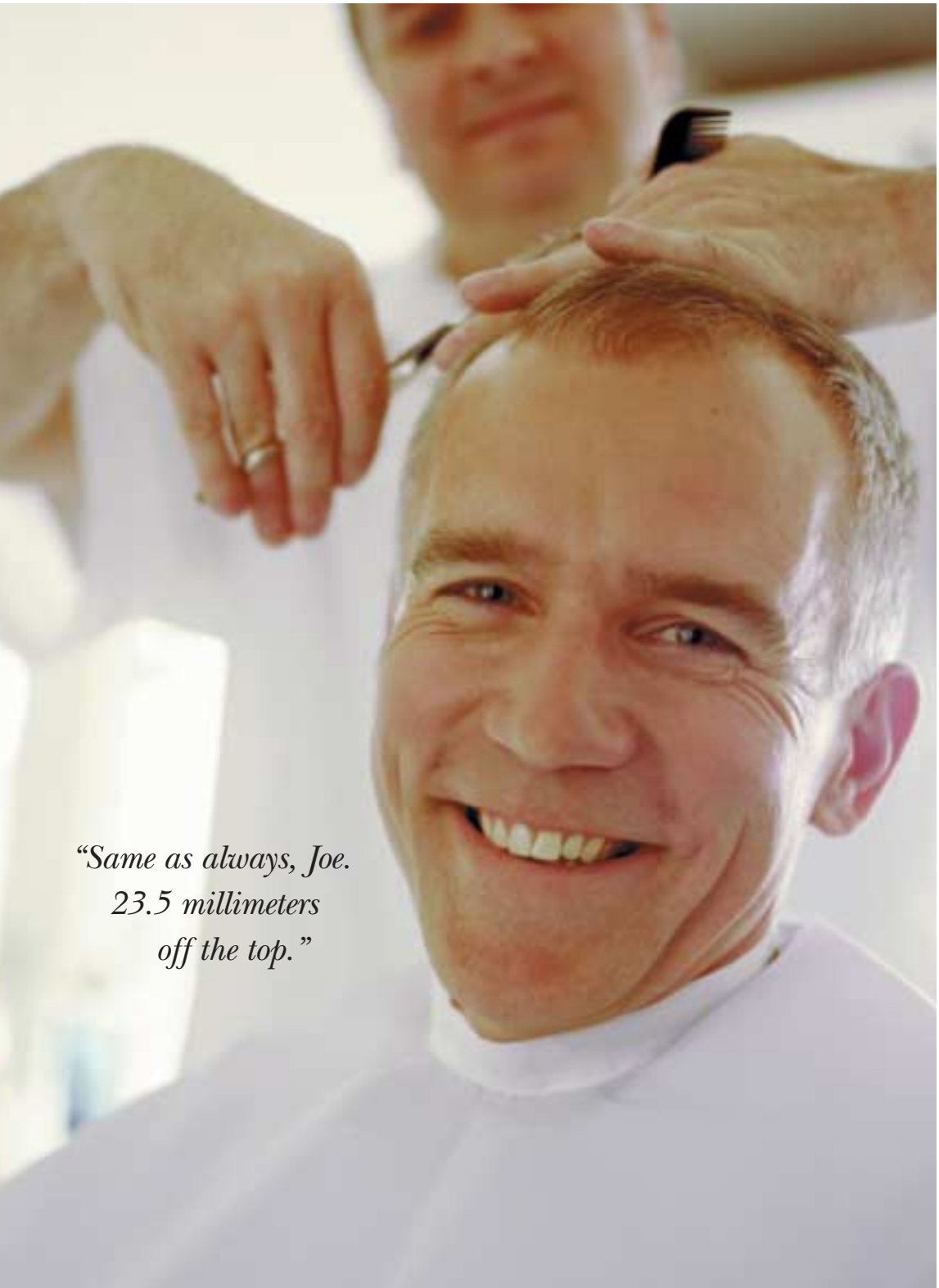

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Calendar of Events

2003

January

January 27–31, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

February

February 5–7, 2003
PDA-TRI Puerto Rico Course Series
Inter-Continental San Juan
San Juan, PUERTO RICO
Lecture Courses:
February 5
A Comprehensive Guide to OOS Regulations
Auditing Techniques for CGMP Compliance
Current Good Manufacturing, Quality and Compliance
February 5–7
Active Pharmaceutical Ingredients: Manufacture & Validation
Introduction to Competency Based Training
February 6
Change Control and Documentation
Risk Assessment Training
February 6–7
Validation by Design
February 7
Annual Product Reviews: How to Comply with FDA & ICH Requirements

February 6, 2003
UK & Ireland Chapter Meeting
BSE/TSE
Crowne Plaza, Heathrow, UK

February 12–14, 2003
PDA-TRI Laboratory Course:
Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance
PDA-TRI Baltimore, MD

February 19–21, 2003
PDA-TRI Laboratory Course:
Cleaning Validation
PDA-TRI Baltimore, MD

February 24–28, 2003
2003 PDA International Congress, Courses and Exhibition
Back to the Future—Ahead to the Past: Mastering the Fundamentals of GMPs to Manage the Challenges of Escalating Demands
Congress: February 24–26
Courses: February 26–28
Exhibition: February 24–25
Hilton Prague, Prague, CZECH REPUBLIC
PDA-TRI Lecture Courses:
February 26–28
Requirements and Preparation of Pharmaceutical Grade Waters
February 27
GMP for Investigational Medicinal Products—Draft GMP Annex 13 and the European Clinical Trials Directive
Beyond the GMP/ISO Basics—Practical Strategies for Everyday Compliance
February 28
Aseptic Processing Validation—Trends and Issues

February 27–28, 2003
Special Meeting in Conjunction with the 2003 PDA International Congress, Courses and Exhibition
Scientific Considerations for Comparability of Biopharmaceuticals
Hilton Prague, Prague, CZECH REPUBLIC

March

March 1–2, 2003
DUPHAT 2003
PDA International Pharmaceutical Manufacturing Issues Conference
Airport Expo Dubai, Dubai, UNITED ARAB EMIRATES

March 3–7, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

March 6, 2003
UK & Ireland Chapter Meeting
Validation & Operation of Aseptic Processes
Manchester Airport Hilton, UK

March 13–14, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

March 17–21, 2003
2003 PDA Spring Conference, Courses and Tabletop Exhibits
Bridging the Gap between Science and Compliance: The Impact of Today's Regulatory Environment on Biopharmaceutical Development and Approval
Conference: March 17–19
Courses: March 20–21
Tabletop Exhibits: March 17–18
Paradise Point Resort, San Diego, CA
PDA-TRI Lecture Courses:
March 20
Achieving CGMP Compliance during Development of a Biotechnology Product
Good Documentation Practices in the Pharmaceutical Industry
March 20–21
A Practical Approach to Aseptic Processing and Contamination Control
Assessing Packaging and Processing Extractables/Leachables
Preparing for a FDA Pre-Approval Inspection
Validation: An Introduction
March 21
Conducting Compliant Deviation Investigations for Pharmaceutical Industry

April

April 7–11, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

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

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