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PDA Letter

March 2004

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

Eli Lilly Enhances Anticounterfitting Measures—page 40

Vicki Dedrick Joins PDA

Victoria Ann Dedrick has joined PDA as Vice President, Quality and Regulatory Affairs, effective February 2, 2004.

Ms. Dedrick is fundamentally strong in the areas of international regulatory affairs, harmonization and quality assurance, following a 25-year career as an executive in the pharmaceutical, biopharmaceutical and medical device industries. Her experiences include: serving as the head of two European healthcare associations; creating international harmonization task forces; acting as a healthcare consultant; and guiding numerous product applications through regulatory processes. She received a B.S. in Chemistry from Mary Baldwin College and did M.S. studies in Physical and Analytical Chemistry at the University of Virginia. She has divided her career on two continents, living in both North America and Europe for significant periods. She is conversational in Dutch and French and holds dual U.S. and Belgian citizenship.

Join us in welcoming Ms. Dedrick to PDA

Particularly relevant to PDA members at a time of rapid globalization is Ms. Dedrick's extensive involvement with the global harmonization of regulatory standards. She participated in the Global Harmonization Task Force (GHTF), which has been harmonizing regulatory standards for medical devices since 1991. Ms. Dedrick contributed to the U.S. – EU Mutual Recognition Agreement negotiations for medical devices and GMPs. Moreover, she worked with the EU, FDA, Health Canada and Australia's Therapeutic Goods Administration to pioneer the International Human Tissues Task Force that formed in 1996 to harmonize regulations in this sector. As part of her involvement developing the task force, she closely collaborated with EuropaBio and a number of major manufacturers—including Novartis, Genzyme,

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Validation Alternatives: A Case Study

"To best ensure the lowest risk to the safety of your clinical subjects, the continued confidence of your sponsors and the uneventful approval of regulatory agencies, only the highest-quality clinical data will do—along with documented evidence that your computer system can deliver it consistently."—David Weitz, CIO, Covalent Group.

Introduction

Some recent *PDA Letter* articles have approached the subject of computer systems validation (CSV) from the angle of looking outside of the pharmaceutical industry for standards and practices that may help to reduce costs and improve systems quality. This article is a case study of just such a project at the Covalent Group, a mid-sized contract research organization (CRO). During this project, we applied the concepts and standards of the IEEE 1999 Software Compendium (now adopted as ISO/IEEE Std 12207), The Hollis Group's C3Q™ Methodology and the document management nomenclature set from the PDA Training and Research Institute's course "Implementing an Electronic Document Management System." I described many of the concepts outlined in this article at the 2003 PDA/FDA Joint Regulatory Conference and I encourage PDA Members to review that presentation[1] also.

Project Background

In late 1999, Covalent was embarking on a project to substantially upgrade its existing Information Systems (IS) capabilities in support of clinical operations. Covalent had an existing Oracle Clinical 3.1 (OC 3) clinical data application environment running on a heterogeneous Windows/ Unix/ TCP/IP infrastructure. We had decided to upgrade to the Oracle Pharmaceutical Application 4.0 (OPA 4) suite in order to add MedDRA dictionary support and remote data capture (RDC) capability to our services portfolio. This capability expansion project

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- **June 1**—EMEA xenogeneic cell therapy medicinal products "points to consider" document" becomes effective, page 18.
- **June 8**—FDA E-Labeling Rule becomes effective, page 20.
- **July 1**—EMEA Note for Guidance on Minimising Risk of TSE becomes applicable, page 18.
- **July 5**—Deadline for public comment on FDA CDER Draft Guidance on CMC submissions for drug substances.

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Walter Morris, *Senior Editor*
Janet Raysick, *Production Manager*
Matthew Clark, *Director of Marketing Services & Membership and Chapters*
Joseph Bury, *Web Editor*

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

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

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

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Neal G. Koller
PDA President

President's Message

PDA's "New Innovative Technologies Exhibition™" Program

Starting with the 2004 PDA International Congress in Basel and the SciTech Summit™ in Orlando, PDA conferences and exhibits are being designed to spotlight and bring to the membership the newest, most innovative and relevant technologies for the pharmaceutical and biopharmaceutical communities. Mindful of the rapidly changing scientific and technological environment in which our members work, PDA is strengthening its commitment to keeping members abreast of the latest advances relevant to their careers.

PDA is strengthening its commitment to keeping members abreast of the latest advances relevant to their careers.

Under the "New Innovative Technologies Exhibition™" program, PDA is clearing and confirming science and technology that is new, relevant and important to our members and assuring that new technologies are introduced to PDA. This program adds value to the conference and training experience by ensuring that our members are exposed to the latest scientific breakthroughs and technological advances, not only from the podium and in the training lab, but also in the exhibition hall. Under this program, participants in PDA events can be assured that they will "go home" knowing about the latest technological tools that will help them perform their jobs.

Innovators of new technologies just recently on the market or nearing commercialization are encouraged to use PDA events as a launching pad for their products. By participating in the NITE™ program, exhibitors can be assured that they will gain exposure to the PDA membership—the senior decision makers for technology—and qualify for special benefits.

PDA conferences and training are the hallmark of the PDA experience and represent a significant fulfillment of the Association's mission of "promoting scientifically sound and practical technical information and education."

I encourage all members to watch this column, check www.pda.org and to look for future announcements regarding this exciting new science and technology program. Also, make sure you visit the exhibits at the next PDA conference you attend to learn about the latest technological advances that impact your career. Technological innovators should contact Nahid Kiani, PDA's Senior Sales Manager, at +1 (301) 656-5900, ext. 128 or Kiani@pda.org to learn how to participate in the program.

By facilitating cooperation and collaboration among scientists, industry experts, regulators, technological innovators and academics, PDA will remain an indispensable force during this era of rapid scientific discovery and technological change. ■

New Faces at PDA!

PDA welcomes four new staff members. At PDA Global Headquarters in Bethesda, Maryland, **Nancy Berlin**, **Sabrina Powell** and **Lee'Tonja Scott** have joined the team to help PDA serve its members better.

Nancy joins the Programs and Meetings Department as Manager of Audio and Web conferences, where her primary responsibility is to develop audioconferences for members. She previously ran the audioconference division at FDANews.

Sabrina and Lee'Tonja join the Customer Service Department. Sabrina is responsible for processing registration for speakers, attendees and exhibitors at PDA events, and invoices, as well as to responding to customer inquiries. She has previous experience as a registrar in a not-for-profit association setting and also has call center experience. Lee'Tonja performs various duties in the department, including assisting with membership inquires and registration, as well as working with PDA's publication manager. She previously worked as an intern with PDA.

James Wamsley has joined the PDA Training and Research Institute as Assistant Laboratory Training Coordinator. In this role he will be responsible for supporting all aspects of the lab training programs, including faculty assistance, laboratory setups, ordering and preparing supplies and maintaining the facility's ongoing and preventive maintenance programs. ■

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M

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Biological Defense: Fighting the "Dark Side" of Biotechnology

The specter of biological attack or bioterrorism has been haunting us since the publication of such novels as *Cobra Event*. Since 9/11 and the *Bacillus anthracis* (anthrax) attacks less than a month later, the public perception of the possibility of such incidents has taken on an air of inevitability. We, as PDA members, are enmeshed in this fight supporting medical biological defense and bio-detection efforts worldide.

Before I became your Vice President for Science and Technology in January, I had been involved in biological defense at several levels. I would like to discuss some of the programs the U.S. is supporting and some of the details that you might find to be interesting.

We, as PDA members, are enmeshed in this fight supporting medical biological defense and bio-detection efforts worldwide.

The ***Bio Shield*** initiative of the U.S. Department of Homeland Security (DHS) has the most relevance for those of us in the pharmaceutical industry. Project BioShield is a Federal effort to "develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens." More information on the program is available at: www.whitehouse.gov/new/releases/2003/02/20030203.html.

We have already seen this in the anthrax vaccination program for the military, the making available smallpox vaccine for medical first responders and the strengthening of the National Pharmaceutical Stockpile. The U.S. government plans to spend over $6 bil. (U.S.) over the next ten years for research, development, acquisition and maintenance of these capacities. The FDA has been given the ability to make new treatments available in certain emergency situations. These initiatives include such programs as expedited licensing and the use of animal data when classical Phase 3 clinical trials would be impossible, due to small numbers or concerns about withholding treatment for a "placebo" group. More information on this is available at: www.fda.gov/oc/opacom/hottopics/bioterrorism.html.

Not all of biological or bioterrorism defense involves treatment, however. In the military, we included the detection of biological agents in the category of "Contamination Avoidance". The military has been trying to field biological detection systems for years, with limited success. The problem there was always extended acquisition cycles and the need to make them "fieldable", i.e. fit in the back of a truck, driving on unpaved roads. Many new and exciting technologies are developed for the military through DARPA (Defense Advanced Research Project Agency, www.darpa.mil)—yes, the same people who brought you the Internet, among other things. Some of the research they support includes: threat agent cloud tactical intercept and countermeasure, the immune building program and the spectral sensing of bio-aerosols program.

The Department of Homeland Security, not to be outdone, has implemented its own complementary R&D agency, HSARPA, or Homeland Security Advanced Research Projects Agency. I would like to discuss a project with which I was involved to give you an idea of the incredible requirements for these "environmental monitoring" systems.

The DHS, in conjunction with the Environmental Protection Agency (EPA) and the Centers for Disease Control (CDC) has been operating urban bioaerosol monitors in many cities as part of the *BioWatch* program. This is a first generation system, where filters are manually retrieved and analyzed at a central laboratory (see *Analytical Chemistry*, 75: 5293–5299, 2003 for an example of a slightly improved system). DHS recognized that this system must be improved, and in 2003, they issued a call for proposals for a bioagent autonomous networked detector (BAND).

To give you an idea of the complexity of what they were expecting, I would like to review the operating characteristics. The plan calls for "fully autonomous, multiplexed, detection systems capable of continuous (24 hr) operation including sample collection, preparation, and analysis, waste handling and cleaning between analyses if needed. Integration sampling window of three hours or less, with results of the analyses provided within one hour of the sampling period." The device was also supposed to simultaneously analyze for a minimum of 20 agents, have its own communications system and be the size of a two-drawer filing cabinet!

Not exactly monitoring a clean room, is it?

They say that wars serve as a catalyst for advancing technology (RADAR and mass production of penicillin, for example). We can only hope that ambitious projects, as discussed above, can provide technical advances in our profession as well. ■

—George Robertson

PDA

An International Association For Pharmaceutical Science And Technology

PDA Journal of Pharmaceutical Science and Technology

Call for Papers

From Lee Kirsch, Ph.D., Editor

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

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

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

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

Lee E. Kirsch, Ph.D., Editor
PDA Journal of Pharmaceutical Science and Technology
c/o The University of Iowa
Pharmacy Building S221
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Recent Sci-Tech Discussions

"Depyrogenation of Glassware" & "Moisture in Excipients" & "Headspace Vacuum for Lyophilized Product"

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

This month's posting...

Question 1

In a pharmaceutical manufacturing facility which is terminally sterilising product in 50–500ml Glass vials/bottles for sale in Europe and US; does anyone rely on washing of incoming glass vials/bottles for a 3 log reduction of endotoxin in lieu of a depyrogenation tunnel?

In the current manufacturing set up there is a vial washer in operation but no tunnel. With space limitations it is not easy to install a tunnel and data from the vial washer will have to be relied upon for depyrogenation.

Whilst the washing process can be validated to demonstrate a 3 log reduction, I am interested in people s experiences of presenting this data to the European and US regulatory bodies.

Response 1

There is an ITG (Inspector's Technical Guide - FDA) produced by the FDA. ITG 40 (Bacterial Endotoxins/Pyrogens) discusses reduction of endotoxin by means of washing or dilution. This is an older document but may be a starting point for you. Try this... http://www.fda.gov/ora/inspect_ref/itg/itg40.html

Response 2

Although I am not a person working on LVPs, I feel tunnel destroys the endotoxins while washing only removes endotoxins.

The difference is same as that between sterilisation and disinfection for example if equipment can be sterilised we do not compromise its sterility by mere disinfection (instead of sterilisation). Similarly washing can not replace Dry heat depyrogenation.

Response 3

If glass is exposed to higher levels of endotoxin sometimes it is adsorbed to the glass and very difficult to remove. One can run an experiment where glass is contaminated with endotoxin and allowed to dry. If you then do a water wash you find some level of endotoxin. If you then take the same glass and sonicate it you will recover a higher level of endotoxin. Washing is not a common method of removing endotoxin from glass.

Response 4

The only effective method for the removal of endotoxin is dry heat sterilization. In the unit preparation area where all the glass wares are washed, most probably do not induce endotoxin to the glass wares, still for injectables either but exposure of 250 degree centigrade for two hours or 300 degrees for 3 minutes will certainly produce sterile effects on glass wares.

Question 2

I am wondering what is common practice in the industry:
Suppose you are using starch—with a moisture content between 10% and 15% m/m—as an excipient in a wet granulation process. The residual moisture after fluid bed drying is around 1.5%.

Do you compensate for the loss of mass caused by the loss of moistures in the starch?

Response 1

You have no choice but to compensate with additional excipient may be other than starch, otherwise you will have higher assay results and poor yields. All these calculation to be mentioned in the master documents.

Response 2

Some of pharmaceutical companies will compensate the loss because of 2 reasons, i.e. to maintain the % active ingredient or % colorant content in granules, and to maintain production yield. They believe this is the best practice.

However, in day to day activities, it will be complicated and difficult to be applied. For each batch, production department or PPIC should re-calculate the weight of starch based on its %moisture and approved by QA. This will also impact the documentation side, e.g. the production computer system should be able to

receive "non-fixed" formulation to be proceeding (while usually the system will work only if the weighted formulation matches to master formulation in computer system).

The problem becomes more complicated when in one batch of product we should mix 2 different batches of starch. In some cases, miscalculation did happen. Some industries also argue this kind of practice due to "non-fixed" formulation (please note in some countries they should state the complete composition on product packaging at which the weight of starch will be always stated fix). Also, please remember PPIC will be difficult to plan and control the stock of starch since the weight of starch will be used from batch to batch is different.

Both practices have its own benefit and risk, so the decision is yours.

Response 3

We are adding additional starch to compensate the losses. But are you getting moisture 1.5%? Because we do not get it below 4%.

Response 4

Although basic the question is quite interesting. Interesting because basics have created all question marks? Let's analyze this question through basic dialogues: 1) Would you like to get around 15% w/w losses in final batch output? 2) Don't you compensate for LOD for actives? 3) Why treat actives and non-actives differently? $) Why not apply the rule of thumb of compensating for LOD whether it's actives or other wise. The answer to your question lies in above answers.

Question 3

I am trying to understand the logic behind the need for a head space vacuum in vials containing lyophilized products. I accept that a slight sub atmospheric pressure is needed to ensure the stoppers do not pop up after being pushed in to the vials.

During the period between fully inserting the stopper, done inside the lyophilizer, and capping the stopper onto the vial, the stopper is not fixed in place. There is a definite risk that the vacuum will be lost. For example any small surface imperfection of the vial or stopper, a powder deposit on the vial/stopper surface formed during lyophilization, a knock or a twist during handling or capping can all potentially cause complete or partial vacuum loss. Does every firm manufacturing products with head space vacuum then check every vial produced to ensure a vacuum is present? How do firms provide assurance that the vacuum present is within predetermined and validated limits? If the specified limit is not almost a complete vacuum then how is the need for a partial vacuum justified as there will then be some air in the vial which the vacuum was originally created to remove? Does the presence of the vacuum in fact result in a higher risk than normal for the sterility of the vial before capping; air can rush into the vial at any time up to the point at which the vial is capped. Would an inert gas overlay eliminate most of the above problems? I would be please to hear comments on this issue.

Response 1

The main reason for head space vacuum in vials containing lyophilized is to facilitate transfer of diluents into the vial containing lyophilized product. If the vial is at atmospheric pressure or slightly positive, the amount of effort required injecting the diluents may be significant.

Response 2

As well as ease of reconstitution, vials of lyophilized product are sealed with a vacuum so as to minimize the amount of moisture that goes back into contact with the product.
That moisture is after all the main reason products are lyophilized to begin with.

Response 3

When vials are sealed under high vacuum, spark testing them right after crimping can give you 100% leak proof test proving 100% its tight sealing (hence proving no possibility of bacterial leak) in non destructive way. This possibility is not applicable with vials containing solutions or nitrogen in its head space. I think that this big advantage tends to be ignored.

Response 4

Parenteral products are stored under vacuum for a variety of reasons:

- Allows the reconstituting diluents to be easily drawn into the vial by vacuum.
- Promoting product stability (low in moisture and oxygen).
- Aid to stopper sealing.
- Assuring vial sterility through preventing air entering it.

How it works:

Spark testing uses a high frequency, but low voltage electrical discharge to ionize residual gas within the vial. The discharge pattern of the vial is recorded and analyzed by the system to provide a reading of the absolute pressure within the vial. The low voltage test used is safe for both operators and the product and minimizes ozone emissions. ■

Validation Alternatives, from Cover

came at the same time as a company-wide cost control initiative.

As we began the planning for the OPA 4 project, it rapidly became clear that the computer systems validation component would be a major cost driver. Our recent experience with the OC 3 validation and a survey of similar projects in our industry revealed that CROs usually spend between 40% and 50% of the total project expenditures for computer and software validation. With such a large percentage of the project cost driven by one line item—validation—we decided that we needed to take a sharp pencil to that item.

We spent long hours discussing the computer systems validation (CSV) requirements for a clinical data system with our current and prospective clients. We also attended several conferences and symposia. These discussions revealed two inescapable axioms: The first was that regulatory agencies and sponsors now require rigorous, meticulous CSV as a minimum standard for credibility as a clinical service provider; the second was that there is an emerging set of requirements for computer and network infrastructure (CNI) qualification to demonstrate that the CNIs underlying clinical systems have the capability to protect data integrity and patient confidentiality.

We were very surprised to learn that civilian aerospace flight control software development typically budgeted 20% to 25% of project expense for VV&Q, as opposed to our industry's typical CSV overhead of 40%–50%.

The net result of this planning was that our project goals included the typical IS ones of user satisfaction, functional completeness, etc., but also included:

- Delivering the project at a substantial cost savings over the OC 3 project;
- Performing and documenting "best in class" computer systems validation; and
- Qualifying OPA 4's supporting CNI as part of the project.

Validation and Qualification Research

These were some seriously challenging goals. When IS reviewed them in an open and frank discussion with Data Management and QA, all three departments decided that Covalent needed to "think outside the box" to succeed.

As a team, we began to consider alternative approaches to validation that could reduce cost while maintaining or improving quality. Our data management vice president had suggested that we attend a conference on 21 Part 11. There we heard a fascinating presentation on an approach to CSV including the integration of CNI qualification with computer systems verification, validation and qualification, or VV&Q. The methodology presented, C3Q, included application software validation that was based on IEEE standards and newly developed methodology for CNI Qualification (CNIQ). The IEEE-based VV&Q philosophy was a straight-forward requirements-design-test model and CNIQ was based on in-service qualification and history records for the infrastructure and all of its elements.

Our team was also intrigued by the financial analysis that compared aerospace VV&Q cost overheads to CSV cost overheads in the pharmaceutical industry. We were very surprised to learn that civilian aerospace flight control software development typically budgeted 20% to 25% of project expense for VV&Q, as opposed to our industry's typical CSV overhead of 40%–50%. We identified validation as a key area for cost reduction.

After extensive follow-on work to verify the substance of the C3Q methodology, Covalent decided to implement it for the OPA 4 project.

Project Results

Our team has done two presentations of the detailed project results, and it would be redundant to list the details here. For all of the particulars of the verification, validation and qualification of the OPA 4 application software and CNI, I will direct you to The Hollis Group's Web site download area at www.hollisgroup.com/download.htm and the following presentations:

- DIA_Meserve
- DIA_Weitz
- DIA_Browne
- DIA_Quinn
- IQPC_Weitz
- IQPC_Meserve
- IQPC_Browne
- IQPC_Fiorito

In summary, these presentations describe how we completed the project approximately 40% more quickly than expected and with about a 45% reduction in cost over the OC 3 project.

Skills Transfer

Early in the project planning process, we decided that, to permanently reduce costs, Covalent needed to bring VV&Q skills in-house. For the OC 3 project, we had purchased commercial test scripts and retained the authoring firm to validate the systems. When they left, their skills left with them and we were still an unwilling "locked-in" consumer of the "validation industry." We were determined to break this pattern.

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PDA Interest Group Leaders

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

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

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

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

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

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

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

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

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

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

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

Packaging Science
Edward J. Smith, Ph.D.
Wyeth Pharmaceuticals
500 Arcola Rd., B2202
Collegeville, PA 19426
Tel: +1 (484) 865-9254
Fax: +1 (484) 865-9680
E-mail: smithej@wyeth.com

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

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

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

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

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

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

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

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

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

Validation Alternatives, from page 12

When we acquired the C3Q methodology as the SPRIITS document set, we were quite surprised to learn that we were acquiring a perpetual license, and that the standards were supplied as editable documents, templates, spreadsheets, etc. We were also surprised to learn that The Hollis Group (Hollis), the methodology developer, was actively engaged in transferring C3Q skills to any- and everyone, including third-party consultants as well as pharmaceutical companies. This seemed to be a solution that would work for us.

We acquired C3Q, designed an internally staffed validation process based on it, selected a "project lead," built a team, and retained two of the methodology developers as mentors. One was a skilled data center manager, and the other was a QA/RA documentation expert. We deliberately limited the mentor's participation role to one or two days per week, stressing that we wanted them to "teach us to do for ourselves" and not "do it for us."

I am very pleased to report that the method worked. We now have skilled VV&Q people within our organization, and we use our OPA 4 project as a template to rapidly start and stub out project documentation systems for new projects. This saves us considerable labor, schedule time and cost. Thanks to PDA's rollout of C3Q training (beginning with the Orlando course series at the SciTech Summit in March), we can depend upon a pool of already-trained, proven VV&Q talent when large "short schedule" projects require us to augment our staff. We are very happy with this way of doing validation.

Risk-Based Approach

The spotlight on patient safety and product quality has a recently been fitted with a new lens by the FDA. When shining upon CROs like Covalent this spotlight seeks to illuminate risk-based approaches to the regulated activities associated with clinical data acquisition, clinical data management, project and document management, safety systems, and overall operations. Sponsor organizations, typically sterner stage directors than the regulatory agencies, have begun to use even bright lights to verify that the confidentiality, integrity and availability of clinical data and systems are proportionate to the risks these systems could pose to patient safety and product quality.

Fortunately, the consideration of risk has been an integral part of the C3Q design from its beginning. Hollis has presented a risk-based model as long ago as 1999[2] and C3Q systemically incorporates risk assessment as impact analysis for document and arrangement creation and change management, and as criticality assessment for system design and disaster recovery/business continuity planning. Because of this, Covalent's systems have always been "risk aware" and we have had no need for redundant, costly, and time-consuming discrete "risk assessments" as remediative measures.

We have, in fact, received several unsolicited commendations of the quality of the team's work, including some from independent, third-party auditors.

Summary

In summary, I would first like to commend the OPA 4 team from IS, Data Management, and QA here at Covalent. They dug in, did the work themselves, and we're a better team and a better company for it. By way of results, I am quite proud to report that for more than two years now—and throughout numerous visits, inspections and audits—we have received no substantive observations of our VV&Q package for OPA 4. We have, in fact, received several unsolicited commendations of the quality of the team's work, including some from independent, third-party auditors.

For the Covalent Group, "thinking outside the box" helped us permanently reduce our computer system verification, validation, and qualification costs, while making us more independent and self-sufficient. The IEEE model for VV&Q is simple to learn and even easier to explain to sponsors, auditors and inspectors. C3Q gives us continuous feedback on the qualified status of our infrastructure and its commonality of service has improved IS operating efficiency, quality and morale. The PDA document system nomenclature has allowed me to install a rigorous and workable document control system inside the IS Department. This keeps QA, RA and the regulators happy, and it really contributes to my good nights' sleep.

I fervently hope that PDA continues to disseminate information about novel solutions like this through their relationships, Interest Groups, Task Forces and training programs. ■

—David Weitz, CIO, Covalent Group

[1] D. Weitz, "Design for Excellence Not Compliance" — 2003 PDA/FDA Joint Regulatory Conference, www.pda.org/membersonly/Presentations/2003-PDA-FDA/30-Weitz.pdf

[2] T. Quinn, "Interpreting and Enforcing 21CFR11 to Reduce Data Integrity" — 1999 CHPA/FDA Annual Seminar, www.hollisgroup.com/downloads/Print-Sign.PDF

Excited To Be Here – Vicki Dedrick

Dear PDA Members,

It is with great pleasure that I join the staff of PDA in Bethesda as the Vice President of Quality and Regulatory Affairs. When I interviewed for this position, what struck me most was the abounding number of opportunities that exist that make PDA a really dynamic association and the ability to work with a strong network of individuals that excel in their profession. We are all working in very exciting times with many challenges and opportunities on the regulatory horizon. One of the greatest of these is the global technical harmonization of regulation. This is a shared goal where PDA, with its global presence, has the opportunity to make a real difference through its proactive and responsive contribution to guidances and regulations as they are promulgated globally.

I had the opportunity between 1990 and 2000 to work closely on the Global Harmonisation Task Force (GHTF) for medical devices and on the EU–U.S., EU–Canada and EU–Australia mutual recognition agreements (MRAs). This was a great opportunity to learn how a common goal motivates people to roll up their sleeves and work shoulder to shoulder to achieve a desired outcome. The development of Common Technical Document for regulatory submission and the harmonization of technical standards have greatly improved the environment for product development and introduction of medical devices. These same opportunities exist for medicinal products, and we need to work actively to ensure that this becomes a reality.

PDA's members possess incredible expertise and a knowledge base that is well respected by health authorities, globally. I am excited to work together, leveraging this strength and using it more effectively to achieve our objectives of harmonized regulations, guidances and technical understanding. While there are a number of areas that I will personally focus on, initially, I plan to concentrate on five specific areas: **1) Involve more PDA members actively in RAQC Task Forces**. Your contribution of knowledge and expertise to PDA's Task Forces allows us to undertake and address more issues and activities, comment in a timely fashion and become proactive in addressing emerging areas of manufacturing and regulation where guidance is needed; **2) Engage and support the chapters** to further strengthen PDA's global presence and ensure greater participation at the chapter level in PDA's key expert activities. I want to know what is needed to support you; **3) Continue to grow and enhance PDA's relationships with worldwide health authorities** providing good science and technology as the basis for regulation); **4) Work to improve and strengthen the content and focus of PDA's educational activities**. We need to ensure that PDA is the "go to" for the highest quality and most informative educational opportunities in the fields of quality, regulatory, science and technology as relates to our centers of excellence; and **5) Most importantly, ensure that PDA meets your individual needs** for information, service and education at the highest quality standards. I want to know what PDA can do for you.

Having previously worked more than 10 years as an association executive, I know that an association is only as strong as its members.

Having previously worked more than 10 years as an association executive, I know that an association is only as strong as its members. PDA has grown significantly in the last few years; it needs to leverage this growth by ensuring member involvement and member satisfaction.

I have great hopes for getting to know as many of you as possible in the near future and involving you in PDA's many activities. By the time you read this, I will have had an opportunity to meet members at the International Congress in Basel and the SciTech Summit in Orlando. I look forward to greeting and exchanging ideas with more members at our upcoming meetings, such as PDA's first ever conference in Singapore (see p. 25) and the annual PDA/FDA meeting (see p. 28), as well as a host of chapter events I will be attending, including meetings sponsored by the Japan, Italy and UK Chapters.

I view an association as a big family and the closer the family, the stronger the family. I urge you to share your thoughts and ideas with us and become involve. Please contact me at any time; I am here to serve you. I can be reached at PDA by phone or email: +1 (301) 656-5900, ext.: 147; dedrick@pda.org. ■

—Vicki Dedrick

Dedrick Joins PDA, *from Cover*

Stryker, IsoTis and Medtronic—to gain a better understanding of processes, industry needs and synthesize equitable positions and applicable standards. These collaborations allowed Ms. Dedrick to author the EU industry's position paper on human tissue regulatory harmonization. Furthermore, Ms. Dedrick has extensive experience in the global harmonization of quality standards within ISO, particularly those for sterilization, biocompatibility and quality management.

Ms. Dedrick has over 10 years senior executive experience in life science not-for-profit associations, with heavy focus on regulatory affairs and sterile products including aseptic processing. In 1990, she joined Belgian-based EUCOMED as Technical Director and later served as the association's acting Director-General. Representing over 40 major medical device manufacturers and 27 associations throughout Europe, Ms. Dedrick served primarily as a spokeswoman for industry to the European Commission, international government agencies and the EU Medical Devices Experts Group. She was responsible for directing all of the association's activities, including meetings, symposia and conferences, annual budgets, staff, cost and facility management, and recruited and grew association membership.

In July 1997, Ms. Dedrick joined Belgian-based International Association of Medical Prosthesis Manufacturers (IAPM) as Secretary-General. Wile at IAPM, which represented 25 of the largest global manufacturers of high technology invasive medical products, she oversaw all of the association's activities, grew the membership and represented the association before government bodies and public forums. In 1999, she guided IAPM in a merger with EUCOMED.

Public speaking and communications is one of Ms. Dedrick's strengths. She has delivered more than 100 presentations at conferences worldwide on a wide variety of technical and regulatory topics, including human tissue regulations, medical products regulations, TSEs, medical technology assessment and the role of the regulatory affairs professional in industry. As an author, Ms. Dedrick has been published in a number of places, including the *European Regulatory Affairs Journal*, *Clinica*, RAPS *Focus* and the *CEN Yearbook*. In 2000, she authored for EUCOMED a detailed and comprehensive document profiling the European medical technologies and devices industries. Ms. Dedrick drafted several industry educational publications, including "The Re-use of Single Use Medical Devices" and "CE Marking."

Ms. Dedrick spent eight years in the pharmaceutical industry. She joined the Upjohn Company (now Pharmacia) in 1978 as a chemist in research and development, and later served as an international quality assurance professional. In the latter role, her focus was on the development of specifications, preparation of documentation for clinical trials (domestic and international) and development of operating procedures for compliance with GMP and pharmacopeial requirements worldwide. She also was involved with new products production start-up and qualification of subsidiaries, complaint support, product test validation, and special projects. Following Upjohn, she joined American Cyanamid subsidiary Storz Ophthalmics, and successfully navigated a pan-European registration via France for the Lederle Pharmaceuticals' therapy, Ocuvite.

Ms. Dedrick's accomplishments in the medical device industry included the navigation of 28 Class III products through the premarket application (PMA) process with the U.S. FDA, which involved making presentations to and working with FDA Advisory Panels.

Ms. Dedrick's accomplishments in the medical device industry included the navigation of 28 Class III products through the premarket application (PMA) process with the U.S. FDA, which involved making presentations to and working with FDA Advisory Panels. Of significant note is each was approved on initial application and/or presentation. Under her guidance, the first IDE for an implantable biofocal intraocular lens was approved on initial application.

Before joining PDA, Ms. Dedrick spent three years with HSN, advancing from Director, Regulatory to Operating Vice President of Quality. Starting with the quality and regulatory responsibility for regulated products, including OTC products and medical devices, she was promoted to the quality responsibility for all products sold by HSN. Responsible for approximately $1B in regulated products, she interfaced with a number of U.S. regulatory agencies, including FDA, the Federal Trade Commission, the Environmental Protection Agency, the Department of Transportation and the Federal Communications Commissions, as well analogous agencies at the state level.

Please join PDA in welcoming Ms. Dedrick to our staff. Do not hesitate to contact her via e-mail: dedrick@pda.org. ■

Meet the Regulator

Ali Afnan—FDA's New PAT Expert

Dr. Ali Afnan is FDA's new Process Analytical Technology expert. He has been involved with the deployment of analytical technologies for process control at the manufacturing site his entire career.

Following receipt of a Ph.D. in Instrumentation and Analytical Science at the University of Manchester Institute of Science and Technology in 1990, Ali Afnan joined the On-Line Analysis and Measurement Group at ICI Engineering. His was responsible for the development and installation of on-line and at-line analyzers for process control, mainly in heavy chemical divisions of the company.

In 1993 he joined the International Technology Development Group within the Pharmaceuticals Engineering Group of Zeneca (now AstraZeneca), when it demerged from ICI. His responsibilities included problem solving, development of Process Analytical Technology, undertaking feasibility studies, specification of inspection and analytical equipment and project management. His main project for the last three years was the development and implementation of Process Analytical Technology.

Ali Afnan, Ph.D.

Dr. Afnan has been active speaking about PAT over the past few years, and he has been quoted in industry publications like "The Gold Sheet."

Dr. Afnan recently joined FDA in the CDER Office of Pharmaceutical Science (OPS). There he is working on FDA's policy to help industry adopt PAT as a member of the PAT Policy Team. He is an active spokesperson for FDA on PAT, appearing at several conferences already in 2004, most recently, PDA's SciTech Summit in Orlando. ■

Regulatory Briefs

Important Dates

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

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

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

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

EMEA

At the EMEA's Committee for Proprietary Medicinal Products (CPMP) 100th meeting, Jan. 20–21, Dr. Daniel Brasseur was reelected CPMP chairman and Dr. Eric Abadie vice-chairman. The EMEA Executive Director, Thomas Lönngren, joined Dr. Brasseur in cutting a special cake with one hundred candles to mark the 100th meeting. Mr. Lönngren said, "The CPMP has established itself over the past years as a premier scientific body, not just in Europe but internationally. The Committee has a solid foundation, under Daniel Brasseur's leadership, as we prepare for its extended public health role in an enlarged Europe and the consequences of the new EU medicines legislation."

GMP—Compilation of Community Procedures on Inspections and Exchange of Information On behalf of the EC the EMEA is now responsible for maintaining and publishing the "Compilation of Community Procedures." The Compilation is a collection of GMP inspection-related procedures and forms agreed by the GMP inspectorates of all member states and designed to facilitate administrative collaboration, harmonization of inspections and exchange of inspection-related information. EMEA is going to reformat, review and update the procedures and incorporate new additions as soon as possible after they have been accepted. More information is available at: www.emea.eu.int/Inspections/GMPhome.html.

EMEA Publishes Draft Guideline on Epidemiological Data on Blood Transmissible Infections for Inclusion in the Guildeline on the Scientific Data Requirements for a Plasma Mater File (EMEA/CPMP/BWP/3794/03). Public comments on this document are due by the end of April 2004. For further details please visit the Web site: www.emea.eu.int/pdfs/human/bwp/012504en.pdf

Updated Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 Rev. 2 October 2003) is now available in all languages of the EU. This joint CPMP/CVMP Note for Guidance is the second revision of the Note for Guidance on minimising the risk of transmitting TSE via medicinal products. This Note for Guidance will become applicable on July 1, 2004 and replaces the previous version (EMEA/410/01 Rev. 1 July 2001). Compliance with this Note for guidance has to be demonstrated according to Directive 2001/83/EC and Directive 2001/82/EC for human and veterinary medicinal products, respectively. The guidance can be found at: www.emea.eu.int/pdfs/human/bwp/041001en.pdf.

The revised TSE Guidance Note also makes redundant the CVMP Position paper on the use of starting materials of ruminant origin in veterinary medicinal products intended for use in ruminant species (EMEA/CVMP/121/01 February 2001). The CVMP Position paper on the assessment of the risk of transmission of animal spongiform encephalopathy agents by master seed materials used in the production of veterinary vaccines remains applicable.

EMEA Launches Action Plan for Improvements for Human Medicines. The initiatives contained in the action plan are part of the Agency's ongoing integrated quality management initiative and also take into account an audit of the scientific committee responsibility for human medicines (the CPMP) held in 2003. The impact of EU enlargement in May 2004 and the need to prepare for future revisions to pharmaceutical legislation are also considered. More information is available at: www.emea.eu.int/pdfs/human/press/pr/088504en.pdf.

ISO

Cleanroom Standards Guide Contamination Control on the Ground and in the Stars—Open Comment on ISO Cleanroom Standard Invited at ESTECH 2004 ISO 14644-1, Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness, is part of a series of international standards concerned with cleanrooms and associated subjects. The document is one of nine international cleanroom standard documents at various stages of development by ISO Technical Committee 209 (ISO/TC 209), Cleanrooms and associated controlled environments. It was issued as a standard in 1999. ISO 14644-1 supercedes U.S. Federal Standard 209E, Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones, which was canceled in November 2001. The ISO/TC 209 family of International Standards governs all aspects of the cleanroom community, from design inception to daily operations. ISO 14644-1 covers the classification of air cleanliness in cleanrooms and associated controlled

environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles. More information on ISO 14644-1 is available at the American National Standards Institute's Web site: web.ansi.org/news_publications/news_story.aspx?menuid-7&articleid=608.

The Institute of Environmental Sciences and Technology (IEST), an ANSI member and accredited standards developer, has issued an invitation to users of ISO 14644-1 to voice their comments and recommendations for improving the international standard. A public session is scheduled for Monday, April 26, during ESTECH 2004, the 50th annual meeting and exposition of IEST, as part of the Systematic Review process for ISO 14644-1. ESTECH 2004 will be held April 25-28, 2004, in Las Vegas, Nevada.

At this forum, participants can provide input to a panel representing the national standards bodies responsible for developing and maintaining the document. These comments will be reviewed by the U.S. Technical Advisory Group (TAG) to ISO/TC 209 and may be incorporated into the U.S. vote on the document. The purpose of the ISO Systematic Review is to ensure standards remain current and valid. ISO 14644-2, Specifications for testing and monitoring to prove continued compliance with ISO 14644-1, will come up for Systematic Review next year.

Founded in 1953, IEST is a multidisciplinary, international not-for-profit society whose members are recognized for their contributions to the environmental sciences in the areas of contamination control in electronics manufacturing and pharmaceutical processes; design, test, and evaluation of commercial and military equipment; and product reliability issues associated with commercial and military systems.

For more information about ESTECH 2004, visit www.iest.org.

U.S. FDA

FDA Issues Correction to Final Electronic Labeling Rule, published Dec. 11, 2003. FDA issued the correction to the e-labeling rule on Feb. 5, 2004, in light of recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics and mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173), which have created a new role for electronic labeling information. Electronically formatted content of labeling will be used to support health information management technologies such as electronic

continues on page 20

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prescribing and the electronic health record (EHR). FDA has determined that the "Portable Document Format," or PDF, is not adequate to support these initiatives. To meet the new mandates, the Agency is proposing to change the way it processes, reviews and archives the content of labeling. The Agency is proposing to adopt a new technology for exchanging information between computer systems called Clinical Document Architecture (CDA). CDA was developed by Health Level Seven (HL7), an ANSI accredited standards development organization. CDA allows information to be exchanged in extensible markup language (XML) and is the standard being investigated for the EHR. The e-labeling rule still becomes effective June 8, 2004.

Human dura mater and human heart valve allografts exempted from HCT/P's definition. FDA has issued an interim final rule to except human dura mater and human heart valve allografts, currently subject to application or notification requirements under the Federal Food, Drug, and Cosmetic Act (the act), from the scope of the definition of "human cells, tissues, or cellular or tissue-based products (HCT/P's)" subject to the registration and listing requirements contained in 21 CFR part 1271.

In an earlier related rulemaking entitled "Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing," the agency defined an HCT/P as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." Examples of HCT/P's included, but were not limited to, ligaments, skin, bone, dura mater, heart valves, corneas, peripheral and cord blood hematopoietic stem cells, manipulated autologous chondrocytes, oocytes, and spermatozoa.

That rule further provided that HCT/P's meeting the criteria established in part 1271 (21 CFR part 1271) in Sec. 1271.10 would be regulated solely under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The effect of these two provisions was that human dura mater and human heart valve allografts meeting the definition of HCT/P and the criteria in Sec. 1271.10 for regulation solely under section 361 of the PHS Act would be removed from the scope of regulations established under the authority of the act. Instead they would be regulated solely under the comprehensive HCT/P regulations that the agency intended to issue under the authority of section 361 of the PHS Act. The agency intended to replace the current good manufacturing practice requirements applicable to human dura mater and human heart valve allografts, which provide protection against the risks of communicable disease and are set out in the Quality System Regulation under part 820 (21 CFR part 820), with donor suitability and good tissue practice regulations, which would be developed specifically to address the risks of communicable disease transmission. Accordingly, at the time the registration and listing rule published, FDA had proposed two other rules to establish the remainder of that comprehensive regulatory framework: 1) Suitability Determination for Donors of Human Cellular and Tissue-Based Products, and 2) Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement.

However, because all three regulations were not in place at the time the registration and listing rule published, the agency delayed, initially for 2 years, the effective date of the definition of HCT/P previously quoted. The agency made the registration and listing rule effective at first only for products currently regulated as human tissue intended for transplantation under 21 CFR part 1270. The agency explained that it did not intend to begin regulating human dura mater and human heart valve allografts that meet the criteria for regulation solely under section 361 of the PHS Act until the donor-suitability and good tissue practice (GTP) components of part 1271 become effective, or other appropriate steps have been taken.

Because finalizing the remaining two rules presented difficult issues and the rulemaking has taken more time than initially foreseen, FDA delayed the effective date for an additional year, until January 21, 2004. However, the rules remain incomplete. Rather than again delay the effective date of this provision, FDA believes that the provision should take effect, provided that the agency issues this interim final rule to assure that human dura mater and human heart valve allografts remain subject to appropriate provisions under the act, and including CGMP requirements, until the comprehensive regulatory framework is in place. (FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, because the donor suitability and GTP rules are not yet finalized.

Once the comprehensive framework is in place, the agency intends to revoke this interim final rule, so that the comprehensive regulatory framework would then apply to human dura mater and human heart valve allografts, and these products would no longer be subject to regulation as medical devices under the act. ■

—compiled by Vicki Dedrick, Gautam Maitra and Walter Morris

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www.pda.org/careers

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PDA
An International Association For Pharmaceutical Science And Technology

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

Chapter Focus
Canada

More information on the Canada Chapter is available at: **www.pda.org/chapters/Canada/contact.html**.

More information on this and other PDA chapters is available in the *PDA Chapter News* (the association's monthly, electronic communication for members specifically targeted towards those active in our chapters), at: **www.pda.org/chapters/index.html**.

When PDA first started considering the formation of Chapters outside the U.S. in the late 1980's, we turned immediately to Canada because of it was a place were PDA membership was growing.

Through the guidance of industry consultant Edward Fitzgerald, work to form the Canada chapter began in 1988. After the PDA Board approved the Chapter, it went right to work. In 1989, its first meeting was held in Toronto. In 1991, the Chapter held meetings in Toronto and Montreal. In 1993, the Chapter's "Montreal Program Committee" launched the first full-day seminar to be conducted totally in French. For a brief time, the Chapter published a newsletter, entitled the *Canadian Information Letter*, a French and English publication.

Current Chapter officers are: President Grace Chin (Vice President of Validation, SNC Lavelin Pharma); Vice President Ameera Al-Jabore (Validation Manager, Grantek Control System); Treasurer and Toronto Program Chair Hein Wick (President, HWMR Ltd.); and Secretary and Montreal Program Chair Patrick Bronsard (Project Manager, SNC Lavelin Pharma).

The Chapter's goals for 2004, include: Recruiting PDA members, initiating liaisons with health authorities; arranging programs with PDA's Training and Research Institute; and holding more Chapter events.

To serve PDA members spread across the vast Canadian landscape, the Canada Chapter has held two regional meetings and an annual meeting each year since the early 1990s.

This year, the Chapter is hosting a meeting on current regulations and compliance issues in Montreal. This one-day meeting will be held April 26, at the Holiday Inn in midtown Montreal. Featured speakers include: Warren Campbell, Program Manager, Computer Systems Validation; Harvey Greenawalt, President, Audit Repository Center; Stephen Desrosiers, Director of Projects, Sabex; and Jeffrey Priem, Director of Knowledge Management, KMI, a division of PAREXEL International. ■

—compiled by KiKi Coffman

— April —

1: **Mountain States Chapter**, "An Approach to Risk Management in Validation"—Longmont, Colorado

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

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

28–29: **UK & Ireland Chapter**, "What to Do When Things Go Wrong"—London, England

TBD: **Israel Chapter**, 2-day course on PIC/S Inspections—Tel Aviv

— May —

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

— June —

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

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

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

New member contact information is forwarded to Chapters on an ongoing basis. For immediate notification of Chapter events, please contact your local representative and ask to be placed on the Chapter mailing list.

Europe & Middle East

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

France Chapter
Contact: Phillippe Gomez
Sartorius Corporation
Tel: +33-0607-453868
E-mail: philippe.gomez@sartorius.com

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

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

Prague Chapter
Contact: Zdenka Mrvova
Léciva A.S.
Tel: +420-2-67242275
E-mail: zdenka.mrvova@zentiva.cz

Spain Chapter
Contact: Jordi Botet
STE Compliance Services
Tel: +34-935-923150
Fax: +34-935-923152
E-mail: jbotet@stegroup.com

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

North America

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

Capital Area Chapter
Areas Served: MD, DC, VA, WV
Contact: Barry A. Friedman, Ph.D.
Cambrex Bio Science Baltimore, Inc.
Tel: +1 (410) 563-9200 ext. 285
Fax: +1 (410) 563-9229
E-mail: barry.friedman@cambrex.com
Web site: www.pdacapitalchapter.org

Delaware Valley Chapter
Areas Served: DE, NJ, PA
Contact: Art Vellutato, Jr.
Veltek Associates, Inc.
Tel: +1 (610) 983-4949 x110
Fax: +1 (610) 983-9494
E-mail: artjr@sterile.com
Web site: www.pdadv.org

Metro Chapter
Areas Served: NJ, NY
Contact: Frank R. Settineri
Chiron Corporation
Tel: +1 (908) 730-1222
Fax: +1 (908) 730-1217
E-mail: frank_settineri@chiron.com

Midwest Chapter
Areas Served: IL, IN, OH, WI, IA, MN
Contact: Amy Gotham
Northview Labs
Tel: +1 (773) 562-1451
E-mail: PDAMidwest@comcast.net

Mountain States Chapter
Areas Served: CO, WY, UT, ID, NE, KS, OK, MT
Contact: Jeff Beste
Pendelton Resources
Tel: +1 (303) 832-8100
Fax: +1 (303) 832-9346
E-mail: cmdjeff@aol.com
Web site: www.mspda.org

New England Chapter
Areas Served: MA, CT, RI, NH, VT, ME
Contact: Mark A. Staples, Ph.D.
MicroCHIPS
Tel: +1 (781) 275-1445 x223
E-mail: mstaples@mchips.com

Puerto Rico Chapter
Contact: Silma Bladuell
Wyeth Lederle, Inc.
Tel: +1 (787) 776-4180
Fax: +1 (787) 776-4144
E-mail: bladues@wyeth.com

Southeast Chapter
Areas Served: NC, SC, TN, VA, FL, GA
Contact: Mary Carver
Eisai, Inc.
Tel: +1 (919) 474-2149
Fax: +1 (919) 941-6934
E-mail: mary_carver@eisai.com
Web site: www.pdase.org

Southern California Chapter
Areas Served: Southern California
Contact: John Spoden
Allergan
Tel: +1 (714) 246-5834
Fax: +1 (714) 246-4272
E-mail: spoden_john@allergan.com
Web site: http://www.pda.org/chapters/Website-SoCal/SoCal-index.html

West Coast Chapter
Areas Served: Northern California
Contact: Randall Tedder
Tel: +1 (415) 841-0373
Fax: +1 (415) 841-1961
E-mail: randall@iconnova.com

Pacific Rim

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

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

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

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

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

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

The Ritz-Carlton Millenia Singapore • May 17–19, 2004 • Courses: May 19–21, 2004

All PDA members in the Pacific Rim region will benefit from this 2½-day conference. Sessions will cover process analytical technologies (PAT), biotechnology, outsourcing, aseptic processing, regulatory affairs, national compendia and international harmonization.

The congress will provide PDA members a unique opportunity to hear expert presentations from international health authority officials in China, Europe, Japan and Singapore.

Keynote addresses will be delivered by Dr. Chor Hiang Tan, CEO, **Health Sciences Authority of Singapore** and David Cockburn, Principal Scientific Administrator, **Inspections Sector, EMEA**. A presentation on Drug Development and Pharmaceutics will be provided by Dr. Ding Jian Hua, Deputy Director, Division of Pharmaceuticals for the **State Food and Drug Administration of China**. Japan Pharmacopeaia issues will be the topic of a presentation by Dr. Tsuyoshi Tanimoto, Director, **Division of Drugs, National Institute of Health in Japan**. Speakers have also been invited from the **Japan Ministry of Health, Labour and Welfare** to speak on compliance and drug development issues.

In the **aseptic processing** track, speakers from around the world will provide an international perspective. Speakers include: Paul Humphreys, Managing Director, PRH Quality Consulting **(Australia)**; Robert Reich, President, Pharmaceutical Systems **(U.S.)**; S. C. Singhai, Ph.D., General Manager, Dr. Reddy's Laboratories **(India)**; and Maha Nassar, Consultant, Seer Pharma **(Australia)**.

The conference will conclude with a comprehensive analysis of "Singapore—the Biopolis of Asia: Building a World-Class Hub for Pharmaceutical and Biopharmaceutical Development & Manufacturing," by Dr. Beh Swan Gin, 2nd Director, Biomedical Sciences, **Singapore Economic Development Board**.

Networking Opportunities

The conference offers attendees ample time to converse and connect with colleagues. A traditional Singapore High Tea will be offered in the exhibit hall and lunch is provided for the attendees on both Monday and Tuesday. All attendees are invited to attend the Gala Reception at the Millenia Hotel on Monday night, a great opportunity for all to unwind and meet other attendees at the conference.

For a **conference brochure** and to **register**, go to **www.pda.org**.

ICH Q7A Workshop

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

Educational Courses

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

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

Exhibits

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

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2004 PDA Biennial Training Conference and PDA Training and Research Institute Courses

No Trainer is an Island—Developing and Leveraging Your Training Network for Success

Westin Rio Mar • May 16–19, 2004 • Puerto Rico

Where can you **network** with trainers specializing in CGMPs and technical training, **learn** from world-renowned experts in the field of training and human performance technology, **hear** the most current regulatory thought on CGMPs, **discover** the latest in training products, *and* **see** stimulating presentations on the real issues facing GMP trainers? **At the 2004 PDA Training Conference.**

Since this year's theme is *"No Trainer is an Island—Developing and Leveraging Your Training Network for Success,"* we have provided one location where you can easily find tools and information to develop and leverage your training network. There will be many formal and informal opportunities to network and interact with your peers, regulatory experts, leading speakers on training, and vendors of training materials and services. The vendor exposition, which will be located in the foyer directly outside the meeting rooms, has been more closely integrated into the conference with 20 + exhibitors participating

This conference, designed for CGMP and Technical trainers in the pharmaceutical, biotech, medical device and related industries, will give participants the opportunity to hear, first hand, from our distinguished panel of U.S. FDA speakers about the Agency's new Risk-Based CGMP initiative including inspectional trends, updates on the new Pharmaceutical Inspectorate, training at CBER and CDER, and innovative programs and activities happening in the districts.

Featured speakers include Harold Stolovitch, Ph.D., author of the award-winning bestseller *Telling Ain't Training*. Dr. Stolovitch is a leader in the field of human performance technology and will present two sessions, one based on his bestseller and the other on his book, *Order Taker to Performance Consultant*. Also, back by popular demand, Dave Arch from the Bob Pike Group will conduct a full-day session entitled "Beat the Blah's: The Blended Learning Solution." Dave has written such training resources as *Tricks for Trainers*, Volumes 1 & 2, *First Impressions/ Lasting Impressions*, *Showmanship for Presenters*, and *Red Hot Handouts*.

Conference attendees can choose from over 20 concurrent sessions, on topics like curriculum design, innovative classroom techniques, developing e-learning, building training communities, and establishing trainer qualifications, to name a few. They also will see and vote on the finalists for PDA's **2004 Trainers Choice Awards**, submitted by their peers; Meet and benchmark with the authors of these creative submissions.

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

Come join us in Puerto Rico for the education and networking and delight in the ambiance of the Caribbean in May for this unique learning experience. More than 500 years of rich history and a vibrant blend of cultures await your arrival. There is something for everyone in this bustling hub of the Caribbean. Plus indulge yourself in the perfect setting for this year's conference the world class Westin Rio Mar Beach Resort & Golf Club and its captivating 500 acres on one mile of secluded tropical beach. Register early; our 2002 conference, with over 200 trainers, was a huge success and we expect attendance to increase this year. Don't miss this exciting opportunity! ■

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

Register by **April 16** to receive an **Early Bird Discount**.

Go to **www.pda.org** for more information.

2004 PDA Biennial Training Conference, Courses and Tabletop Exhibit

The PDA Training and Research Institute is offering six training courses:

- **Training For Performance**—May 20, 2004
- **Maximizing SOPs—An Untapped Resource of Training Solutions**—May 20, 2004
- **SME (Subject Matter Expert) to STAR (Superior Trainer and Reviewer)**—May 20–21, 2004
- **Developing & Administering GMP Training**—May 20–21, 2004
- **Designing Training That Works**—May 21, 2004
- **Regulation Without Motivation: Spark A Change Without Shorting Your Circuit**—May 21, 2004

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

Omni Shoreham Hotel, Washington, DC • September 20–22, 2004

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

Topics covered will include:

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

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

Toronto Course Series

June 15, 2004

- **Sterile Manufacturing w with Blow/Fill/Seal Technology** – #355

June 15–16, 2004

- **Basic Concepts in Cleaning and Cleaning Validation** – #381
- **Cleanroom Management** – #361
- **Computer and Network Infrastructure (CNI) Qualification Using C3Q™** – #416
- **Preparing for an FDA Pre-Approval Inspection** – #455

June 16–17, 2004

- **Qualification and Validation of API Manufacturing Operations** – #505

June 17, 2004

- **Analytical Problem Solving for CAPA Systems** – #362
- **GMP Fundamentals** – #493
- **How to Develop Validation Protocols** – #401
- **Radiation Dosimetry and Calibration** – #313

For more information, go to www.pda.org.

Scientific, Industrial and Regulatory Aspects of Clean Products and Devices

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

Once again, PDA has teamed up with the R³ Nordic Association to offer the 2004 PDA/R³ Nordic Conference. For two days, manufacturers of products in clean rooms will assemble in Stockholm to discuss the latest issues in pharmaceutical and biopharmaceutical manufacturing science and technology.

Registration for this conference has begun so be sure to send your registration form in soon to make sure you don't miss out! Go to www.pda.org for more details and for registration information for this conference.

The conference features representation from various regulatory agencies in Europe. The **EMEA's** Emer Cooke, Section Head, Inspections, will deliver the keynote address on the European Regulatory Perspectives on Pharmaceutical Manufacturing & Medical Devices. Tor Gråberg, Acting Chief Inspector of the **Medical Products Agency in Sweden** will discuss the role of PIC/S in Europe. Additionally, a presentation on current issues in sterile manufacturing will be given by J.L. Saubion, Ph.D., Regulatory Affairs Manager, **Unite de Fabrication, France**.

Presenters from the U.S. FDA include **Anthony Mire-Sluis**, Ph.D., CDER, **Dan Schultz**, CDRH, **Brenda Uratani**, Ph.D., CDER, and **Christopher Watts**, Ph.D., CDER, will present.

Industry experts from the U.S. and Europe, including Mats Johansson and Norman Winskill of Pfizer, Stephen Bellis and Anders Löfgren of AstraZeneca and Gordon Farquharson of Bovis-Lend Lease Pharmaceuticals, will cover a variety of regulatory and scientific issues.

This important two-day conference is being offered by PDA in cooperation with R³ Nordic, the Nordic Association for Contamination Control and Clean Rooms. The foundation for the R³ Nordic co-operation was laid in 1967 when the Swedish R³ committee was formed. In 1970, Denmark, Norway and Finland expanded that committee, which was renamed the R³ Nordic Association. The association is led by a management board and by national boards in each of the Nordic countries. The association is a member of ICCCS, the umbrella organization for international cooperation in the field of contamination control. Since 1995, a special cooperation agreement has been in place between R³ Nordic and PDA.

The conference is being offered in collaboration with Kungl Tekniska Högskolan (The Royal Institute of Technology). KTH is responsible for one-third of Sweden's capacity for engineering studies and technical research at the post-secondary level. The university has over 11,000 undergraduate students and 1,500 active postgraduate students, and a staff of 3,100 people. ■

VP's Message

It's Spring—Wake Up!

Spring! For those of us in the colder climates of the northern hemisphere, we cannot wait for the promise of warmer weather. For those of us who travel frequently, we will not miss the de-icing delays at the airports. And for those of us with proverbial "green thumbs" (not I, unfortunately), it is time for planting some new color into a dormant landscape.

It is also a great time to review your options for professional training. In this spring season, the PDA Training and Research Institute will offer at least 40 lecture and laboratory training opportunities worldwide for you to increase your understanding of pharmaceutical manufacturing, quality assurance issues, training functions and validation programs.

PDA members got off to a great start this spring by attending the Orlando Course Series at the PDA SciTech Summit, March 10–12. Yes, I know that was technically still wintertime (March 20 is the Vernal Equinox), but being in Orlando, it sure didn't feel like winter!

The remainder of March and the month of April are filled with opportunities for hands-on laboratory training in aseptic processing, cleaning validation, sanitization and disinfection at our Baltimore training facility. In May, as the flowers bloom across the temperate zones of the north, the Institute's offerings spring up around the globe. Courses are scheduled at the biennial Training Conference at the beautiful Westin Rio Mar in Puerto Rico (*see p. 27*). At the same time, a full roster of PDA Training and Research courses is planned 10,000 miles away in Singapore (*see below*). For the first time, PDA and the PDA Training and Research Institute will fulfill its mission to bring the latest science and technology information and education to our members in this important Pacific Rim pharmaceutical market. We are also bringing courses to San Diego (*below*).

In June, just before the Summer Solstice signals spring's end, look to Toronto, Ontario, Canada, where the Institute will hold 11 courses.

So wake up from your winter hibernation. This spring will blossom with PDA training and education courses. Visit www.pda.org for more details on these and all our courses. ■

San Diego Course Series

May 3, 2004

Conducting Compliant Deviation Investigations for Pharmaceutical Industry—#114
Environmental Monitoring in Pharmaceutical Manufacturing—#181

May 3–4, 2004

A Practical Approach to Aseptic Processing and Contamination Control—#110
Pharmaceutical Water Systems: A Practical Approach—#388

May 4, 2004

Good Documentations Practices—#451

May 4–5, 2004

Assessing Packaging & Processing Extractables/ Leachables—#190
Sterile Pharmaceutical Dosage Forms: Basic Principles—#352

May 5, 2004

Achieving cGMP Compliance during Development of a Biotechnology Product—#286
Analytical Problem Solving for CAPA Systems—#362
Design and Validation of a Cleaning and Disinfection Program—#440

PDA Training and Research Institute In the Pacific Rim—May 2004

The PDA Training and Research Institute is Brining Four of Its Most Popular Courses to Singapore in conjunction with the PDA 2004 Pharmaceutical & Biopharmaceutical Manufacturing Science & Technology Congress, Training Courses, and Exhibition, starting May 17:

May 19–21

Requirements and Preparation of Pharmaceutical Grade Waters—#394

May 20–21

A Practical Approach to Aseptic Processing and Contamination Control—#110
Qualification and Validation of API Manufacturing Operations—#505
PDA Computer Product Supplier Auditing Process Model: Auditor Training—#474

For more information on the courses offered and other related questions, please contact the PDA Training and Research Institute at +1 (410) 455-5800 or see the complete brochure and register online at: www.pda.org/PDF/Meetings/04Singapore-Bro.pdf.

2004 Aseptic Processing Training

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

The 2004 dates are as follows:

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

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

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

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

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

For Hotel Information, go to www.pda.org

Upcoming PDA Training and Research Institute Lab Courses

Course No.	Title/Topic	Dates
NEW 319	**What you need to know to select adequate thermal validation equipment**	April 1–2, 2004 November 22–23, 2004
NEW	**Developing and Validating Cleaning and Disinfection Programs**	April 15–16, 2004 November 18–19, 2004
400	**Cleaning Validation**	April 19–21, 2004 November 15–17, 2004
230	**Environmental Mycology Identification Workshop**	May 13–14, 2004 December 2–3, 2004
322	**Validating a Steam Sterilizer**	March 11–12, 2004
142	**Designing, Operating and Controlling High-Purity Water Systems for Regulatory Compliance**	May 5–7, 2004 October 25–27, 2004
NEW	**Remediation of Existing Computer Systems**	November 18-19, 2004
NEW	**Developing a Moist Heat Sterilization Program Within FDA Requirements**	August 9–11, 2004
NEW	**Advanced Environmental Mycology Workshop**	September 1–3, 2004
301	**Fundamentals of D, F and z Value Analysis**	October 14–15, 2004
NEW	**Rapid Microbiological Methods**	October 18–22, 2004

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

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PDA Training and Research Institute Registration Form

R
LTR 03/04

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

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

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

Job Title _____ Membership Number _____

Company/Organization _____

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City _____ State/Province _____ ZIP+4/Postal Code _____

Business Phone _____ Fax _____ E-mail _____

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

Were you referred to this event by a PDA Chapter? ❑ Yes ❑ No If so, which Chapter? _____

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

Plus…

✓ Save on PDA meetings, conferences and publications

✓ Connect to global and regional science and regulatory expertise

✓ Gain access to expert, peer-reviewed information relevant to your career

✓ Become a part of the world's leading international network of pharmaceutical and biopharmaceutical professionals.

Check below to become a PDA member:

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

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

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

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TR-32 Update

by Harvey F. Greenawalt, ARC and Janis V. Olson, EduQuest

Buyer Beware

FDA expects pharmaceutical manufacturers to qualify computer software vendors. While the methods used to provide this qualification are varied, the use of on-site audits to verify the vendor's process and familiarize the buyer with the vendor's operation and integrity are the norm. Audits of vendors are very useful. They provide the buyer with a picture of the initial quality of the product, quality of the vendor's response to concerns, maintenance, and how upgrades or changes are conveyed to the buyer. This level of understanding on how the products were produced and of the supplier's performance must be coupled with a monitoring mechanism to provide a high degree of assurance that products delivered to market are and continue to be safe and reliable. The buyer must have a good relationship with the vendor, and must manage them.

The use of computer products and services in the pharmaceutical and biotechnology development and manufacturing processes pose a unique dilemma. Now more than ever, the methods and systems used in computerized product development are varied and vendor centric.

Computerized systems are not for one batch nor do they have a shelf life. They are not consumable. It is not a small task to change vendors of a computerized system. Once installed, they become an integral part of our business processes and are used in the long term. A sound knowledge of the vendor's ability and commitment to maintain the product and understanding of how the product is developed is crucial to a successful operation.

The questions, "Will the product we are purchasing do what they say?" and "Will it sustain the level of performance we need?" become paramount. How do you know the answer to these questions unless you are familiar with the development process of the product? Audits are the weapon of choice when evaluating suppliers of computer products and services.

Computer supplier audits to support computer validation began over 14-years ago. Since then, suppliers have experienced dramatic increases in the number of audits being conducted by the industry while the scope of audits also increased due to new and emerging technologies being used by pharmaceutical companies. The burden of external auditing is costly and unmanageable for both the pharmaceutical companies and suppliers. Suppliers have reported that:

- The length of audits have doubled since 1996
- Average annual cost per supplier, to host pharmaceutical company audits, are estimated to be $150K–$200K.
- There is duplication of audits both within and across pharmaceutical companies

Another problem is that the competency of auditors has not kept pace with the evolving technology concepts.

On the buyer side (pharmaceutical companies), duplication of effort has similarly been observed resulting in inefficient use of limited resources. Diverse auditing methods and inconsistent results have produced costly information with limited utility. At an average cost of $10K per audit, some companies are spending an estimated $450K per annum in audit execution costs, not including the internal costs associated with these audits.

In response to this at the 1996 PDA/FDA joint conference, the FDA challenged the industry to establish a standard methodology to assess suppliers providing computer products and services for regulated pharmaceutical operations. The assessment process was to infer the structural integrity of acquired computerized products, e.g. software, and to lower overall costs of validation to the industry. As a direct result of that challenge, a Supplier Auditing and Qualification Task Group (SA&Q) was established by PDA to investigate an appropriate solution to meet the challenge and solve the escalating problems.

A standard methodology was published in PDA *Technical Report #32, Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*, in January of 2000. The SA&Q Task Group which included pharmaceutical companies, suppliers, third party auditors and FDA, used their experiences with supplier audits and performed research to draft a common practice to meet the needs of the industry. The scope of the project included audits of computerized products and services required as part of the system validation process to establish documented evidence that provides a high degree of assurance that a specific computer product and/or services will consistently produce a product meeting its predetermined specifications and quality attributes.

The efforts of the SA&Q Task Group resulted in a process model, a data collection tool, and an Audit Repository Center to provide consistent, reliable audit information that can be shared at reduced cost within the industry.

TR-32 is designed to provide information, which makes the user a knowledge worker rather than a data collector. After all, most of the personnel from a given corporation who perform the audits are only reporting what they collected during the audit and do not use the information. It is reported for the use of others.

continues on page 34

TR-32 Update, from page 33

The completeness of the information contained in TR-32 reports on file with the repository can be used to determine what and how much in house validation is required to implement and use a certain computerized product or service. This can save time, money, and help reduce risk.

Subscribers indicate that the quality of information contained in audits performed using the PDA process provides their audit analysts sound evidence to use in determination of compliance to the regulatory expectations for validation of commercially available computer products. Subscribers are able to predict the likelihood of technology use problems along with other risk factors and establishing mitigation schemes that result in win–win for both supplier and customer.

Subscribers have reported the following benefits:

- 50% reduction in cost of doing audits
- 400% increase in the number of audits that can be managed by a single individual
- Enterprise wide sharing of audit information for system validation
- Standardization of method for analysis and consistent look and feel to reports
- Seamless integration with acquisition and SLC practices
- Fulfillment of Part 11 expectations with regard to computer validation and the use of commercially available computer products

Agency personnel in open forum in the U.S. and Europe have verbally endorsed the PDA audit process. Representatives from the FDA have stated that the process defined in Technical Report #32 implemented by qualified personnel will provide reliable data as to the structural integrity of computer systems and products.

TR-32 continues to gain recognition as a reliable and cost effective method to address the aspects of validation of commercially available computer products in meeting the regulatory expectations of the "Draft Guideline for the Validation of Blood Establishment Computer Systems," "Guideline on General Principles of Process Validation," "General Principals of Software Validation, Final Guidance for Industry and FDA Staff," and 21 CFR Part 11.

The participation of suppliers such as IBM, Documentum, SSA Global Technologies, ProPack Data Corporation, Fisher Rosemount Systems, Sparta Systems, Mercury Interactive, and Waters Corporation affirms the value of the TR-32 Process Model. The large number of pharmaceutical personnel responsible for validation, quality management, regulatory compliance, quality assurance, and corporate computer systems seeking qualification to perform audits using TR-32 is an indication of the rapid acceptance of the TR-32 Process Model.

Availability of Audits

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

The table below provides a summary of the thirty (30) audits that are currently available for distribution from the repository.

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

Supplier Name	Supplier Product
1. Access360, Inc.	enRole 4.0 (Provisioning Software)
2. Agilent Technologies	Cerity for Pharmaceutical QA/QC. Network data system for analytical laboratories.
3. Alacris, Inc.	idNexus, Alacris products are designed to simplify identity management and maximize trust associated with Public Key Infrastructure (PKI) implementation and security technologies.
4. Applied Biosystems, Inc.	SQL*LIMS™ Software - Laboratory Information Management System
5. Automation Tooling Systems, Inc.	Custom programming services for Process Control Software
6. Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set.
7. Docent	Docent Learning Management Server Docent Content Delivery Server
8. Documentum, Inc.	• Content Authentication Services (CAS) • Document Control Manager (DCM) • Documentum eContent Server • GXPharma
9. Documentum, Inc.	• Document WebDAV Server • Documentum Digital Asset Manager • Document Media Services • Document Desktop for Macintosh

Supplier Name	Supplier Product
10. Documentum, Inc.	• Documentum DocApp Installer • Documentum Administrator • Documentum Application Builder • Documentum DeskTop • Documentum Website Manager • Documentum WebTop • Web Development Kit • Documentum Workflow Manager
11. Epicentric, Inc.	Foundation Enterprise Server 4.0, which is a tool for coordinating information from disparate sources and for disparate uses.
12. First Consulting Group, Inc.	Custom information based strategy software, operations improvements, management and integration services
13. Fisher-Rosemount Systems, Inc.	Distributed Factory Automation, Delta V product line
14. Foss NIRSystems, Inc.	SLE Near-infrared analysis of chemical and physical properties
15. GE Kaye Instruments, Inc.	Thermal validation systems, monitoring systems, thermocouple references and turbine temperature monitoring equipment - LabWatch™, ValProbe™ and the Validator®2000 systems.
16. Inktomi Corporation	Enterprise Search. Providing performance, scalability, and ease-of-use, Inktomi Enterprise Search is a comprehensive information retrieval platform that delivers access to content across the enterprise, regardless of location, language, or file format.
17. Innovatum, Inc.	DataThread™ - Data audit, workflow, 21 CFR Part 11 and E-signature solution for AS/400 applications, without programming changes.
18. Interwoven, Inc.	Web Publication Management
19. Lexign Corporation	Lexign Flow™ EPR Software
20. LoftWare, Inc.	Loftware Print Server (LPS) Lable Printing System
21. MARC Global Systems	Warehouse Execution Systems
22. Merant	PVCS Dimensions & PVCS Replicator Software Configuration Management Tool
23. Mercury Interactive	Test Management Tools: • QuickTest Professional • Astra QuickTest • Astra LoadTest • Astra FastTrack • LoadRunner • LoadRunner TestCenter • TestDirector • WinRunner
24. Propack Data GmbH	Enterprise Production Management System, PMX 3.2 with Solutions MES and CTM.
25. Rational Software Corporation	Rational Suite® Enterprise • Rational ClearQuest (for team-based change request and defect management) • Rational ClearCase (configuration management for smaller development teams)
26. Serena Software, Inc.	• ChangeMan (ZMF) (DS) • StarTool (STL) • TeamTrack (TT)
27. Sparta Systems, Inc.	TrackWise®. Training, Configuration, Installation and Support for TrackWise®.
28. SSA Global Technologies, Inc.	Mid Range ERP software for manufacturing, supply chain and financial application domains.
29. The Sycamore Group	Custom IT Solutions. Integration suite of COTS products and services to bridge data across multiple internal computer systems, including e-Commerce, LIMS, ERP, enterprise databases, mainframes and wireless and portable devices.
30. Waters Corporation	Empower™ chromatography software and Connections AQT - HPLC System, System Components, Data Management

NEW Technical Books

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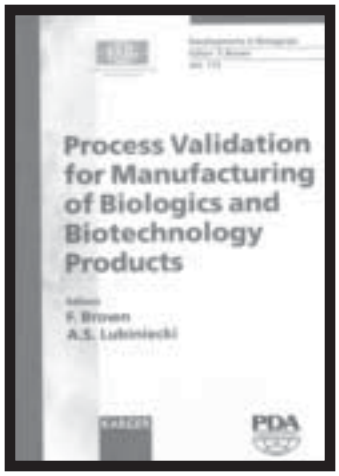
A New PDA/IABs Proceeding

"Process Validation for Manufacturing of Biologics and Biotechnology Products"
Berlin, Germany, September, 2001



This book is a compilation of articles based on presentations made at a joint IAB-PDA conference in Berlin in September 2001. These articles represent "best practices" for biotechnology products from an international perspective. There are contributions from regulatory officials, examples from industry and general commentaries on methods. The examples are organized by stage during the production cycle, providing the reader with a perspective of the validation challenges during both upstream and downstream processes. While there is no one single roadmap on how to validate a biological or biotechnological product, the examples in this book provide an excellent guide of how others have been successful. 120 pages. $110 U.S. member/$595 U.S. nonmember Item no. 04050

Coming Soon ...New PDA-DHI Technical Books

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

Already available from these authors—

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

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

Already available from this editor—

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

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

Already available from these authors—

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

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PDA-DHI Press Books

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

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Selected PDA Technical Reports

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

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

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

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

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

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

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

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

PDA Book

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

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Company, Colleague & Product Announcements

Eli Lilly and Company has enhanced efforts to combat the growing problem of counterfeit prescription drugs in the U.S. drug supply. The company has initiated a broad range of actions, including the addition of enhanced anticounterfeit technologies for Lilly products and packaging in its retail product portfolio and changes in its distribution system to protect patients as well as product integrity. In addition, Lilly is aggressively pursuing and litigating against those who manufacture and market counterfeit medicines.

The most common forms of counterfeiting include: outright fakes; medicines that may be authentic but illegally labeled to show a higher concentration or an incorrect expiration date; generic drugs made for foreign markets, without the same regulatory safeguards as required by the FDA, then diverted for sale in the U.S.; or drugs that have no active ingredient, a different active ingredient, or have been diluted or tampered with in some way.

"Counterfeiters are attempting to exploit the nation's drug supply, and they are doing so with little or no regard for patient care or safety," said Sidney Taurel, President, Chairman and CEO of Eli Lilly and Company. "The exploitative actions of these counterfeiters require Lilly to take the steps necessary to protect the patients who place their trust in our company and its products." Taurel noted that FDA's Counterfeit Drug Task Force Interim Report stated there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply is much more difficult for counterfeiters to overcome than any single method.

Taking this advice, Lilly's multi-pronged strategy includes:

1) Using tamper-resistant and/or anticounterfeit technologies on all retail products. All products in Lilly's retail portfolio incorporate the use of tamper-resistant and/or anticounterfeit technologies.

2) Ongoing evaluation of anticounterfeit technology use on products. Lilly has incorporated anticounterfeit technologies for certain products and is continually evaluating the need for and use of multiple anticounterfeit technologies on products. The company is currently examining the use of emerging anticounterfeit technologies, including several pilot projects assessing the use of radio frequency identification (RFID).

3) Improving Lilly's coordination with U.S. and international organizations. Lilly has taken actions to improve anticounterfeit efforts within various global coalitions and organizations (i.e., World Health Organization, World Trade Organization, Pharmaceutical Security Institute, and global regulatory agencies, etc). This includes sharing information on criminal activities, counterfeit investigations, anticounterfeit strategies and more.

4) Partnering with FDA. Lilly, in conjunction with FDA, is actively researching and monitoring counterfeit traffic of pharmaceuticals. In doing so, the company is working to identify key elements of the criminal business model that allow counterfeit medicines to thrive. Additionally, and consistent with PhRMA's voluntary counterfeit reporting program, the company is sharing key information with FDA's Forensic Chemistry Center to identify and respond to counterfeit Lilly products.

5) Developing and implementing anticounterfeit education and training programs. Lilly is developing and implementing education and training programs for internal and external customers regarding counterfeits. Internally, the company has trained its Lilly Answers Center representatives (the company's customer call center) to better understand and handle specific counterfeiting situations. Externally, Lilly is working with the U.S. Customs Office to develop a product manual that will include photos of and key information about all Lilly products to reduce the importation of counterfeit products and protect public health.

6) Implementing a wholesaler distribution agreement. Lilly requires its drug wholesalers in the U.S. to purchase Lilly products exclusively from Lilly in order to limit the likelihood of counterfeit products entering the distribution system. The company tightly enforces this requirement and has terminated distribution agreements with five U.S. drug wholesalers in the past six months who failed to comply with these terms.

7) Monitoring and pursuing illegal Internet sales of counterfeit products. Lilly's legal and security divisions are actively monitoring numerous Web sites that offer Lilly products or counterfeit versions of Lilly products to U.S. consumers from locations around the world. When instances of wrongdoing have been identified, Lilly has given the information to appropriate government or legal authorities. In other instances, the company is actively pursuing legal action against Internet sources of counterfeit products. The company is working closely with FDA's Office of Criminal Investigations in its pursuit of Web sites illegally selling counterfeit drugs in the U.S.

8) Establishing of a global product protection division. Over the past 12 months, Lilly has developed a global product protection division dedicated to protecting consumers from counterfeit products. This year, the company increased staff and doubled the budget for this division. Its staff includes lawyers, manufacturing and quality control personnel, scientists, and security personnel both in the

United States and overseas to coordinate anticounterfeit efforts. To date, the staff has gathered evidence on 30 counterfeiting operations in 7 countries. Lilly has turned its evidence over to government and law enforcement authorities, who have prosecuted all 30 cases.

"Unfortunately, recent events demonstrate that criminals, who do not share Lilly's focus on patient health or safety, have inserted themselves into the flow of medicines to the marketplace," said Taurel. "Lilly is encountering increasingly sophisticated counterfeiters. With these actions, we hope to protect consumers who know the Lilly brand represents our longstanding commitment to patient safety. We will continue to respond swiftly to assure product quality."

Pfizer Health Solutions has teamed up with CVS Health Connection and the Washington D.C. Public School System to combat diabetes in children.

On Jan. 29, the three groups introduced "Stepping Up to the Plate," a collaborative pilot program designed to reduce the risk factors associated with type 2 diabetes in African American children who live in urban centers. Company and school officials recently launched the first phase of the pilot program—a screening and intervention testing phase—at Noyes Elementary School.

African-American children ages 10 through 18 in fourteen D.C. public schools will be screened for risk factors associated with type 2 diabetes. Children identified as at-risk for the disease will be given basic nutritional advice, as well as a low-impact, goal-based exercise regimen such as walking a number of paces one day, followed by an increased number of steps the next. The results from this phase will be announced in mid-2004.

Pfizer Health Solutions and CVS Health Connection plan to compile the data and findings gathered from "Stepping Up to the Plate" and make them available to schools and communities across the nation.

Ninety to 95 percent of people with diabetes have type 2 diabetes, and occurrence of the disease in children is a growing national problem. A recent report by the American Diabetes Association (ADA) indicated that children are at an increasing risk for developing type 2 diabetes, especially minority children 10 to 18 years of age.

"We live in a 'fast food society' where inexpensive meals with less than ideal nutritional content are easily accessible to our kids," said Ralph Neal, DC Public Schools Assistant Superintendent for Student Services. "Unhealthy eating habits, sedentary lifestyles, and other factors are contributing to rising occurrence of type 2 diabetes in children. We are pleased to work alongside these two great companies to help bring together schools, parents, and children to promote healthier lifestyles in our children and reduce their risk of type 2 diabetes."

"We hear a lot about the 'obesity epidemic' in this country and now we're learning that it can lead to serious chronic disease—diabetes—that is a major contributor to death and disability," said Julia Portale, Director of Community Health, Pfizer Health Solutions. "Our goal is to work with schools, parents, and students in D.C. to help prevent this disease in ways that are practical and relevant to the local community."

Pfizer Health Solutions Inc (PHS) is the care management subsidiary of Pfizer Inc. Pfizer discovers, develops, manufactures and markets leading prescription medicines, for humans and animals, and many of the world's best-known consumer products.

FedEx Custom Critical launches TEMP-ASSURE Validated, a new service to facilitate regulatory compliance for temperature-sensitive shipments. FedEx announced the new service in February, stating that it conforms to current Good Manufacturing Practices (cGMPs) and includes a validation master plan. It also sets standard operating procedures for the shipment of temperature-sensitive materials.

TEMP-ASSURE Validated was developed to address increasing concerns about the proper handling of temperature-sensitive materials. It also facilitates compliance for customers regulated by organizations such as FDA and the United States Pharmacopoeia (USP).

Customers receive a validated service that includes thermal-mapped vehicles, redundant data retention and hard-copy data logs documenting the temperature of the cargo hold during a shipment. This service also includes validation procedures and protocols, ensuring optimal quality according to cGMPs.

In addition to thermal-mapped vehicles, specialized care-in-handling and temperature-control equipment, TEMP-ASSURE Validated vehicles are equipped with a National Institute of Standards and Technology (NIST) traceable data logger and temperature probes that record temperatures at different areas of the cargo box.

According to Jim Snider, vice president and general manager of White Glove Services, TEMP-ASSURE Validated provides a missing compliance link in the cold-chain, ensuring proper shipping temperature and record keeping while products are in transit. "Our objective was to address the regulatory and quality needs of our customers," Snider said. "With this new service, we provide our customers with a validated shipping option that was painstakingly developed to address these needs."

FedEx Custom Critical provides exclusive-use, time-specific shipment services throughout the U.S. and Canada and within Europe. Among its divisions are Surface Expedite, for nonstop, door-to-door transport of critical shipments; White Glove Services, for shipments that require special care in handling; and Air Expedite, which offers an array of air solutions to meet customers' critical delivery times. More information is available at: www.fedex.com. ■

Calendar of Events, *from back cover*

June 16–17, 2004
Qualification and Validation of API Manufacturing Operations
June 17, 2004
Analytical Problem Solving for CAPA Systems
GMP Fundamentals
How to Develop Validation Protocols
Radiation Dosimetry and Calibration

June 21–22, 2004
PDA EuroForum
Common Technical Document—Learning by Doing
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

AUGUST

August 9–11, 2004
PDA Training and Research Institute Laboratory Course
Developing a Moist Heat Sterilization Program Within FDA Requirements
PDA Training and Research Institute, Baltimore, MD

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

August 30, 2004
PDA EuroForum
Visual Inspection
Berlin, Germany

SEPTEMBER

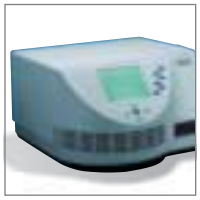
September 1–3, 2004
PDA Training and Research Institute Laboratory Course
Advanced Environmental Mycology Identification Workshop
PDA Training and Research Institute, Baltimore, MD

September 6–8, 2004
Pan European PDA Training and Research Institute Lecture Course
Fundamentals of Aseptic Processing
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

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

September 20–24, 2004
2004 PDA/FDA Joint Regulatory Conference
Conference: September 20–22
Courses: September 23–24
Exhibition: September 20–21
Omni Shoreham Hotel, Washington, DC
PDA Training and Research Institute Lecture Courses
September 23, 2004
Change Control and Documentation
September 23–24, 2004
Auditing Pharmaceutical Microbiology Laboratories
Basic Concepts in Cleaning and Cleaning Validation
Compliance Auditing of Cleanrooms and Controlled Environments
Qualification and Validation of API Manufacturing
September 24, 2004
Auditing Techniques for CGMP Compliance

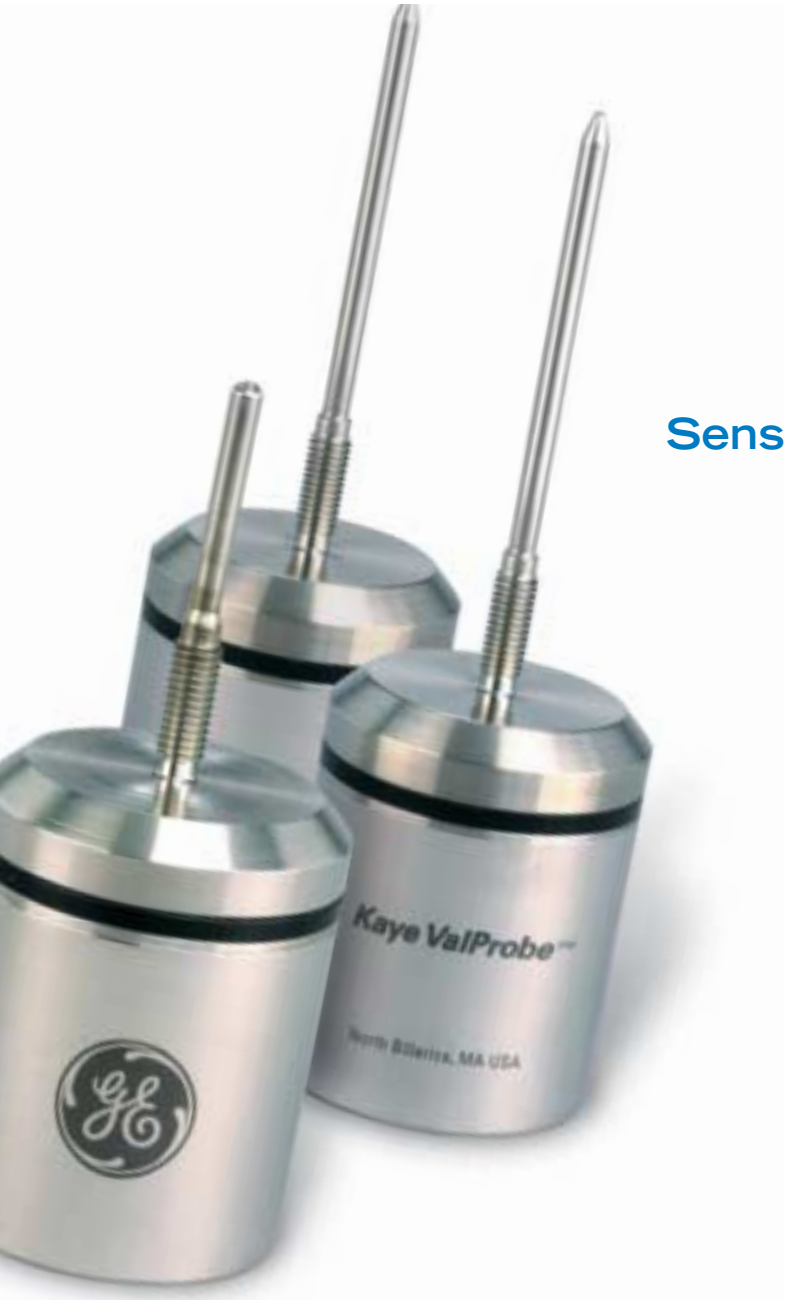
September 27, 2004
PDA EuroForum
Biosafety
Biotech Interest Group—European Section
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland



For over forty years the **Kaye** name has been recognized for uncompromising accuracy and reliability in thermal process measurement. We've always been very good at what we do, and we're about to get even better.

With GE's technical expertise, global reach and financial strength we now have the horsepower to take on even greater challenges. In the months and years ahead look for new and exciting solutions from the people you've trusted for decades, but look for us under a new name.

GE Infrastructure - Sensing



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imagination at work

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For now, you can still find us at gekaye.com

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

Calendar of Events

2004

APRIL

April 1–2, 2004
PDA Training and Research Institute Laboratory Course
What You Need to Know to Select Adequate Thermal Validation Equipment
PDA Training and Research Institute, Baltimore, MD

April 15–16, 2004
PDA Training and Research Institute Laboratory Course
Developing and Validating Cleaning and Disinfection Programs
PDA Training and Research Institute, Baltimore, MD

April 19, 2004
PDA EuroForum
PAT from the Horse's Mouth
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

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

April 26, 2004
PDA Canada Chapter
Current Regulations and Compliance
Holiday Inn – Midtown
Montreal, Quebec, Canada

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

MAY

May 3–5, 2004
PDA Training and Research Institute San Diego Course Series
May 3, 2004
Conducting Compliant Deviation Investigations for Pharmaceutical Industry
Environmental Monitoring in Pharmaceutical Manufacturing
May 3–4, 2004
A Practical Approach to Aseptic Processing and Contamination Control
Pharmaceutical Water Systems: A Practical Approach
May 4, 2004
Good Documentations Practices
May 4–5, 2004
Assessing Packaging and Processing Extractables/Leachables
Sterile Pharmaceutical Dosage Forms: Basic Principles
May 5, 2004
Achieving cGMP Compliance during Development of a Biotechnology Product
Analytical Problem Solving for CAPA Systems
Design and Validation of a Cleaning and Disinfection Program

May 5–7, 2004
PDA Training and Research Institute Laboratory Course
Designing, Operating, and Controlling High Purity Water Systems for Regulatory Compliance
PDA Training and Research Institute, Baltimore, MD

May 10–11, 2004
PDA Training and Research Institute Laboratory Course
Remediation of Existing Computer Systems
PDA Training and Research Institute, Baltimore, MD

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

May 17–21, 2004
2004 PDA Biennial Training Conference, Courses and Vendor Exhibit
The Westin Rio Mar Beach Resort and Golf Club, Puerto Rico
PDA Training and Research Institute Lecture Courses
May 20, 2004
Training for Performance
Maximizing SOPs – An Untapped Resource of Training Solutions
May 20–21, 2004
Developing and Administering GMP Training
SME (Subject Matter Expert) to STAR (Superior Trainer and Reviewer)
May 21, 2004
Designing Training That Works
Regulation Without Motivation: Spark a Change without Shorting Your Circuit

May 17–21, 2004
PDA 2004 Pharmaceutical and Biopharmaceutical Manufacturing Science and Technology Congress, Training Courses, and Exhibition
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia, Singapore
PDA Training and Research Institute Lecture Courses
May19–21, 2004
Requirements and Preparation of Pharmaceutical Grade Waters
May 20–21, 2004
A Practical Approach to Aseptic Processing and Contamination Control
PDA Computer Product Supplier Auditing Process Model: Auditor Training
Qualification and Validation of API Manufacturing Operations

May 24, 2004
PDA EuroForum
Biotech Forum on Harmonization
Biotech Interest Group—European Section
Florence, Italy

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

JUNE

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

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

June 15–17, 2004
PDA Training and Research Institute Toronto Course Series
The Westin Harbour Castle
Toronto, Canada
June 15, 2004
Sterile Manufacturing w with Blow/Fill/Seal Technology
June 15–16, 2004
Basic Concepts in Cleaning and Cleaning Validation
Cleanroom Management
Computer and Network Infrastructure (CNI) Qualification Using C3Q™
Preparing for an FDA Pre-Approval Inspection

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

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