Volume XL, No. 2

PDA Letter

February 2004

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

A Message from PDA Chair Nikki Mehringer, page 7

PDA SciTech Summit™ – *The* Resource For Innovation

Don't wait any longer to register for PDA's premier science and technology event of the year: The 2004 PDA SciTech Summit™, March 8–12, in beautiful Orlando, Florida.

Combining the best of PDA's Spring Conference and fall Annual Meeting, the SciTech Summit is PDA's newest program focused on the latest science and technology impacting the pharmaceutical and biopharmaceutical industries.

The SciTech Summit is a week-long event that includes scientific presentations, PDA Training and Research Institute courses, PDA Interest Group and Task Force meetings, and exhibits of the most advanced technology available for pharmaceutical and biopharmaceutical manufacturers.

The SciTech Summit conference features global industry and regulatory experts from Abbott Laboratories, Amgen, AstraZeneca, Aventis-Behring, Baxter, Chiron, Eli Lilly, EMEA, GlaxoSmithKline, Johnson & Johnson, Pfizer, FDA and more. Presentations will focus on the use and application of new science and technologies to meet regulatory demands.

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

Plenty of networking time will be available so that attendees can enjoy sunny Orlando in between conference sessions, courses, etc. **Bringing your family?** Go to www.pda.org right now to take advantage of specially discounted "Park Hopper" passes to Walt Disney World available exclusively to SciTech Summit registrants.

Participants can focus on one of several tracks or choose to attend a variety of sessions. Featured tracks will examine process analytical technologies, new sterile filling technologies, combination products, MEMs and nanotechnologies, the science

continues on page 30

George A. Robertson, Ph.D., Joins PDA

George A. Robertson, Ph.D., has joined PDA as Vice President of Science and Technology, effective January 5, 2004.

With 20 years experience in the pharmaceutical, biopharmaceutical and biodefense industries, Dr. Robertson is experienced in process development, manufacturing, QA/QC, aseptic processing/filling, and operations and facility management. By hiring a scientist with Dr. Robertson's broad experience, PDA ensures that its science and technology programs will continue to play a constructive and important role in the development of sound regulatory policy at a time of extensive and rapid change in the pharmaceutical and biopharmaceutical industries worldwide.

Dr. Robertson's experience in the biodefense industry is equally extensive. As part of a 30-year career in special operations and intelligence with the U.S. Army Reserve, Dr. Robertson was selected to join the United Nations' biological weapons inspection team that searched for biological weapons in Iraq in 1995. Subsequently, he participated in Department of Defense teams visiting former Soviet biological weapons facilities. His biodefense experience includes time with ITT Industries – Advanced Engineering Sciences (Alexandria, Va.). As Chief Scientist in the Special Projects Department, he contributed to the development of technologies that detect nuclear, biological and chemical agents for arms control. Dr. Robertson also has worked as an independent contractor for the U.S. intelligence community since 1995. In 2000, Dr. Robertson retired from the Army Reserve, having attained the rank of Colonel.

Distinguished academic accomplishments are key to Dr. Robertson's success. He earned a Ph.D. in Molecular Biology from the University of Pennsylvania (Philadelphia, Pa.) in 1977, and a Business Administration Certificate from the Wharton Management Program. He holds an M.S. in Biology from Villanova University (Villanova, Pa.) and a B.S. in Biology from Washington and Lee University (Lexington, Virginia).

continues on page 11

Pharmaceutical Systems, Inc. • 909 Orchard Street • Mundelein • IL 60060

T 847.566.9229 | F 847.566.4960 | www.pharmsystems.com

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #541

The *only* proven solution for all quality and compliance requirements.

No separate "modules" required! TrackWise® already comes with the built-in capabilities for all cGxP applications—with flexible, easy implementation!

TRACKWISE®

The Ultimate Quality Management Software

Benefits of a single integrated solution:

- Consistent "look and feel"
- Scalable, incremental implementation
- Lower validation and training costs
- Shortened deployment time
- Highest ROI

Compare. TrackWise is the only software with out-of-the-box functionality and flexibility to implement all requirements across any cGxP application. This encompasses Deviations, CAPA, Complaints, Change Control, Supplier Quality, Audits and much more. And it's the only software that can be configured to meet all existing business processes. No need to modify your business processes to fit a solution!

Compare. TrackWise now partners with more than 85 FDA regulated companies — making it the most trusted and most validated solution in your industry. It's an off-the-shelf, enterprise-wide, global, turnkey system that provides full control, and compliance with all regulatory requirements. And it's the only QMS tool to pass both a PDA audit (2001, 2003) and receive a vendor audit score of 100% compliance with 21 CFR Part 11. Plus TrackWise offers seamless integration with "best of breed" EDMS systems as well as integration with ERP and MES.

Compare. Compliance, performance, efficiency...why TrackWise is your best choice.

Joining most FDA regulated companies
using a successful and proven solution...
has its rewards!

Sparta Systems, Inc.

Holmdel Corporate Plaza • 2137 State Highway 35, Holmdel, New Jersey 07733
888-261-5948 (Toll Free Number) 732-203-0400 • FAX 732-203-0375 e-mail: sales@sparta-systems.com • www.sparta-systems.com

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #617

Important Dates...

- **March 8–12, 2004**–SciTech Summit™, cover
- **May 17–21, 2004**–2004 PDA Pharmaceutical and Biopharmaceutical Manufacturing Science and Technology Congress, Singapore, page 32
- **March 8, 2004**–Deadline for public comment on FDA CDER Draft Guidance on Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling Assessment, page 18

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

IN THIS ISSUE...

The *PDA Letter* is published monthly by PDA, exclusively for PDA members. Subscriptions are not available. Articles in the *PDA Letter* may be reproduced with permission—contact the Editor for details.

Walter Morris, *Senior Editor*
Janet Raysick, *Production Manager*
Matthew Clark, *Director of Marketing Services*
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*

The TexShield product line includes Sterile 70% Isopropyl Alcohol, Sterile 70% Isopropyl Alcohol with WFI, Isolator Cleaning Tools and Sterile Pens.

The TexShield product line was developed to address the **contamination control** concerns of sterile product manufacturers. We realize you need products that offer **assured sterility** and **uncompromised quality.** We understand the importance of the documentation you receive with every sterile product you buy. We know you are looking to improve safety and reduce waste when using sterile alcohol products.

Packaged in the unique **SteriShield Delivery System™,** TexShield sterile alcohol contents remain sterile three months after first operating the trigger mechanism. The contents can be completely dispensed, **eliminating waste.** The innovative, lightweight Isolator Cleaning System is shaped to clean both flat surfaces and hard-to-reach corners. Each TexShield product is designed to make your job easier. For more information, call 1-800-839-9473, ext. 120 or visit our website.

TW Texwipe®

Better solutions, together.

North America
Tel 201 327 9100
Fax 201 327 5945
E-mail info@texwipe.com

www.texwipe.com

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #407

Neal G. Koller
PDA President

President's Message

PDA Offers Opportunities to Enhance Careers, Impact the Community and Have Fun

The new year is just a month old, yet many exciting developments already have taken place at PDA. None is more notable than the beginning of terms for the newly-elected Board of Directors and Officers, the hiring of George Robertson, Ph.D., as the new Vice President of Science and Technology, and the well-deserved promotions of Wanda Neal to Director, Programs and Meetings, and of Matthew Clark to the added position of Director, Membership and Chapters (*see page 10*). In addition, PDA has launched the new ***PDA Chapter Points Program*** (*see* President's Message, *PDA Letter*, January 2004) and the new **E-Store** for purchasing PDA scientific and technical resources (*see page 8*). Next month, PDA will hold its new annual meeting, the SciTech Summit™ in Orlando, Florida—combining the traditional Spring Conference with the autumn Annual Meeting to produce a truly new science and technology summit.

As important as these developments are, they represent only a few enhancements to what is already one of the most valuable association memberships in the pharmaceutical and biopharmaceutical industries worldwide. Participating in PDA allows members to become involved in the highest levels of scientific advancement and policy making within the pharmaceutical and biopharmaceutical communities. To this end, PDA offers multiple and varied committees, Task Forces, Interest Groups and Chapters for members to grow their careers, impact the community, network and have fun.

PDA Interest Groups, Chapters and Program Committees are a great introduction to all that PDA has to offer. Joining an Interest Group is as easy as contacting its leader. Interest Groups bring together members with common scientific and professional interests to interact with one another, exchange information, network and advance specific scientific issues. Interest Groups are the foundation upon which most of PDA's science and technology initiatives are built. The pharmaceutical and biopharmaceutical communities greatly benefit from the new science, technical reports, points-to-consider, surveys, etc., that grow out of Interest Groups. Currently 21 Interest Groups are active, covering topics like:

- Computer Systems
- Isolation Technology
- Microbiology/Environmental Monitoring
- Packaging Science
- Quality Assurance/Quality Control
- Training
- Visual Inspection of Parenterals.

A complete list of Interest Groups and their leaders is included on page 17 of this issue and more information is available at: www.pda.org/science/IGs.html.

Interest Groups generally meet during PDA events, like the upcoming SciTech Summit in March. Some remain active throughout the year by meeting at Chapter events, teleconferencing, and posting updates on the PDA Web site. Any PDA member can attend an Interest Group meeting. PDA members can suggest the creation of a new Interest Group at any time. For questions related to Interest Groups or suggestions for new ones, contact George Robertson, Ph.D., VP, Science and Technology, at +1 (301) 656-5900, ext. 139 or roberston@pda.org, or Sopita Lapsomphop, Coordinator, Science and Technology Department at +1 (301) 656-5900, ext. 153 or lapsomphop@pda.org.

Becoming involved with PDA Chapters is as easy as joining an Interest Group—simply attend a Chapter event or volunteer to be a Chapter Leader. Currently, 22 PDA Chapters operate around the world, including PDA's two newest, the France Chapter and the Puerto Rico Chapter (*see page 29 for a complete list*). PDA members located in any portion of a Chapter's boundaries can become involved in a chapter.

Chapters offer PDA members numerous opportunities to become involved. These include:

- Serving as publisher for an issue of the chapter newsletter
- Helping plan future meetings and events with the Chapter
- Representing the chapter at PDA events
- Writing an article about an upcoming chapter event
- Writing "regulatory briefs" for the Chapter to submit to the *PDA Letter*
- Taking photos at a chapter event.

For more information on Chapter volunteer opportunities, see the January 2004 *PDA Letter* p. 25 or visit PDA's monthly Chapter e-publication, the *PDA Chapter News*. Questions about Chapters can be directed to PDA Chapter Coordinator KiKi Coffman at +1 (301) 656-5900, ext. 149 or Coffman@pda.org.

The scientific and technical expertise of PDA members is integral to PDA's program and meeting planning. Program Committees comprised of interested members play an essential role in assuring that PDA conferences offer members the kind of information that will help advance their

continues on page 10

A Message from PDA Chair Nikki Mehringer

I have learned a great deal from my many experiences with PDA, including the last 2 years as Chair-Elect, but I must admit that I felt quite humble when Floyd Benjamin presented me with the gavel as the next Chair of the Association. I hold tremendous respect for those who have served in this office before me, and am clearly aware of the history and the responsibility that the gavel represents. I appreciate the trust of the members in electing me along with our new Officers and Board of Directors, who represent excellence in science, regulatory affairs, and quality with impressive resumes of service to the global industry and to PDA. Working with our fine PDA staff and our members worldwide, we are energized to meet the opportunities and challenges we face together.

Our opportunities are plentiful. This is a unique moment in the history of the pharmaceutical industry. Multiple forces around the world are converging to a single vision that can be shared by industry and regulatory agencies globally. A strong force has been the "risk-based" approach where patient safety and science form the basis of a globally harmonized quality systems approach that is applied to design, execution, review and inspection activities. This includes the application of sound scientific principles as the basis for well-designed, capable, validated and controlled manufacturing processes. Regulatory processes that promote and encourage new technology complete this vision. Initiatives such as the International Conference on Harmonization, the FDA quality initiative on "GMPs for the 21st Century," and the Product Quality Research Institute demonstrate the broad interest, and in fact *demand* for all of us involved in pharmaceutical manufacturing to move towards this vision. We support this vision and welcome the initiatives designed to achieve them.

PDA is in a strong position to continue to be a key leader in moving towards this vision based on the credibility we have earned through providing 57 years of important, if not essential, leadership. Throughout our history, PDA has been distinguished by our ability to provide the integration and practical application of expertise in science and technology, regulatory affairs and quality to the issues most important to our members and our industry.

Along with opportunities come challenges. As the industry grows and changes, so does PDA. Over 10,000 members from 63 countries enjoy the benefits of PDA membership. Like every organization, we have more good ideas than we can fully support. For the Board and the staff, the primary challenge is to find the right areas of focus and to manage our resources in ways that best serve the needs of our members. To achieve this, we have convened a new Strategic Planning Committee to assure that this important plan, which guides our decision making, is as dynamic as the external environment and the needs of our members. This committee met for the first time at our annual meeting in Atlanta and has established an aggressive timeline for its work. I would encourage you to participate in the surveys that will be available in the near future—this process represents a great opportunity for all members to be good citizens of the Association.

PDA is in a strong position to continue to be a key leader in moving towards this vision, based on the credibility we have earned through providing 57 years of important, if not essential, leadership.

Borrowing form PDA's Mission statement, the "scientifically sound and practical technical information and education" provided by PDA is an integral part of my daily work. I often find myself pulling out a PDA Technical Report, an article from the *PDA Journal of Pharmaceutical Science and Technology*, checking for a presentation from a conference on the PDA Web site, or calling a colleague I have met through a PDA task force.

Multiplying my personal experience with PDA's 10,000+ members only begins to represent the impact of PDA. It is now our task to build upon and expand this body of work. To this end, I will work during the next 2 years to assure the integration and balance of our key scientific, regulatory, and quality disciplines, realizing that the credibility of our regulatory opinions is grounded in the soundness of our science. I will work to assure the balance of our independence and our collaboration with other entities, realizing that our independent Association of more than 10,000 individuals must be valued by others as a strong partner if we are to maintain the global impact that our members expect. And I will work to have a member-based, data-based Strategic Plan for the Association that will guide our decision making for the future. I begin my term as chair with full confidence in our continued success, based on the strength of our members, our Board and our staff. I ask each of you for your support and to contribute to the exciting opportunities ahead of us.

Once again, I thank all of you for the honor bestowed on me to serve as the Chair of the PDA Board of Directors. I look forward to the two exciting, productive and fulfilling years that lie ahead. ■

Nikki Mehringer
Senior Quality Advisor
Eli Lilly and Company
+1 (317) 276 - 5229

New At www.pda.org!

The *New* **PDA Publications E-store** is the latest in a series of Web enhancements taking place at www.pda.org. The fully-interactive E-store is a one-stop shop of the largest selection of scientific, technical, and regulatory resources PDA has offered in its 57-year history.

Visit the E-store today and search for your favorite publications: PDA published and co-published books, technical books, PDA Technical Reports, back issues and articles from the *PDA Journal of Pharmaceutical Science and Technology*, and a myriad of resources in the field of training.

> **Remember:** You can search the E-store by author, title, publication type, key word(s), item number or publication category (i.e., "Microbiology" or "Computer Validation"). With advanced search features like these, ordering your publications from PDA just got easier!

Don't forget the other resources available at www.pda.org

A *New* **Career Center** just recently launched. In addition to finding new opportunities, job seekers now can set-up and manage their own job search, update their profile, post their resume, and participate in PDA-sponsored Career Fairs. Employers can now do more than post job openings. They can also search the database of resumes for prospective applicants, access their own account using personalized information, and view product and advertising opportunities online. The *New* Career Center is your ticket to the right employee or the right job!

Are you a **Consultant** or **Contract Manufacturer**? If so, have you considered increasing your company's visibility by posting a description of your services in the Directory pages of the Web site? Take a moment and visit these directories today. Your competition is likely to have already posted their listing.

Members: Have you searched the Membership Directory lately? Reviewed/commented on any regulatory documents? Downloaded a Technical Bulletin? Joined an Interest Group? Browsed a recent edition of *Chapter News* or an archived copy of the *PDA Letter* (which, by the way, are available electronically on the Web site much earlier than through the mail)?

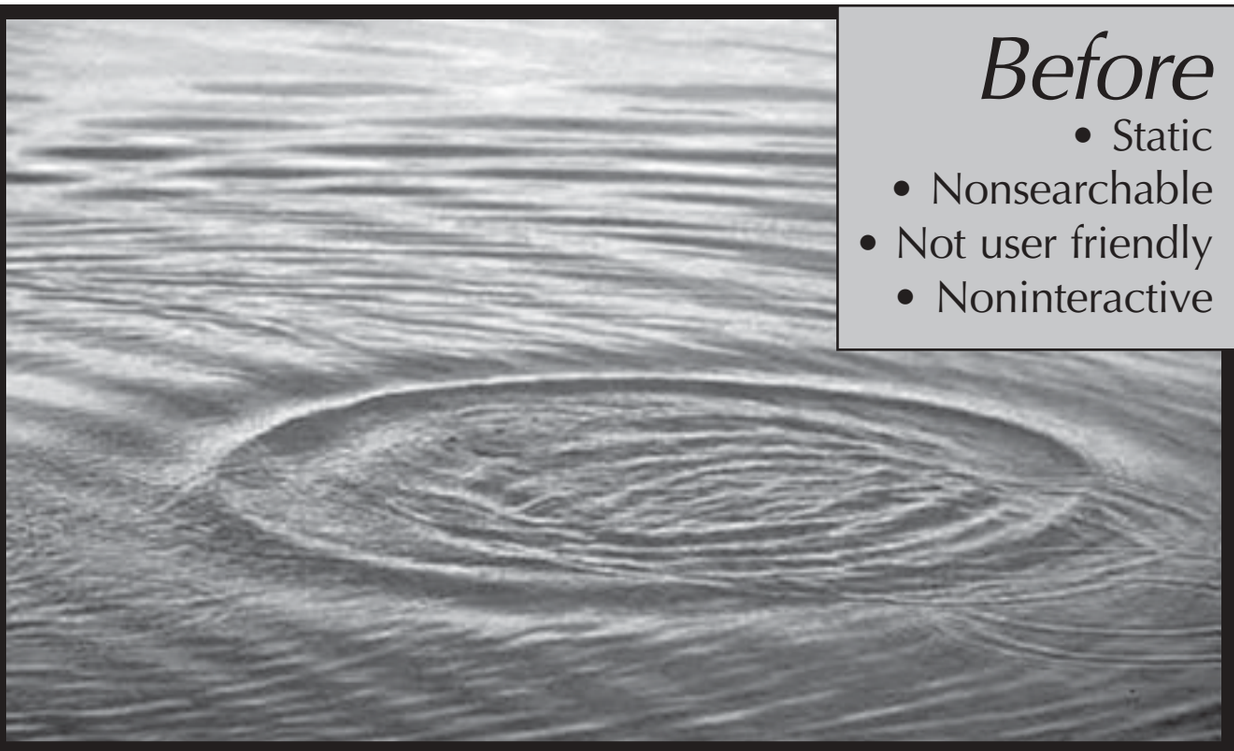
The PDA Web site is a valuable source of information and contains in-depth information about the association's science, technology, and regulatory activities; a calendar of events which is updated daily; information about chapters and affiliates; course information from the PDA Training and Research Institute; recent exhibitor abstracts; and Web seminars.

Continuing to bring you the latest and greatest functionality, the Web site offers such features as online member registration and renewals, online conference and course registration, and member profile (the option to change/update addresses and other membership-related information). Have you registered for an event or updated your membership online lately? Try it. In fact try it anytime. You can register online at PDA 24 hours a day. And when you do so you will be updating our membership database live, in realtime, from wherever you are!

Browsed a recent edition of *Chapter News* or an archived copy of the *PDA Letter* (which, by the way, are available electronically on the Web site much earlier than through the mail)?

New features are being added all the time. During 2003, a new Chapters and Affiliates section was created, a President's Messages page and a press release page were added to the About Us section, and a Director's Messages page was added to the PDA Training and Research Institute's Courses section. Preparations are being made to bring you a fully redesigned Web site with even greater flexibility and functionality. We'll keep you posted. ■

—Joseph Bury



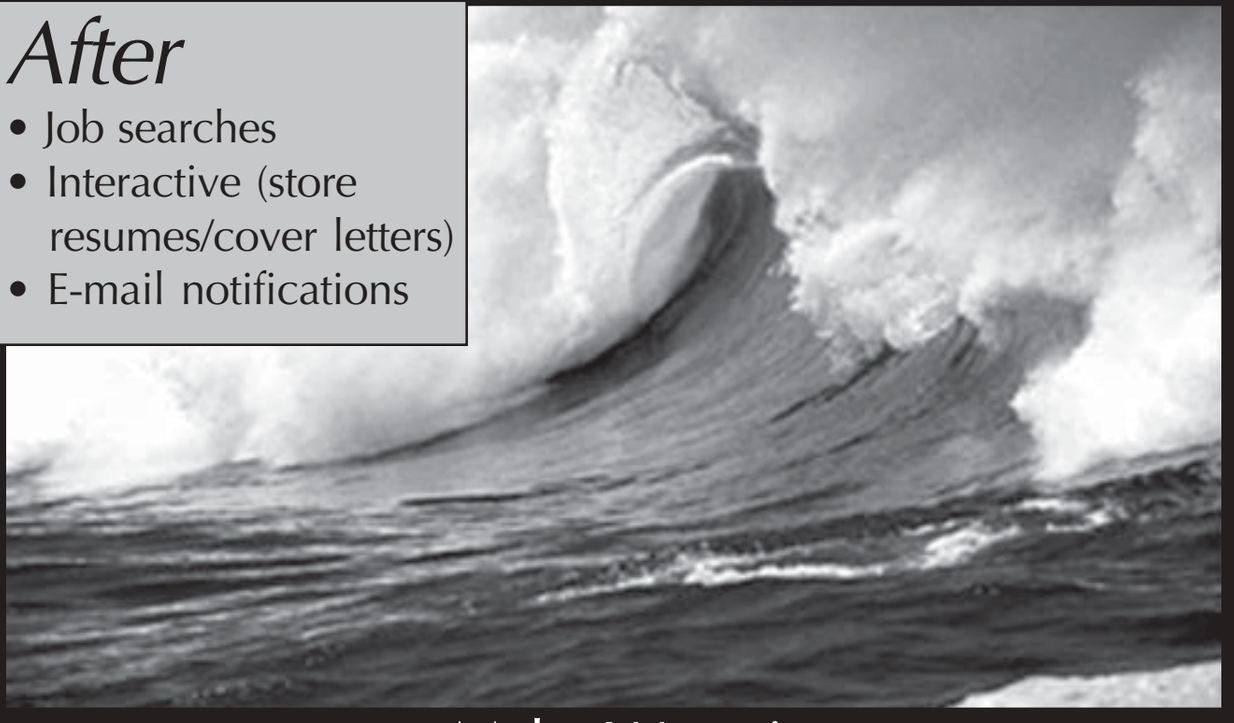
Before

- Static
- Nonsearchable
- Not user friendly
- Noninteractive

The New PDA Online Career Center

After

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



Make Waves!

http://careers.pda.org

PDA
An International Association For Pharmaceutical Science And Technology

Recent Staff Promotions at PDA

PDA is pleased to announce that several staff members have been promoted.

After six years in PDA's Programs and Meetings Department, **Wanda Neal** assumed the position of Director, effective January 6, 2004. Wanda is well-known to PDA conference delegates as a steady hand who "gets things done."

Starting Jan. 1, **Matthew Clark** assumed the position of Director, Membership and Chapters. Currently Director of Marketing Services, Matt joined PDA in mid-2003, having previously worked for the Association of Clinical Research Professionals (ACRP).

Juner Torres has advanced to Manager, Laboratory Training at the PDA Training and Research Institute. Juner will be responsible for the planning, execution, and budgetary control of all laboratory courses at the Institute. He has been with the Institute since March 2002, previously serving as Lab Education Coordinator.

Sopita Lapsomphop has become PDA's new Coordinator for Science and Technology. Sopita has been an executive assistant in the Science and Technology Department for the last year and now will work closely with Science and Technology VP George Robertson.

Last but not least, **Nickia Gouldbourne** has become PDA's new Senior Customer Account Representative in the Finance and Strategic Planning Department. She joined PDA three years ago as a customer account representative.

PDA congratulates these staff members for their well-deserved promotions and looks forward to their continued contributions in 2004. ■

President's Message, from page 6

careers and impact the pharmaceutical and biopharmaceutical communities worldwide. Program Committees ensure that PDA conferences cover the scientific and regulatory topics that members will not find anywhere else. Program committees:

- identify new and relevant scientific and regulatory topics,
- benchmark critical issues for the communities,
- find expert speakers, and
- provide direction to health authority speakers for their presentations.

PDA members involved with Program Committees participate in one of the best networking opportunities available. New Program Committees are being formed now for PDA's strategic conferences in 2005 and 2006. Members interested in volunteering should contact PDA Meetings and Programs Director Wanda Neal (neal@pda.org).

The PDA Volunteer Program is a new program just begun in late 2003. The Volunteer Program provides PDA members an opportunity to attend conferences as well as TRI courses and laboratories, network and learn at a 50% discounted registration fee by working a few hours at the event. Members who want to take advantage of the PDA Volunteer Program should contact PDA Membership and Chapters Director Matthew Clark at clark@pda.org.

Members who take advantage of the networking opportunities and the exposure received while participating in Interest Groups, Chapters and Program Committees often are asked to serve on Science Advisory Board (SAB) or Regulatory Affairs and Quality Committee (RAQC) Task Forces, based on their qualifications, credentials and interest in the project. SAB Task Forces produce PDA's Technical Reports and "Points to Consider," and RAQC Task Forces comment on new regulatory guidances and policies. Once on a Task Force, PDA members begin interacting more closely with SAB and RAQC members. Those with the interest, the credentials, and who have distinguished themselves through their PDA work may be invited to join SAB and/or RAQC when openings are available.

Members involved with Interest Groups, Chapters, Task Forces, and Program Committees often are asked to speak at PDA meetings and workshops. Ultimately, members who distinguish themselves through their service to PDA may be nominated for a position on the Board of Directors.

PDA offers a wealth of possibilities for its members to participate in the highest levels of scientific advancement and policy making within the pharmaceutical and biopharmaceutical communities. These opportunities enable PDA members to enhance their careers, impact their communities, and have fun in the process.

I want to thank all of PDA's volunteers. Those who participate in our committees, Task Forces, Interest Groups and Chapters truly make PDA one of the best values and most respected associations in the world today. ■

Serving PDA: A Great Opportunity and Privilege

It is a great privilege and opportunity to be PDA's Science and Technology Vice President. As a member of several professional societies, PDA always has impressed me as being the most prestigious. The September Joint PDA-FDA meeting is without peer in the industry. The *PDA Journal of Pharmaceutical Science and Technology* and PDA's Technical Reports are the standards by which other associations are judged. PDA's members are skilled experts in their professions. For all these, to reiterate, being a part of this organization's technical program is a great privilege and opportunity.

When I first met with PDA President Neal Koller, he asked what attracted me to the position; to which I replied: "professional development." For certainly, the various duties of the Science and Technology VP will be as fulfilling as they will be challenging. For this edition of the *PDA Letter*, I would like to discuss *some* of the objectives Neal has laid out for me.

First on my agenda is the establishment of scientific "Centers of Excellence." The goal is to capitalize on the scientific interests and expertise of our members and identify with the help of the members the core competencies of the association. A handful of core competencies will become the focal points for these "Centers of Excellence." The centers, in turn, would integrate PDA's variety of services to advance the science and technology in focus. This concept could work the following way: An Interest Group would direct the technical thrust of one of the "Centers of Excellence"; the technical or scientific area would become a topic for PDA meetings; a Science Advisory Board Task Force could be formed to devise a Technical Report or Reports in the area; *PDA Journal of Science and Technology* articles on the topic would be published; and, finally, appropriate training at the PDA Training and Research Institute would be offered.

In essence, PDA already has several "Centers of Excellence": aseptic processing, environmental microbiology and validation, to name a few. I would like to help strengthen these programs and expand to others, such as nanotechnology and Process Analytical Technology. We are limited only by the ideas and enthusiasm of the membership.

Another responsibility I have been given is staff oversight of the *PDA Journal of Science and Technology*. My first official travel for PDA will be to visit the journal's Executive Editor, Professor Lee Kirsch, Ph.D., at the University of Iowa School of Pharmacy (Iowa City). Dr. Kirsch and I will review the results of the first Editorial Board meeting at PDA's Annual Meeting in November 2003. The Editorial Board identified several initiatives to build upon the strengths of the journal and to increase the number and diversity of submissions. Dr. Kirsch and I shall be developing plans for implementation of selected ideas and submit them to the PDA Board of Directors. I plan to report on these next month.

Another responsibility I have been given is staff oversight of the *PDA Journal of Science and Technology*.

I also have been tasked with developing a Graduate Student Research Symposium for the 2005 PDA SciTech Summit. If all goes as planned I shall be able to report on a preliminary program and the selection process in my report next month.

In working with Jim Fernandez and the Scientific Advisory Board, I will be supporting the publication of at least three Technical Reports by the end of the year. Jim and I have already spoken, and we are looking forward to a fruitful collaboration in this and many other areas.

Without a doubt, PDA derives its strength from the membership. I am looking forward to working with you, individually and collectively to continue the excellent scientific programs that are a hallmark of PDA. ■

—George Robertson, Ph.D.

New VP, from cover

From 1977–1983, Dr. Robertson participated in four scientific studies as a postdoctoral researcher:

1) With the Washington State University Department of Veterinary Microbiology and Pathology (Pullman, Wash.), he participated in structural and immunological studies on equine infectious anemia virus envelope glycoproteins. The results were published in *Intervirology* (14: 44–50, 1980).
2) He worked on a study to develop cell culture and immunological assays to monitor expression of endogenous murine retroviruses at the Wistar Institute (Philadelphia, Pa.).
3) The development of immunoassays to monitor host responses to hemorrhagic fever viral antigens was the subject of a study he performed under BL-3 and BL-4 containment at the U.S. Army Medical Research Institute for Infectious Diseases (Fort Detrick, Md.).
4) He returned to the University of Pennsylvania's microbiology department to conclude his postdoctoral studies, looking at the expression of extracellular matrix genes during transformation and differentiation and molecular cloning of core protein of chick chondroblast proteoglycan.

Dr. Robertson received numerous honors for his academic work. He was a National Institutes of Health (NIH) pre- and postdoctoral fellow. He

continues on page 12

New VP, from page 11

received the Sigma Xi Award for Excellence in Graduate Research from the University of Pennsylvania. The National Research Council bestowed its Research Associate Award to Dr. Robertson for his postdoctoral work at the U.S. Army Medical Research Institute.

Following his education and postdoctoral work, Dr. Robertson became the Technical Director of the University of Pennsylvania's Cell and Molecular Genetics Center in the Department of Human Genetics. In this position, he managed the accounts with over 300 clients, supervised seven subordinates, provided technical advice to university researchers, and maintained five collaborative research programs. At the time, the laboratory was exploring the production and screening of hybridomas, screening for expression of oncogenes, and the generation of cDNA libraries using phage vectors and establishment of cell lines.

Dr. Robertson has received recognition from his peers for his excellence in the pharmaceutical and biopharmaceutical industries.

Next, Dr. Roberston joined Cytogen Corporation (Princeton, New Jersey) as Principal Research Scientist. There he managed the cell culture facility that provided the company with characterized tumor and hybridoma cell lines. He performed preclinical cytotoxicity testing of immunoconjugated drugs and radioisotopes. At Cytogen, Dr. Robertson was introduced to cGMPs while conducting cell line characterization, safety testing and scale-up.

Pharmaceutical giant Merck lured Dr. Robertson away from Cytogen. At Merck's West Point, Pa. plant, Dr. Roberston held three positions in seven years, starting out as a Senior Research Virologist and rising to Senior Microbiologist. In the latter role, he was primarily responsible for the development of Merck's Hepatitis A vaccine. He authored and obtained approval for 15 GMP documents for the production, purification, inactivation and filling of the Hepatitis A virus. He established the approved quality standards for the vaccine, its production intermediates and raw materials. Also, his efforts to validate the production and purification of the product resulted in better definition of the Hepatitis A production process. George also developed a method for quantifying Hepatitis A infectivity by reverse transcriptase – polymerase chain reaction to monitor inactivation kinetics by formaldehyde. From 1990 through 1993, Dr. Robertson authored 21 internal technical reports for Merck on topics ranging from Hep-B-Gammagee to black widow spider antivenin quality control.

Moving on, Dr. Roberston returned to Maryland to work for the NCI-Frederick Cancer Research Center as the head of its Monoclonal Antibody/Recombinant Protein Facility. His staff of 15 scientists produced, purified and aseptically filled monoclonal antibodies, recombinant proteins and virus vectors under GMP conditions for use in clinical trials and advanced preclinical testing. A major accomplishment for Dr. Robertson was the successful oversight of every stage in the design, construction, commissioning and validation of a production facility, which included clean rooms and an aseptic hand-filling suite.

After five years at NCI, Dr. Roberston joined BioReliance Corporation (Rockville, Md.). There he took advantage of his previous experience in facility design and construction and managed the design, construction, commissioning and validation of a 50,000 sq. ft., multimillion dollar GMP manufacturing facility for virally-based therapeutics. This facility included clean rooms and an isolator-based aseptic filling suite.

Dr. Robertson most recently worked in the pharmaceutical industry with Wyeth Vaccines in Marietta, Pa. In three years with Wyeth, he rose from Associate Director of QC Bio-Analytical Services to Director of Quality Control charged with managing a 50,000 sq. ft. laboratory and over 120 employees.

Dr. Robertson has received recognition from his peers for his excellence in the pharmaceutical and biopharmaceutical industries. Following a term as a nationally-elected member of the USP Convention (1995–2000) Committee of Revision and of the Bioproducts, Biopolymers and Vaccines Subcommittee, he now sits on the U.S. Pharmacopeia ad hoc committee to revise Chapter <111> Biological Assays. He also served as a Special Consultant on the National Academy of Sciences Institute of Medicine Committee to Assess the Safety and Efficacy of the Anthrax Vaccine.

PDA went through a rigorous screening process to find a highly qualified and motivated candidate for the Vice President, Science and Technology position. Beginning in early September, a "retain search firm" collected resumes from more than 100 qualified candidates. Using a screening criteria provided by PDA, the search firm narrowed the list down and presented PDA with six extremely well-qualified candidates. Following phone interviews with PDA President Neal Koller, three candidates went through a round of interviews with Neal Koller and the President's staff in Bethesda and with PDA board members Nikki Mehringer, John Shabushnig and Richard Levy. Not satisfied, a second search round was launched with over 100 additional well-qualified candidates considered. The ultimate result was the hiring of Dr. Robertson. ■

Interest Group Session Reports from the 2003 PDA Annual Meeting

At the 2003 PDA Annual Meeting in Atlanta, Georgia, various PDA Interest Groups, Task Forces and Discussion Groups met to review current issues and/or report on their progress. The following groups have submitted reviews of their meetings:

Packaging Science Interest Group

Leader: **Edward Smith, Ph.D., Wyeth Laboratories**
Ph: **+1 (484) 865-9254**
Email: **smithej@wyeth.com**

Fifty-one PDA meeting attendees were present for the PSIG meeting. Edward Smith led the discussion, starting off with an update on the international harmonization of USP Chapter <381>, a review of the Oct. 12–15, 2003 USP Open Conference on Packaging, Storage, and Distribution, and concluding with a discussion of extractables and leachables.

In discussing the harmonization of <381>, Dr. Smith reminded attendees that the tests in the Chapter "are to be used for initial screening purposes and are not intended to serve as the sole evaluation criteria for the selection of an elastomeric closure for a specific drug product." Following a review of the proposal, he presented the PSIG's response:

- Letter summarizing PSIG comments sent to PDA 5 March 03; letter with comments sent by PDA to USP 27 May 03.
- USP responded to PDA 20 August 03. Accepted virtually all recommended improvements.
- Individual companies have also submitted comments. USP also responded to these companies.
- The revised USP<381> will appear shortly in the *Pharmaceutical Forum*.

(Note: Ed Smith's complete presentation and the following two presentations are available at: www.pda.org/membersonly/PDF/IGs/PackagingScience/2003-01-AnnMtg.pdf).

Next, Michael N. Eakins, Ph.D., founder of and principal consultant for International Consultants to the Device and Pharmaceutical Industries, discussed "Cyclic Olefins as a Clear Alternative Plastic for Pharmaceutical Packaging." As part of the presentation, he outlined important developments and considerations:

- New cyclic olefin polymers have been developed for use as pharmaceutical containers.
- An increasing number of container vendors will offer vials and pre-fillable syringes in cyclic olefins.
- Development of drugs in cyclic olefin containers requires the cooperation of the plastic manufacturer and/or the container vendor with the drug company.
- The use of consultants familiar with the development and registration of drugs in plastic containers, particularly pre-filled syringes, can greatly assist the drug development process.

Finally, attendees at the PSIG meeting heard a presentation on "Performance Qualification of a New Drug Container and Sterile Filling System" by Bob Myers Beacon Pointe Consulting; Dave Matsuhiro, Aseptic Concepts; John Guthy, Medical Instill Technologies; and Jim Agalloco, Agalloco & Associates.

The four PDA members were involved in a study to determine the ability of an innovative closed drug container and sterile filling system to maintain sterility in an operational situation. The contributors developed an evaluation plan with an aseptic simulation demonstration run that represented a rigorous challenge to the system. The work was carried out at the PDA Training and Research Institute in Baltimore, Maryland.

The presenters listed the following results:

- The InTact™ Vial and Filling System passed performance qualification testing including:
  —Three 10,000 + media fills
  —No contaminated units
- Container closure integrity tests were successful
- No elastomeric particles were observed.

Other Observations:

- Closed vial system reduced chance of contamination(Interventions, training were planned to represent worst case)
- Sterile preassembled containers reduce number of operations
- Overall reduction in system complexity
- Faster system installation and validation.

Conclusions:

- The InTact Closed Vial and Filling System can be quickly validated for filling of sterile drugs
- The InTact closed vial system reduces risk of contamination in filling operations
- The InTact System eliminates several processing steps, thereby reducing complexity and costs.

The Packaging Science Interest Group will next meet at the PDA SciTech Summit™ March 8–12, 2004 in Orlando, Fla. (*see cover*). Since the SciTech Summit represents the merger of the traditional Spring Conference and the autumn Annual Meeting, PSIG agreed to meet, starting in 2004, each spring at the SciTech Summit and each September at the PDA-FDA Meeting. ■

Recent Sci-Tech Discussions

"Media Fills" and "Occupancy Calculation" and "Validation of Analytical Procedures"

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: "Media Fills"

I have a few doubts that the group could kindly help me with. If I have limitations on my injectable filling speed can I extend the duration of my filling time to 2 sessions in one go, i.e. 16 hours instead of an eight hour shift? I of course will have to do an appropriate media fill validation. But are there any special concerns for this extended aseptic filling process? Any special approaches to the validation? I would appreciate any references to any guidelines as well.

Response 1

One Point - Sterilizing Filter

If the process results in extended time for sterilizing filtration, you would need to pay special attention that the filter is effective for the duration of the time it is used. You would need to validate extended hold times for in-process materials. Other points to consider would depend on your process. I am not aware of guidelines that would clarify what you should do to JUSTIFY your specific process.

The regulatory approach is really quite simple in an intellectual sense. You do not ask "What the Regulator Wants". You determine what you must do, on basis of science and technology, to support and justify the suitability of the process and efficacy of your sterilization process. Then make the case, in writing, in an appropriate report that clearly demonstrates, on the basis of YOUR validation protocol, that the process meets regulatory requirements.

Response 2

What is the product? If it is dry vial injection, what type of pump you are using for media filling? I think if you choose the right pump this problem may not be there.

Also please check what is the number of vials filled during one shift? Are you able to complete one batch of standard b.size within a single shift? If not then you can do media fills separately for two shifts. Extending duration of media fill to 16 hrs will be very difficult to control since you may not be able to control the microbial and particulate environment. You may also not get desirable results. You can refer PDA technical reports on validation of aseptic processing.

Response 3

In the case of media fill validation, you have to cover not only regular shift but also the extended or second or third shift if at all your regular production also continues to second or third shift. Second, media preparation for media fill run should not be prepared more than what is regularly consumed in the regular shift just to cover the second shift by extending its filling time or keeping media fill stopped to continue in the second shift too. The best way is to use new media and start filling in the second shift rather than using the left over or kept over media from the second shift. In short, media fill should also encompass all the shifts if regular injectable filling process regularly continues beyond regular shift. Remember media fill is nothing but filling the media, synchronizing regular production and its practices, no artifacts are allowed.

Question 2: "Occupancy Calculation"

I would like to know what "Occupancy calculation" of RMG/Blender is. How to calculate it? Is there any reference material to study about any where?

Response 1

When different materials having different bulk densities and particle size distribution are mixed together, the occupancy or void space is an important parameter for efficient/homogeneous mixing.

In RMG, mixing is by mechanical force and hence occupancy is not a critical factor. Care must be taken such that material will not come out during dry mixing or wet mixing. However the minimum occupancy should be such that during wet mixing or granulation the chopper should be covered by material. In general the occupancy may be between 50–85% v/v.

Coming to blenders the mixing efficiency depends on shape also. I have experience in cylindrical, double cone, and octagonal blenders having formulations with 2–5% of active ingredient. In cylindrical and double cone blenders the optimum occupancy can be between 40 to 65% v/v. In octagonal blenders the occupancy can be between 35 to 75% v/v, however one has to demonstrate the homogeneity through uniformity

and "Thioglycollate" and "Vent Filters"

of content and RSD.

To calculate the occupancy you need the following information.

1. Overflow capacity of the equipment
2. Untapped bulk density
3. Batch size in kilograms

% Occupancy = [(Weight of materials / bulk density) / Over flow capacity of mixer in liters]* 100

Response 2

From my experience the approximate blend time (min) corresponding to volume% of rapid mixer granulator is equal to cube root of the volume%.

Question 3: "Thioglycollate"

Re- sterility test BP2003

Please help a lowly chemist struggling with the logic of a microbiological issue

Validation test requires thioglycollate media to be validated with the 3 aerobic and 1 anaerobic organisms and soy-bean media to be validated with the 2 fungi, BUT under culture media, thioglycollate is primarily intended for anaerobic (but will detect aerobic) bacteria, and soy-bean is primarily for aerobic bacteria (but will detect fungi). Surely the validation species should be matched to those they are intended to detect? i.e. why is the soy-bean media not validated with an aerobe?

I have noted that under growth promotion test, thioglycollate is tested against an anaerobe and an aerobe and soy-bean is tested against a fungi and an aerobe (it appears this specific organism to media match was introduced in 2000, as it was not in BP1998).

Response 1

Anaerobic media fills are rare in the industry. Unless your product is filled in an isolator filled with nitrogen or other inerting gas, there is really no need to do an anaerobic media fill, even as low as 0.5% oxygen will inhibit (kill) anaerobic growth. Using SCDM for all media fills and replacing any product inerting gas with air delivered through the same delivery system will work in virtually every instance.

Response 2

Many inspectors have asked for anaerobic media fills for lines that manufacture oil based products, where anaerobes would be likely contaminants.

Question 4: "Validation of Analytical Procedures"

The precision of an analytical procedure is usually expressed as the variance, standard deviation or coefficient of variation of a series of measurements. My question is there a maximum limits for such attributes in order to qualify that the analytical procedure is precise.

Response 1

You might find the following reference useful:

Analytical validation, Carr G P R and Wahlich, J C. in *International Pharmaceutical Product Registration Aspects of Quality Safety and Efficacy* (Cartwright and Matthews, eds) CPR Press/Taylor and Francis.

Response 2

Precise is an attribute such as 'large', 'small', 'big', 'laud', etc. It needs a reference, a purpose and a number attached to it. An air craft may be considered as being quiet on take off on the airport. The same air craft noise in your living room would not be considered as being 'quiet'.

continues on page 16

Recent Sci-Tech Discussions, from page 15

The standard deviation of a bioassay that may be considered as being 'precise' is not precise is respect of an HPLC assay of a small molecule.

Short: No there is not such a thing as a precise procedure. It can only be precise enough for its purpose or precise than another procedure.

Response 3

Precision is judged adequate with regard to specification or requirement. It cannot be judged adequate without a frame of reference.

See PF, 22(5) in 1996 for Hansen, Zirk and D'Esposito's article entitled "Guidelines for Assessment and Determination of Method Capability" for quantitative explanation.

Question 5: Vent Filters

Please to advice regarding vent filters, we are using stainless steel tanks which are sterilized using steam up to 130 °C at 1.5 bar pressure then cooled down to less than 20 °C. My question: Is it essential (from regulation side) to provide these tanks with Vent filters? And what precautions we have to take to avoid blockage of filters which will prevent compensation with air during cooling down leading to damage of tanks.

Response 1

Vent filters is used for WFI storage tanks where the generation and storage of such water is located in areas where particulates and microbes are not subject to monitoring activities. On the contrary solution storage tanks are located in controlled and classified areas where the preset limits for particulates and microbes are to be observed.

Regarding your second question, filters have to be jacketed to prevent condensate or water from blocking the hydrophobic vent filter.

Response 2

Vent filters are generally located at the high point in a tank. Since the bleeder valve (and generally all valves) is cracked opened during steaming, they allow steam to vent out during sterilization. Without a vent at the high point, you would have difficulty assuring saturated steam throughout the chamber and thus give inconsistent sterility results. After steaming, the vent filter is used to allow air back into the tank as it cools, thus stopping the tank from potentially collapsing. When you are filling the tank with your liquid product, the vent filter allows the release of pressure and allows you to fill the tank. Regarding precautions, contact your filter manufacturer for proper use and applicability of their filters for your purpose, including help in validation. ■

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

USP Update—January, 2004

The first call for candidates for membership in USP Expert Committees has been made in November 2003. The deadline for submitting candidates is November 1, 2004. For additional information on USP Expert Committees, the nomination process, and the names of the various committees consult the USP Web site at www.usp.org. You can apply online as well as by mail. The USP is an authoritative standards-setting organization for drug products and biologics as well as nutritional supplements and excipients. These standards are developed by volunteers on our Expert Committees, which are the decision making bodies. Decisions by the Expert Committees may affect these public standards. The Chairs of our Expert Committees compose USP's Council of Experts. The Chairs are elected for five-year terms by the USP Convention. In turn the Council of Experts elects the members of the various Expert Committees. Nominations as well as self-nomination are being accepted for the 2005–2010 revision cycle.

The *Pharmacopeial Forum* of Nov.–Dec. 2003 contains a large number of proposed new USP and NF monographs generally targeted for the 2nd Supplement of USP 27. USP encourages readers and interested parties to comment on proposals for new monographs and new general chapters, changes to current monographs and general chapters, and for current official monographs. In the in-process section of USP, 15 new monographs are being proposed. In the in-process section of NF, three new monographs are being proposed. In USP, 218 monographs are being proposed for revision while seven NF monographs are proposed for revision.

In the Stimuli for the revision section of PF, a paper by R. Karmarkar and D. Jenke on "Applications of Ion Chromatography in Pharmaceutical and Drug Analysis" describes the principles and instruments for IC and review a number of applications. Few IC procedures are listed in current USP monographs and the authors recommended that additional IC procedures be introduced in USP. Also in the Stimuli section, D. Singer and A. Cundell from the USP Analytical Microbiology Expert Committee discuss the "Role of Rapid Microbiological Methods within the Process Analytical Technology Initiative." The authors identify critical microbiological tests where rapid methods could be applied. ■

—Roger Dabbah, Ph.D.
Director, Complex Actives, USP

Regulatory Briefs

Important Dates

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

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

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

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

U.S. FDA

CDER Publishes Draft Chemistry, Manufacturing and Control Guidance for Drug Substances, Jan. 7. The guidance will replace when final a 1987 "redbook" guideline on the same subject. The draft guidance provides recommendations on the drug substance information to be submitted in new and abbreviated drug and animal drug applications (NDAs, ANDAs, NADAs, and ANADAs).

The guidance provides recommendations on the CMC information that should be included for the following topics:

- Nomenclature, structure, and general drug substance properties
- Manufacture
- Characterization
- Control of drug substance
- Reference standards or materials
- Container closure system
- Stability

The recommendations provided in the guidance apply to the following types of drug substances:

- Drug substances manufactured by chemical synthesis
- Highly purified and well characterized drug substances derived from plants or animals
- Semisynthetic drug substances manufactured by the chemical modification of a highly purified and well characterized intermediate derived from plants or animals
- The synthetic portion of the manufacturing process for semisynthetic drug substances manufactured by the chemical modification of an intermediate produced by conventional fermentation.

The guidance does not provide specific recommendations relating to the following:

- Monoclonal antibodies
- Peptides
- Oligonucleotides
- Radiopharmaceuticals
- Medical gases
- Drug substances that are not well characterized (e.g., botanicals, some proteins) derived from plants or animals

- Drug substances derived using transgenic technology
- Drug substances derived directly from or manufacturing operations involving fermentation (conventional fermentation or using rDNA technology) or tissue or cell culture.

Like the drug product CMC draft guidance published in 2003, the CMC drug substance guidance adheres the format of the International Conference on Harmonization Common Technical Document. A section of the drug substance draft covers regional-specific information required in a CMC submission. FDA is still in the process of reviewing public comments for the drug product draft guidance.(*Note: PDA members in Spain and the PDA European Headquarters have organized a one-day workshop on the CTD. See page 23*).

The drug substance draft guidance covers drug substance manufacture, characterization, control, reference standards, container closure systems, and stability.

Two "attachments" are included with the draft guidance covering "starting materials for synthetic drug substances" and "starting materials of plant or animal origin." Both attachments address post-approval issues. A link to the draft guidance is available on PDA's Web site: www.pda.org.

CBER Announces Revision of the Requirement for Spore-Forming Microorganisms; Companion to Direct Final Rule. The proposal will amend the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. The agency is proposing this amendment due to advances in facility, systems and equipment design and in sterilization technologies that would allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas. FDA is taking this action as part of their continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection.

This proposed rule is a companion document to the direct final published in the *Federal Register*. For further information contact: Valerie Butler, CBER (HFM-17) Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, +1 (301) 827-6210.

The revision of the requirements for spore-forming microorganisms can be found at: www.fda.gov/OHRMS/DOCKETS/98fr/2003n-0528-npr0001.pdf.

The direct final rule can be found at: www.fda.gov/OHRMS/DOCKETS/98fr/2003n-0528-nfr0001.pdf.

EU EMEA

Concept Paper on GMPs for Gene Therapy and Somatic Cell Therapy Medicinal Products published by the EMEA on Dec. 22, 2003. The EMEA states that manufacturers of gene therapies (GT) and somatic cell therapies (SCT) are required to comply with existing EU GMPs, but supplementary regulation is necessary. For GT products, regulations specific to gene delivery systems and potential biohazards "should be added to minimize the potential adverse effects of the deliberate release of genetically modified organisms into the environment," writes the EMEA. For SCT products, additional rules might address "specific measures" to ensure "safety, quality of tissues and cells of human and animal origin." The document clarifies that some EU Member States enforce regulations for these products. The EMEA is circulating a questionnaire to Member States in order to track these rules. An "expert working group" will be assembled to draft Annexes for each product type. The Concept Paper can be found at: www.emea.eu.int/Inspections/docs/337903en.pdf.

"Points to Consider on Xenogeneic Cell Therapy Medicinal Products" published by the EMEA's Committee for Proprietary Medicinal Products (CPMP) on Dec. 17, 2003. The document was officially adopted by the European agency in December and will be official in June 2004. The "points to consider" document is intended to provide "general principles to be taken into consideration for the development and assessment of xenogeneic cell therapy products without prejudice to medical practice or national legislation, which may be applicable." The comprehensive guide covers sourcing of animals, manufacturing, non-clinical testing, human efficacy and safety, and pharmacovigilance and special surveillance methods. The document is available at: www.emea.eu.int/pdfs/human/regaffair/119902en.pdf.

European Parliament Pass EU Pharmaceutical Legislation, Dec. 17, 2003. In its second reading plenary vote on the review of EU pharmaceutical legislation, the European Parliament accepted a package of compromise amendments. This paves the way for rapid adoption of the revised legislation by the EU Council.

It is to be hoped that the long-awaited reform of the EU pharmaceutical legislation will encourage pharmaceutical research, which is vital for new treatments and cures, and will provide more rapid access by patients to medicinal products. Moreover, the EU pharmaceutical legislation is viewed as an opportunity to strengthen the regulatory framework for medicines in an enlarged Europe

The European pharmaceutical industry supported the legislation: "Even though this package does not fully meet the needs of the research-based pharmaceutical industry, we recognize that compromises had to be made", said Brian Ager, European Federation of

continues on page 20

Regulatory Briefs, from page 19

Pharmaceutical Industries and Associations (EFPIA) Director General. "It is now in everyone's interest to avoid any delay to the implementation of this important legislation, which will set in place a pharmaceutical regulatory framework to meet the needs of all 450 million citizens in the enlarged European Union.

"The continuous dialogue between the European parliament, the council and the European Commission has resulted in a set of compromise amendments, which, overall, strike a reasonable balance on many of the important issues in the legislative package," continued Ager. "This package does not fully meet the needs of the innovative pharmaceutical industry. However, we recognize that a compromise had to be found between the interests of the various stakeholders involved. It is now essential to move forward rapidly to set in place a modern, stable and robust pharmaceutical regulatory framework to meet the needs of all 450 million citizens in the enlarged European Union. Consequently, EFPIA believes that the whole legislative package should now be finalized on the basis of the agreed compromises, thus avoiding conciliation and any potential delay to the implementation of this most important legislation."

Health Canada

"GMP Inspection Policy for Canadian Drug Establishments" and the "Drug Identification Number (DIN) Enforcement Directive" became effective Jan. 1, 2004. Health Canada's Health Products and Food Branch Inspectorate released published both "policy documents" in December. The inspection policy document outlines the Inspectorate's "approach to planning and cycles of GMP inspections in relation with the issuance of Establishment Licences." The new policy is based on a number of GMP changes that have occurred since 1996, principally a new establishment licenses regulation, acceptance of Canada into PIC/S, and mutual recognition agreements with the European Community and the European Free Trade Association. The inspection policy applies to all Canadian drug establishments for which an EL is required, excluding blood establishments. Under the policy, fabricators, packager/labelers and testing labs should be inspected every 24 months, and importers, distributors and wholesalers every 36 months.

The DIN enforcement directive provides the Inspectorate "with direction regarding the uniform enforcement of the *Food and Drugs Act and Regulations* as they pertain to Drug Identification Number (DIN) violations." The new "policy document" supersedes a 1998 policy, and applies to all human and veterinary drugs in dosage form for which a DIN is required by law. A DIN is "an eight digit numerical code assigned to each drug product marketed under or in accordance with the *Food and Drugs Act and Regulations*." Denied entry into Canada, recall and seizure are among the enforcement options listed in the Directive. The "enforcement approach" is to focus the Inspectorate's resources at the manufacture and importation levels, rather than at the retail level.

The two documents can be found at: www.hc-sc.gc.ca ■

—compiled by Gautam Maitra, Bill Stoedter, and Walt Morris

Australia Therapeutic Goods Administration

The following is an outline of the new Audit Procedures being used by TGA inspectors following the adoption of the 2003 Therapeutic Goods Amendment Act. This outline was presented by TGA Chief GMP Auditor Tony Gould at the 2003 Australia Chapter Annual Meeting. A full story on the meeting begins on page 23.

New Audit Procedures

- Unannounced audits
- Increased number—some with significant difference in outcome
- Some in response to intelligence, e.g. tip-offs
- Increase in number of tip-offs
- Unless allegation(s) can be discounted they are taken seriously
- As a compromise to all audits being unannounced:
- Notice of audits reduced—max now the week before the audit
- Audit plan will not be provided
- Reasons for postponing an audit will generally not be accepted

- **Audits will be thorough:**
  - Longer—average now 3–4 days
  - Greater use of TGA expertise
  - More time on critical requirements, e.g. validation
  - Bigger sample of records reviewed
  - Rigorous close out—follow up audit if necessary
  - All audits will be subjected to review
- **Changes to audit reporting:**
  - Deficiency Report immediately after the audit
  - Enough time must be allowed for effective exit meeting
  - Audit Report will be prepared after all deficiencies have been closed out
  - Changes in the Manufacturer Assessment Section

Your One Source Validation Company

VTS Consultants, Inc.

One Source. No Doubt.

www.vtsconsultants.com

For further information
and to speak to one of our Directors please contact us at:
VTS Consultants, Inc.
Tel. (508) 870-0007
Fax (508) 870-0224
email: contact@vtsconsultants.com

Computer Validation and Compliance

- Computer Controlled Systems and Software Validation
- Software Quality Assurance Vendor Audits
- 21 CFR Part 11 Compliance Audits

Validation Services

- Turn Key Validation
- Utilities Validation
- Sterile Products
- Solid Dosage Products
- Ointment and Liquid Products
- Quality Laboratories
- Medical Devices
- Cleaning Validation
- Training Services

Regulatory and Compliance Services

- Corporate Compliance Audits
- 483 Issue Resolution
- Consent Decree Compliance Assistance
- Understand Current Regulatory Trends
- Practical approach to solve issues and improve compliance
- BLA / NDA / ANDA Submissions Consulting
- Batch Record Review
- Regulatory and Compliance Consulting

VTS CONSULTANTS, INC.

"Servicing Your Global Validation and Regulatory Consulting Needs."

PDA Chapters Organize Valuable Events on Regulatory Policy

"Practical Experiences and Challenges with the Implementation of CTD in Europe"

An exciting one-day forum on the Common Technical Document has been organized by the PDA Spain Chapter and the PDA European Headquarters. The forum will take place at the Hilton Barcelona Hotel in Barcelona, Spain on March 15, 2004. New perspectives on the CTD will be presented by EMEA, Austrian and Spanish health authorities during the forum.

Senior industry experts from companies like Novartis, GlaxoSmithKline, Aventis, Pfizer and Eli Lilly will also participate. Current developments with the electronic-CTD (e-CTD) will be shared and discussed during the forum throughout the day. Ample time for networking will be provided during panel discussions and breaks. ■

Israel Chapter to Hear Dr. Jörg Neuhaus, March 2

The Israel Chapter is organizing a one-day course on inspections, March 2, 2004. The course will be taught by Dr. Jörg Neuhaus, the recipient of the 2003 PDA award for excellent service especially in relation to his contribution to the PDA Italian Inspectorate Training Program. The course will cover:

- Expectations of a European Inspector
- How to prepare a PIC/S Site Master File
- How to prepare for an inspection with special emphasis to aseptic manufacture
- Q & A, panel discussion.

This conference is part of an overall strategy to bring Israel under the PIC/S umbrella. ■

Australia Chapter Annual Meeting Addressed Amended Pharmaceutical Legislation

The PDA Australia Chapter had a very successful annual meeting on Nov. 25, 2003, in Melbourne. Over 100 PDA members assembled to hear a discussion of the 2003 Australian Therapeutic Goods Amendment Act and PDA President Neal Koller's overview of PDA's worldwide accomplishments in 2003 and the association's 2004 goals.

The industry perspective of the 2003 Therapeutic Goods Amendment Act was provided by Louise White, Senior Consultant, SeerPharma. Ms. White has over 20 years experience in the pharmaceutical industry, specializing in manufacturing, production planning and quality assurance. She is an expert in Australian (national) and international requirements for cGMPs.

The 2003 law amends the 1989 Therapeutic Goods Act by tightening the requirements on manufacturers and sponsors of therapeutic goods to further ensure the quality, safety and efficacy of products supplied in Australia or exported from Australia.

The Therapeutic Goods Administration (TGA) notes that the revision grew out of a recent incident involving the failure of a manufacturer to meet GMP requirements and the difficulties encountered in quickly identifying affected therapeutic goods for the purposes of a recall. That case highlighted the need to more clearly define the responsibilities and obligations of both sponsors and manufacturers of therapeutic goods, and the need for such persons to be held more accountable for their statutory responsibilities and obligations.

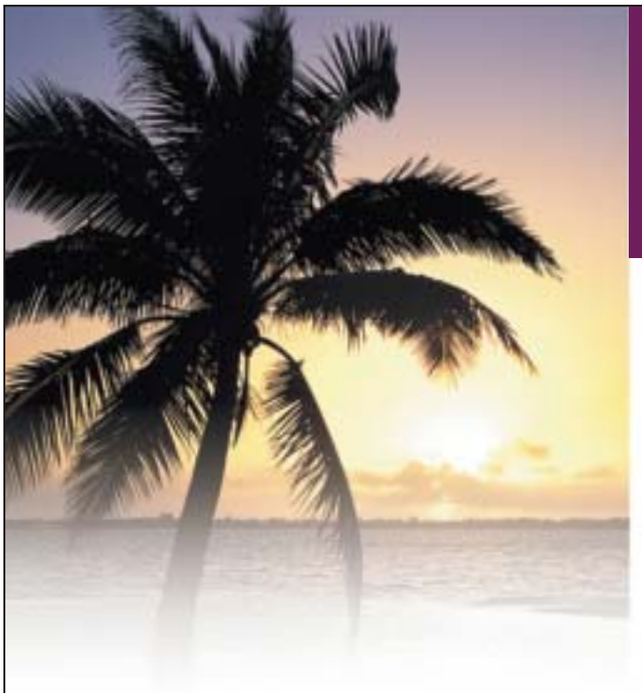
The purpose of the revision is to strengthen the offences and penalties portion of the Act in order to provide a more adequate deterrent to breaches of standards and other statutory requirements designed to maintain the safety and quality of therapeutic goods.

Ms. White outlined a number of the new offences in the law, including: falsification of any document created, retained or issued for the purpose of the Act; and supplying goods from a manufacturer or manufacturing site not notified to the secretary.

The law also contains expanded compulsory public notification and recall provisions and lists new requirements for drug license sponsors. Many of the new requirements are tailored toward tighter control over manufacturing and better tracking of drug products. For example, sponsors are now expected to maintain records of all manufacturing, have them available for inspection at any time, notify TGA of any change, and provide for better identification of therapeutic goods in event of recall. Furthermore, the law calls for improvements to adverse event reporting for listed products.

Ms. White maintained that the 2003 law demonstrates a "much stronger focus on compliance with the Marketing Authorisation."

continues on page 25



Had enough of winter?

Join us in sunny *Orlando, Florida!*

MARCH 8-12, 2004
ORANGE COUNTY CONVENTION CENTER

This March, PDA and CleanRooms Group are teaming to bring the pharmaceutical manufacturing and contamination control communities the science, technology and regulatory event of the year.

PDA SciTech Summit™ • March 8-11

First-Time Scientific & Technology Sessions:

- The Future of Pharmaceutical Manufacturing
- Nanotechnology
- Process Analytical Technology
- New Filling Technology

QA/Regulatory Updates:

- Pharmacopieal/National Requirements to Approve Plastic Containers
- Emerging Issues in Drug Development: European Regulations for Investigational Medical Products

New, Innovative Training Courses • March 10-12

- Design and Validation of a Cleaning and Disinfection Program
- Computer Network Infrastructure (CNI) Qualification Using C3Q™

CleanRooms East Conference & Exhibition • March 8-10

New Contamination Control Sessions:

- EH&S Focus: Cleanroom Facility Decontamination/Decommissioning
- Modular Cleanroom Construction for cGMP Facilities
- Water System Design for Clean Scientific Laboratory Facilities
- Cleanroom Design/Construction: Where Does the Money Go?
- The Evolution of the Gravity-Free Cleanroom

PDA SciTech Summit™ & CleanRooms East Exhibition • March 9-11

See the latest state-of-the-art tools and technologies for pharmaceutical manufacturing and contamination control. Exchange ideas and success stories with a high-level group of professionals and management executives all interested in pharmaceutical, biopharmaceutical and contamination control issues.

For exhibit and sponsorship opportunities, e-mail Nahid Kiani at PDA, *Kiani@pda.org* or Richard Arzivian at *CleanRooms*: *dicka@pennwell.com*.

Also Featuring:

Career Center ◆ Golf Tournament
Networking Receptions
… and a chance to take home an exciting grand prize giveaway!

For complete event dates and to view conference agenda and course descriptions, visit *www.pda.org* or *www.cleanrooms.com* today.

To register or for additional information call toll free: +1 (888) 299-8016 or +1 (918) 831-9160

Australia Chapter Meeting, from page 23

Since the law has been in effect, she stated, the number of inspectors and the number of inspecting days "has risen rapidly." Therapeutic Goods Administration (TGA) inspectors are conducting more "unannounced audits" and are going into greater depth. Wording on audit reports is more detailed and the implications of the wording is "stronger," she said.

Ms. White's full presentation, including her evaluation of other developments in Australia and the evolving regulatory systems in other countries, can be found at the PDA Australia Chapter Web site: www.pda.org/chapters/australia/contact.html.

The TGA's perspective on the new law was provided by Chief GMP Auditor Tony Gould, who focused mostly on the law's qualification/validation provisions.

Mr. Gould also highlighted common GMP issues found by TGA inspectors during audits. Regarding the sampling and testing of materials, inspectors typically cite firms for: not sampling every starting material container; invalid reference materials; test methods not properly validated; electronic raw data not properly retained; reduced testing without justification and control; GMP audit issues; failure to perform content uniformity testing; starting materials not tested on the basis of "release" by unlicensed contract giver; and inadequate lab resources.

TGA inspectors routinely cite manufacturers for inadequate "organizational culture," said the TGA auditor. Compliance and QA/QC is the ultimate "responsibility of senior management" and it is a "24/365" endeavor, Gould explained.

Mr. Gould also presented slides outlining the new TGA audit procedures (*see page 20*). His presentation is also available at the PDA Australia Chapter Web site.

The 2003 Therapeutic Goods Amendment Act sends the unambiguous message that "every batch of every product must be made in compliance with GMP requirements," declared Mr. Gould.

In conclusion, Mr. Gould reminded meeting attendees that the TGA is "committed to maintaining a healthy, constructive relationship with industry" and that together they share the "common objective" of ensuring a "healthy manufacturing industry producing quality medicines."

PDA President Neal Koller provided a detailed overview of the association's 2003 worldwide accomplishments. Each accomplishment, he noted, is directly linked to one of the six strategies outlined in ***PDA's Strategic Plan*** which ensures that PDA membership remains one of the most fulfilling and valuable to professionals in the pharmaceutical and biopharmaceutical industries. A detailed discussion of the 2003 accomplishments and what can be expected in 2004 was also provided in the December 2003 *President's Message*, available in the *PDA Letter* (Dec. 2003) and separately at www.pda.org/PDF/Pres-Messages/2003/12-2003-Koller.pdf. ■

Your Source For Micro Services

Lancaster Laboratories has been providing quality microbiological services with personal attention to clients' requirements since 1961. With our comprehensive scope of services, experienced microbiologists, and large capacity, we can handle all your microbiological testing needs.

Lancaster Laboratories

To find out more about any of our extensive pharmaceutical capabilities, please contact Pharmaceutical Business Development.

2425 New Holland Pike, PO Box 12425
Lancaster, PA 17605-2425
(717) 656-2300 Fax: (717) 656-3772
www.lancasterlabs.com

Non-Sterile Products

Microbial Limits
Antimicrobial Effectiveness Testing
Bioburden Studies
Water Activity

Sterile Products

Sterility
Endotoxin
Particulate Matter
H_2O_2 D-value Studies
AAMII Sterilization Validation
Microbial Immersion Studies
Media Fills

Method Development

Bacteriostasis/fungistasis
Inhibition/enhancement
Screening for Endotoxin
AET and Microbial Limit
Product Validation

Organism Identification

Fatty Acids Analysis (FAME)
Ribotyping
Mold Identification

Facility Validation Support

Biological Indicators
On-site Sample Collection
Cleaning Validation and Consulting
Process Water Testing
Environmental Monitoring
Endotoxin Indicators

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #534

sartorius

HPLC Chromatogram

What good is a great dry cleaner if it takes 3 months to get your shirts?

Sartorius offers the most comprehensive, documented extractables analysis possible in just 30 days.

30 days

commitment

It's tough enough getting reliable and thorough analysis. Now try getting it in a timely manner. That's where Sartorius Extractables Testing Services comes in.

Sartorius helps you validate with CONFIDENCE® by offering a completely documented analysis that meets or exceeds regulatory guidelines **in just 30 days**. We offer 'model-solvent' testing as well as 'reality-stream' testing using **your** product, **your** process and **your** components - even from other manufacturers. We specialize in complete Validation and Qualification testing that includes: Bacterial Challenge Tests, Integrity Tests, Long-term Stability studies plus adsorption and chemical and biocompatibility testing. Check with us today to get the most thorough, buttoned-up analysis. We make it possible.

For all the details, contact the Extractables Hotline at **1-800-368-7178, ext. 8373**, email **extractables@sartorius.com** or visit **www.sartorius.com**

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

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #401

PDA Chapter Focus: PDA Welcomes Two New Chapters!

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**.

In December, the PDA Board of Directors approved two new PDA Chapters: the France and Puerto Rico Chapters. This brings the total number of chartered PDA Chapters to 23.

The France Chapter was founded following a number of inquiries from PDA's 91 members in France. In Paris on Jan. 13, 2004, the first officers and board for the France Chapter were selected:

- President Jean Louis Saubion, Ph.D. (UFCH-BP);
- Vice President Philippe Gomez (Sartorius);
- Treasurer Jean-Luc Clavelin (Eli Lilly-France); and
- Secretary Christian Renaux (Baxter Healthcare).

The Chapter officers were appointed by the PDA Board of Directors upon the suggestion of the founding members of the France Chapter. In the future, PDA members in France will elect Chapter leaders.

The France Chapter's goals for 2004 include: hold forums where experts from the EMEA, FDA and the French health authority, AFSSAPS, address issues of main concern, and coordinate with the PDA Training and Research Institute to arrange for Web-based training programs. The Chapter is now working toward the development of a PDA European Summit-Regulatory Compliance.

Through the work of PDA staff and officers and active PDA members, the France Chapter has established contact with other already well-established associations, institutions and governmental agencies—most notably the Société Française des Sciences et techniques Pharmaceutiques (SFSTP), A3P, AFSSAPS and EMEA.

The Puerto Rico Chapter was chartered so that PDA can better serve its 150+ members in Puerto Rico.

As was the case with the France Chapter, the PDA Board of Directors appointed the initial officers for the Puerto Rico Chapter:

- President, Silma Bladuell (Wyeth);
- Vice President Jorge Ros (Janssen);
- Treasurer James Feshold (Wyeth);
- Secretary Eliezer Hernandez (Pfizer); and
- Chapter Liaison Faris Yany (ISS).

A group of Chapter "Vocals" (members who participate as part of the Chapter Council) was also named: Victor Batista (LG Scott); Victor Agosto (Millenium); Amaury Torres (Amgen); and Wanda Jimenez (Steris).

The Puerto Rico Chapter's goals for 2004 include holding educational activities throughout the year.

The Puerto Rico Chapter is seeking volunteers to launch its newsletter and Web page. ■

—KiKi Coffman and Walter Morris

Upcoming Chapter Events

March

3: Metro Chapter Meeting, Clark, New Jersey.

15: Spain Chapter, "Practical Experiences and Challenges with the Implementation of the CTD in Europe," Barcelona, Spain.

25: Midwest Chapter, Planning Meeting, Chicago-Northbrook, Illinois

29: Central European Chapter, "Principles and Practical Aspects of Steam Sterilization and Aseptic Processing," Basel, Switzerland.

April

26: Canada Chapter, "Current Regulations and Compliance," Montreal, Quebec.

28–29: United Kingdom Chapter Meeting, London, England.

June

9: Metro Chapter Meeting, Clark, New Jersey.

TBD: **Central European 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: mrvova@leciva.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: (787) 776-4180
Fax: (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: van@bcasj.or.jp
Web site: http://www.j-pda.jp/index.html

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

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

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

Don't miss the closing keynote presentation: **"Imagineering"** presented by the Disney Institute.

SciTech Summit, from cover

of media fills, and risk assessment of microbiological contamination.

The SciTech Summit will provide key information on the most critical issues facing you today. The week-long series of scientific sessions and training courses will provide pharmaceutical and biopharmaceutical professionals with a "one-stop-shop" for training and educational needs. More than 100 presenters will offer expert advice for addressing challenges in the workplace. Expanded opportunities for discovery, discussion and networking include PDA's Interest and Discussion Group sessions.

Featured Sessions:

- Advances in Fluid Processing Technology
- Documentation Prior to Sterility Testing
- Process Analytical Technologies
- Rapid Microbial Methods
- Visual Inspections
- Biopharmaceutical Cold Chain Management
- Counterfeit Issues
- Combination Products
- Microneedle Technology
- Vaporized Hydrogen Peroxide Sterilization Methods
- GMPs in Development/Annex 13

Exhibitors: Take advantage of this exciting event in Orlando, Florida, and increase your brand recognition along with unbeatable visibility for your products and services. What better way to promote your products and services than as a sponsor. Contact Nahid Kiani at +1 (301) 656-5900 ext. 128 for more information.

CleanRooms East/PDA SciTech Summit 2004 Combined Exhibitor List

As of January 6, 2004

Abbott Laboratories
ACCUGENIX
Advanced Cleanroom Microclean
AES Clean Technology
AES-Chemunex Inc.
Afton Developments
Air Filtration Management
Air Liquide - Balazs Analytical Services
Air Techniques International
Alsco-Servitex Corporation
Althea Technologies
American Plastic Technologies, Inc.
American Stelmi
Applied Biosystems
ARAMARK Cleanroom Services
Aramsco
Associates of Cape Cod, Inc.
ATS Automation
Baxter Pharmaceutical Solutions
BD Diagnostic Systems
BD Medical Pharmaceutical Systems
Bellcomb Technologies
Ben Venue Laboratories
Berkshire
Biolog, Inc.
bioMerieux, Inc.
Biopharm International Magazine and Pharmaceutical Executive
Bioprocess International
Bioscience International, Inc.
BioScreen Testing Services
Biotest Diagnostics Corp.
BOC Edwards Pharmaceutical Systems
Burlington Industries
Cambrex Bio Science Walkersville, Inc.
Cardinal Health
Carlisle Life Sciences
Channel Systems Inc.
Charles River Laboratories
Chemtrace Corporation
Chesapeake Biological Laboratories, Inc.
Cintas Cleanroom Resources
Citadel Architectural Products
Clarkston Consulting
Clean Air Products
Clean Air Technology Inc.
Cleanguard.com
Cleanroom Concept Inc.
Clordisys
Comar, Inc.
Compliance Software Solutions Corp.
Connecticut Clean Room Corp.
Contec, Inc.
Cooper Lighting - Fail~Safe
CRB Consulting Engineers, Inc.
Decon Labs, Inc.
Doe & Ingalls of FL, Inc.
Drumbeat Dimensions, Inc.
Duoject Medical Systems, Inc.
DuPont Contamination Control
DuPont Qualicon
Dycem
Eisai USA, Inc.
Ellab Inc.
EMD Chemicals Inc.
ENV Services Inc.
Erland Construction Inc.
FAB-TECH Inc.
Fedders Indoor Air Qulaity
Fisher Container Corp
Fisher Safety
FLEXCO
Gavin Pharmaceutical Services
GE Kaye
Genesis Machinery Products
Gerbig Engineering
Getinge USA
Gordon Cleanroom Products
Grace Engineering & Validation
H.K. Techfloor, Ltd.
Hach Ultra Analytics
HEPA Corporation
Integrated Project Services (IPS)
Intelitec Corporation

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

- PDA Members Only Networking Reception—Monday, March 8
- Reception at Universal Studios—Wednesday, March 10
- Expanded Exhibit Hall: Chance to drive home a Harley Davidson "low-rider!"
- Interest Group and Task Force Discussions

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

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

SciTech Summit includes a comprehensive line-up of PDA Training and Research Institute Courses. For more information see the PDA ***Calendar***, on the back cover.

Join the pharmaceutical and biopharmaceutical manufacturing community in Orlando, Florida, in March 2004. This is one conference you can't afford to miss! ■

Can't-Miss Session:

Don't miss presentations on PAT and current applications for process analytical technologies, including Ali Afnan, Ph.D., FDA, CDER, Office of Pharmaceutical Science, and a presentation on rapid microbial methods by Michael Miller, Ph.D., of Eli Lilly and Company. Other confirmed FDA presenters include: Christopher Joneckis, Ph.D., CBER John Finkbohner, Ph.D., CBER; Christine Nelson, CDRH; and Laurie Norwood, CBER.

View the agenda, topics, speakers and activities planned for each day of the SciTech Summit, by visiting the PDA Web site: **www.pda.org**. Access the agenda or a PDF of the registration brochure with additional highlights and details.

ITW ALMA/Texwipe
J.M. Coull Inc.
Kanomax USA, Inc.
Kenall Lighting
KMI a division of PAREXEL International
L&L Maintenance Company
la Calhene
Lancaster Labs
Learnwright, Inc.
Lighthouse Instruments
Lighthouse Worldwide Solutions
Luwa Lepco Inc.
LymTech Scientific
McIlvaine Co.
Medical Instill Technologies
Microflex
Micronova Manufacturing, Inc.
MicroTest Laboratories, Inc.
MIDI Inc.
Milliken & Company
Millipore Corporation
Minntech FTG
N.I. Teijin Shoji USA Inc
Neslo Manufacturing
Nicomac Inc.
Nikka USA, Inc.
Nilfisk-Advance America
North Safety Products
Northview Biosciences, Inc.
NovaTek
Nuova Ompi
Oak Technical
OCTANORM USA Inc.
Pall Life Sciences
Particle Measuring Systems
Patheon, Inc.
Perfex Corporation
Performance Contracting Inc.
PharmSys, Inc.
Plascore, Inc.
PML Microbiologicals
PortaFab Corporation
Precision Fabrics Group, Inc.
Prudential Cleanroom Services
PSI
Purified minroEnvironments
Quality Air Control
Remel Inc.
Rommelag USA Inc.
Saint-Gobain Des Jonqueres
Sartorius Corporation
SCA THERMOSAFE
Schering-Plough Corporation
Schott forma vitrum
Sci-Tec, Inc.
Seidenader EquipmentSGM Biotech, Inc.
SIMCO Ionization for Electronics Manufacture
Simplex Isolation Systems
SL Pharma Labs Inc.
Space Island Group
Sparta Systems
Specialty Coatings Company
STERIS Corporation
Stern + Stern Industries, Inc.
STS duoTEK
Sure-Torque, Inc.
TAC Americas
Techniglove International
Technovation Systems Inc.
Tiger-Vac Inc.
Total Source Manufacturing
Ultratape Industries
UniClean Cleanroom Garment Services
ValuMax Protective Apparel Mfg.
Veltek Associates
VirTis
VWR International
W.M. Plastics
West Pharmaceutical Services
White Knight Engineered Products
Worklon

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

For the first time, PDA is bringing the quality speakers and relevant programs our members demand to Singapore. PDA members and nonmembers in the Pacific Rim region will greatly benefit from this two-and-a-half day conference Sessions will cover process analytical technologies (PAT), biotechnology, outsourcing, aseptic processing, regulatory affairs, national compendia and international harmonization.

The congress will offer an opportunity for those in the pharmaceutical and biopharmaceutical industry to hear expert presentations from international health authority officials in China, Europe, Japan, Singapore and the U.S. 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.

Sensor technologies and their application to manufacturing processes will be discussed during a "can't miss" PAT session. An overview of existing technologies will be provided by Mark Balboni, Sr. Compliance Consultant at KMI/Parexel. Norman Winskill, Ph.D., Vice President of Manufacturing at Pfizer, will then provide an update on current research on this industry 'hot topic.' Completing the session will be a video presentation by Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science at FDA, CDER.

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.

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. ■

Coming September 20–22, 2004:

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

Omni Shoreham Hotel, Washington, DC

Mark your Calendars for the must-attend PDA Regulatory and Compliance Conference of 2004!
Topics at the conference to include:

- Quality: Enrolling Senior Management in Quality
- Preparing for, Managing and Recovering from Inspections
- 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, Inc., 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. ■

Mark your calendars and register now for the 5th biennial PDA Training Conference:

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

Conference May 16–19, 2004, Courses May 20–21, 2004 at the Westin Rio Mar, Puerto Rico

This conference is intended for cGMP and technical trainers in the pharmaceutical, biotech, medical device, and related industries, and this year promises to be the best yet. For the first time, the conference is being held in the spring to better meet budgetary needs of members.

Participants at this conference will have the opportunity to hear first hand from our distinguished panel of four U.S. FDA speakers which include: Donald Voeller, San Juan District Director; Rebecca Rodriquez, Office of Regulatory Affairs National Expert Investigator; Gail Sherman, Director, Division of Manufacturers Assistance and Training; and Gary German, Director, Division of HR Development. The panel's discussion topics will include: FDA'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 at the FDA district offices.

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 will have over 21 concurrent sessions to choose from covering topics relevant to both new trainers and seasoned professionals. These sessions will cover such topics as curriculum design, innovative classroom techniques, e-learning, training communities, and trainer qualifications. Optional PDA Training and Research Institute courses targeted for trainers follow the conference. Some of the courses to be featured include "Regulation without Motivation: Spark a Change without Shorting your Circuit" and "Maximizing SOPs–An Untapped Resource of Training Solutions." All courses will be instructed by informative and experienced training faculty.

A new feature this year: Everyone who pre-registers will be able to view available speaker handouts in advance on the PDA Web site. While individual participants will be able to attend only four concurrent sessions, all registrants will be able to "participate" in every session when they receive the slide presentations for the entire conference on a computer CD, shipped following the conference.

True to our conference theme, "No Trainer is an Island," we will provide a valuable and informative vendor expo and other opportunities for registrants to interact and network with peers and vendors of training materials and services. A limited amount of space is still available. For more information, contact Nahid Kiani at +1 (301) 659-5900, ext. 128 or go to the PDA Web site: www.pda.org/exhibits/index.html.

We will also feature all of our finalists for the 2004 Trainer's Choice Awards and provide ample opportunity to "hobnob", benchmark, and be inspired by these very creative individuals. The Westin Rio Mar is perfectly suited to integrate the meeting with the exhibits and the networking opportunities.

The last biennial PDA Training Conference, held in Tampa, attracted over 200 trainers worldwide. Based upon evaluations, our 2002 conference was a huge success, and we expect attendance to increase. Register early and we'll see you in Puerto Rico! ■

—compiled by the Training Conference Committee Chair, William O'Connor, Technical Training Manager, Bristol-Myers Squibb Medical Imaging

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

The year's hottest meeting on sterile product manufacturing is happening in Stockholm, Sweden, June 7–8: The 2004 PDA/R³Nordic Conference—Scientific, Industrial and Regulatory Aspects of Clean Products and Devices.

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 focus of the conference will be the scientific, industrial and regulatory aspects of sterile product manufacturing.

Attendees will hear from European and U.S. industry and regulatory experts in sterile product manufacture. The keynote address will be given by the EMEA's Emer Cooke, Section Head, Inspections, who will address 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.

From the U.S. FDA, senior officials, including Anthony Mire-Sluis, Ph.D., CDER, Dan Schultz, CDRH, and Ajaz Hussain, Ph.D., CDER, will present.

Industry experts, including Mats Johansson 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.

A wide array of individuals will benefit by attending this conference, including: manufacturing personnel, laboratory technicians, QA/QC officials, regulatory affairs and validation personnel, and cleanroom design technicians.

Registration for this conference includes lunch at the Stockholm City Hall for all congress delegates. The Stockholm City Hall was built in the early 1900s and the Noble banquet for Nobel Prizes in Physics, Chemistry, Physiology or Medicine and Literature has been held there since 1934. This is a unique opportunity for our congress delegates to experience historic Stockholm!

Check www.pda.org for more details and registration information for the conference. ■

New Course on Network Qualification at the 2004 PDA SciTech Summit™ Orlando Course Series

The PDA Training and Research Institute Orlando Course Series includes a new two-day course titled, Computer and Network Infrastructure (CNI) Qualification Using C3Q™. The Lead Instructor is PDA Training and Research Institute veteran Barbara Meserve, VP of Quality Assurance, AccuLogix.

What is C3Q? "Concurrent CNI Configuration and Qualification" methodology is designed to assure and document the confidentiality, integrity, and availability of a Computer and Network Infrastructure (CNI). While C3Q includes many new techniques, it is founded upon internationally accepted and proven methods from organizations such as ISO/IEEE, ISC2, and CMU/SEI.

At the 2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits, David Weitz, CIO, Covalent Group, provided a case study on the use of C3Q at his firm. His presentation, "Design for Excellence Not Compliance or 'How I learned to stop worrying and love C3Q™,'" is available to PDA members at: www.pda.org/membersonly/Presentations/2003-PDA-FDA/30-Weitz.pdf.

C3Q departs from commissioning event driven philosophy by introducing the concept of "In-Service Qualification" for qualifying CNIs. In-Service Qualification includes rigorous and formal methods to support the CNI requirements of service continuity, accretive deployment, evolutionary upgrades, and "in-place break-fix." The basic qualification rationale includes combining a system-level CNI Qualification with a plurality of sub-system and element Qualifications.

The system-level CNI Qualification coordinates CNI Requirements and the CNI Design through a Qualification/Design/Requirements Matrix (QDRM) that enumerates Qualification Items that are addressed by paragraphs in the Qualification Plan and the Operations Plan. The QDRM is also correlated with a plurality of Qualification Item and Case Matrices that specify, in detail, the various tasks of: installation, surveillance, test, exercise, etc., and the input/output vectors and values used/expected in the Qualification Plan and Operations Plan.

Element-level (e.g. network devices, servers, and workstations) Qualification includes Pre-Service Qualification and In-Service Qualification for all CNI elements. This Qualification begins with a system for establishing rigorous configuration management and formal specification of elements as System, Software, or Equipment "Arrangements." C3Q uses the mechanism of the Specification Control Document to completely specify the elements included in any given Arrangement, and to track element and Arrangement Versions.

C3Q provides for Qualification of System Arrangements by a combination of Pre-Service Qualification and In-Service Qualification tasks. These paired Qualifications include the formal affirmation of vendor claims for design and function, and the inheritance of qualified status for duplicate systems.

C3Q departs from the IQ/OQ/PQ documentation model, replacing it with detailed Configuration History Records and Qualification History Records that are concurrently maintained to document the continued, qualified state of the Arrangements.

For the PDA Training and Research Institute training in March, Ms. Meserve will begin with a lecture defining and describing the basic constructs of C3Q and then jump right into hands-on applications. She will walk participants through the processes of configuring and qualifying a Generic System Arrangement of a scientific workstation and a Specific System Arrangement of a "base build" for a server.

An important note for anyone who would like to attend the C3Q training in Orlando: The course is part of the C3Q Practitioner Certification Program, and presumes that attendees are licensed to use the methodology. Several people have asked to attend the training in order to evaluate C3Q in detail prior to committing to using it. This will be easy to accommodate, because participants will use evaluation copies of the C3Q document set during the training. Attendees will be required to return these at the conclusion of the course.

We hope to "network" with you in Orlando! ■

—Thomas Quinn, President
Hollis Group

Go to **www.pda.org** right now to take advantage of discounted **"Park Hopper" passes** to Walt Disney World, offered exclusively to SciTech Summit registrants.

2004 Aseptic Processing Training

Robert Mello's message will return in March.

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

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

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

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

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

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

PDA Training and Research Institute Thanks the Following...

Sponsors

Atlantic Technical Systems
Becton Dickinson Microbiology Systems
Berkshire Corporation
bioMerieux Vitek, Inc.
Biotest Diagnostics Corporation
Bonfiglioli Pharma Machinery
Cardinal Health
Electrol Specialties Company
Environmental Monitoring Technologies
General Econopak, Inc.
Kaye Instruments, Inc.
KMI, a division of PAREXEL International, LLC
La Calhene, Inc.
Larson Mardon Wheaton
Micro Diagnostics
Micronova Manufacturing, Inc.
MIDI Laboratories, Inc.
Millipore Corporation
Particle Measuring Systems, Inc.
STERIS Corporation
Ultra Analytics
Veltek Associates, Inc.
VWR Scientific Products
West Pharmaceutical Services
Wilco AG

Contributors

Bioscience International
Charter Medical, Inc.
Cole-Parmer
Contec, Inc.
Corning, Inc.
DuPont Tyvek
Eli Lilly & Company
Fedegari
National Instrument Co., Inc.
Perfex Corporation
PML Microbiologicals
Raven Biologicals, Inc.
Sartorius AG
Sievers Instruments, Inc.
Technovation

Upcoming PDA Training and Research Institute Education Courses

Course No.	Title/Topic	Dates
230	**Environmental Mycology Identification Workshop**	February 12–13, 2004 May 13–14, 2004 December 2–3, 2004
322	**Validating a Steam Sterilizer**	March 16–17, 2004
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
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**	May 10–11, 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.

PDA Training and Research Institute Location/Lodging Information

Unless otherwise noted, PDA Training and Research Institute courses are held at the UMBC Technology Center, 1450 South Rolling Road, Baltimore, MD 21227.

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

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

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

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

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

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

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

Holiday Inn Inner Harbor **
+1 (410) 685-3500
+1 (410) 727-6169 – fax

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

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

Marriott Residence Inn BWI
+1 (410) 691-0255
+1 (410) 691-0254 – fax
+1 (800) 331-3131

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

* A discounted room rate is also available from the Holiday Inn—BWI. You must call the number above and mention the PDA Corporate Rate (3-PDA) when making your reservations.
** A discounted rate is available for Holiday Inn Inner Harbor of $99. To receive this rate call the number above and mention the PDA Training and Research Institute Corporate Rate (ID #100196574) when making your reservations. Rooms are based on availability.

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

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

*** no on-site restaurant

PDA Training and Research Institute Registration Form

R
LTR 02/04

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

Address

City State/Province ZIP+4/Postal Code

Business Phone Fax E-mail

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

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

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

2.

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

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

TOTAL _____

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

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

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

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

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

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

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

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

UBS AG Basel Swift Code: **UBSWCHZH40M**

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

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

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

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

Currency conversions available at: www.forex.com/forex_market_commentary.html

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

4. **Please check the appropriate box:** Charge: ❑ MasterCard/EuroCard ❑ VISA ❑ AmEx ❑ Diners Club

Account Number: _____ Exp. Date: _____

Name *(exactly as on card)*: _____

Signature: _____ Date: _____

Billing Address: _____

Federal Tax I.D. #52-1906152

5. **RETURN COMPLETED FORM WITH CHECK OR BANK DRAFT MADE TO:** PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA **FAX CREDIT CARD REGISTRATIONS TO:** +1 (301) 986-1093 (credit cards only)

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

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
Iowa City, IA 52242, USA

Supplier Name	Supplier Product
Access360, Inc.	enRole 4.0 (Provisioning Software)
Agilent Technologies	Cerity for Pharmaceutical QA/QC. Network data system for analytical laboratories.
Alacris, Inc.	idNexus, Alacris products are designed to simplify identity management and maximize trust associated with Public Key Infrastructure (PKI) implementation and security technologies.
Applied Biosystems, Inc.	SQL*LIMS™ Software - Laboratory Information Management System
Automation Tooling Systems, Inc.	Custom programming services for Process Control Software
Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set.
Docent	Docent Learning Management Server Docent Content Delivery Server
Documentum, Inc.	Content Authentication Services (CAS); Documentum eContent Server; Document Control Manager (DCM); GXPharma
Documentum, Inc.	Document WebDAV Server; Document Media Services; Documentum Digital Asset Manager; Document Desktop for Macintosh
Documentum, Inc.	Documentum DocApp Installer; Documentum Administrator; Documentum Application Builder; Documentum DeskTop; Documentum Website Manager; Documentum WebTop; Web Development Kit; Documentum Workflow Manager
Epicentric, Inc.	Foundation Enterprise Server 4.0, which is a tool for coordinating information from disparate sources and for disparate uses.
First Consulting Group, Inc.	Custom information based strategy software, operations improvements, management and integration services
Fisher-Rosemount Systems, Inc.	Distributed Factory Automation, Delta V product line
Foss NIRSystems, Inc.	SLE Near-infrared analysis of chemical and physical properties
GE Kaye Instruments, Inc.	Thermal validation systems, monitoring systems, thermocouple references and turbine temperature monitoring equipment—LabWatch™, ValProbe™ and the Validator®2000 systems.
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 a cross the enterprise, regardless of location, language, or file format.
Innovatum, Inc.	DataThread™—Data audit, workflow, 21 CFR Part 11 and E-signature solution for AS/400 applications, without programming changes.
Interwoven, Inc.	Web Publication Management
Lexign Corporation	Lexign Flow™ EPR Software
LoftWare, Inc.	Loftware Print Server (LPS) Lable Printing System
MARC Global Systems	Warehouse Execution Systems
Merant	PVCS Dimensions & PVCS Replicator Software Configuration Management Tool
Mercury Interactive	Test Management Tools: QuickTest Professional; Astra QuickTest; Astra LoadTest; Astra FastTrack; LoadRunner; LoadRunner TestCenter; TestDirector; WinRunner
Propack Data GmbH	Enterprise Production Management System, PMX 3.2 with Solutions MES and CTM.
Rational Software Corporation	Rational Suite® Enterprise Rational ClearQuest (for team-based change request and defect management) Rational ClearCase (configuration management for smaller development teams)
Serena Software, Inc.	Serena ChangeMan Automating the Software Lifecycle
Sparta Systems, Inc.	TrackWise®. Training, Configuration, Installation and Support for TrackWise®.
SSA Global Technologies, Inc.	Mid Range ERP software for manufacturing, supply chain and financial application domains.
The Sycamore Group	Custom IT Solutions. Integration suite of COTS products and services to bridge data across multiple internal computer systems, including e-Commerce, LIMS, ERP, enterprise databases, mainframes and wireless and portable devices.
Waters Corporation	Empower™ chromatography software and Connections AQT - HPLC System, System Components, Data Management

PDA Membership Application

M

LTR 02/04

Return your completed PDA membership application, with check or bank draft payment made to: PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA; **Fax Credit Card payments to:+1 (301) 986-1093**.

❑ Mr. ❑ Ms. ❑ Dr. Last Name _____

First Name _____ MI _____

Job Title _____

Company _____

Address _____

City _____ State/Province _____

Country _____ Zip+4/Postal Code _____

Business Phone: _____ Fax: _____

E-mail: _____

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

Join PDA today and save up to 50% on training courses, meetings, conferences!

Plus…

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

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

Payment (*Membership fees are nonrefundable and nontransferable.*)

❑ Individual Membership: ❑ $195 U.S.

❑ Government Agency Employee Membership: ❑ $80 U.S. *(Must be an employee of a government agency or health authority.)*

Business Environment (check only one)

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

Professional Interest (check all that apply)

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

Note for U.S. members:
PDA dues are not tax-deductible as charitable contributions under the Internal Revenue Code of the United States. However, the dues may be deductible as ordinary and necessary business expenses.

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

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

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

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

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

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

UBS AG Basel Swift Code: **UBSWCHZH40M**

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

- ❑ CHF: Account No. 292-568-280-01F
- ❑ EUR: Account No. 292-568-280-60Z
- ❑ GBP: Account No. 292-568-280-61W
- ❑ USD: Account No. 292-568-280-62Q
- ❑ YEN: Account No. 292-568-280-63Y

Please reference code: **DUES**

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

Currency conversions available at: www.forex.com/forex_market_commentary.html

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

4. **Please check the appropriate box:** Charge: ❑ MasterCard/EuroCard ❑ VISA ❑ AmEx ❑ Diners Club

Account Number: _____ Exp. Date: _____

Name *(exactly as on card)*: _____

Signature: _____ Date: _____

Billing Address: _____

Federal Tax I.D. #52-1906152

5. **Return completed form with check or bank draft made to:** PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA **Fax Credit Card Payments to:** +1 (301) 986-1093 (credit cards only)

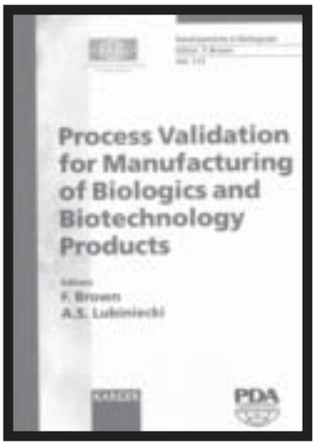
PDA USE:
Date: _____ Check: _____ Amount: _____ Account: _____

NEW Technical Books

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

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

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

- ***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**

PDA-DHI Press Selected Books

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

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

Excellence Through Validation U.G. Barad: Written for a global pharmaceutical manufacturing audience, this book provides well-researched guidance in useful validation practices and standards that were developed by comparing various US regulations from the FDA, EU, EMEA, MCA, Swissmedic, TGA, WHO, the gulf countries MOH, and the FDA in India; guidelines developed by PDA, GAMP, and ISPE; international standards from ISO, IEEE, ICH, and PIC; actual practices followed by more than 15 well-established multinational pharmaceutical companies. New managers and executives will find the help they need in this guide to quickly gain access to what is expected from demanding and growing validation topics worldwide. Intermediate users will find the book a practical reference for every day use, and beginners will use this book as a prescription and guide as they prepare for their career. This concise book is a compilation of the author's more than 20 years of practical experience working with leading multinational pharmaceutical companies and with various regulatory authorities' requirements. Divided into 14 logical sections, it covers all the requirements for achieving total excellence through validation. 2003; 336 pp; ISBN #1-930114-58-3; $160 members/$199 nonmembers; hardcover **Item No. 17205**

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

JUST RELEASED

Laboratory Validation: A Practitioner's Guide, Edited by Jeanne Moldenhauer: In recent years, regulatory inspections have focused on laboratory testing performed to assess the quality attributes of a product. In many cases, the testing is so specialized or complex, that the entire responsibility for validation has been transferred to the laboratory personnel. This excellent, three-part guide provides an overview of validation from a laboratory perspective. Part 1 includes an overview of many of the laboratory support systems and equipment common to both microbiology and chemistry laboratories. Part 2 is dedicated to systems applicable specifically to the chemistry laboratory. Part 3 covers the systems applicable to microbiology laboratories. Where the laboratory predominantly performs—the test—for example, cleaning and disinfection, requirements are included within the text. The book offers validation details representative of the most common types of laboratory systems, yet the information in these 38 chapters will likely be of great assistance in providing resources for compilation of requirements for all other systems. 1,224 pp; hardcover; $250 member/$309 nonmember **Item No. 17201**

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

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

YOUR LIBRARY IS INCOMPLETE WITHOUT THEM!

ORDER TODAY!

To Order, use form on Page 45.

The easiest way to order a PDA book or other technical & regulatory resource is by logging on to PDA's new **E-store**.

REMEMBER: You can search the E-store by author, title, publication type, key word(s), item number, or publication category.

JUST GO TO www.pda.org/pubs/publications/publications_search.asp

Selected PDA Technical Reports

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

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

Technical Report No. 13 (REVISED 2001) Fundamentals of a Microbiological Environmental Monitoring Program 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**

PDA Technical Resource Order Form

S
LTR

Use this form to order PDA Technical Resources. If ordering by mail, include a check payable to PDA to the address below. Be sure to include shipping and handling charges in the total. If ordering by fax, please include all credit card information. All orders must include payment. Prices are subject to change at any time.

❑ Mr. ❑ Ms. ❑ Dr.

Name _____ Member No. _____

Company _____

Address _____

City _____ State _____ Country _____ Zip+4/Postal Code _____

Tel: _____ Fax: _____ E-mail: _____

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

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

Item No.	Title	Qty.	Price	Total

Shipping & Handling Rates—Domestic U.S. orders are shipped via UPS Ground. Second-day and next-day air service is available. Call or e-mail for prices.

International orders

Please add 20%, minimum $18.00, maximum $150.00. Items are sent priority air, with delivery in 3–8 weeks, but express service is available for some countries; please call for details.

U.S., Puerto Rico & Canada

If your order totals:	*Add:*
$15.00 and under	$5.95
$15.01–$75.00	$7.95
$75.01–$150.00	$9.95
$150.01–$250.00	$11.95
$250.01 or more	$13.95

Subtotal	
Shipping & Handling	
5% Tax *(Maryland residents only)*	
TOTAL	

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

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

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

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

❑ C. **Wire Transfer Payments**/By bank-to-bank transfer to: (required if paying in foreign currency; Contact Janny Chua at +1 (301) 656-5900 ext. 133 or chua@pda.org for quotes in various currencies.)

UBS AG Basel Swift Code: **UBSWCHZH40M**

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

❑ CHF: Account No. 292-568-280-03Z
❑ EUR: Account No. 292-568-280-68L
❑ GBP: Account No. 292-568-280-69R
❑ USD: Account No. 292-568-280-70P
❑ YEN: Account No. 292-568-280-71K

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

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

4. **Please check the appropriate box:** Charge: ❑ MasterCard/EuroCard ❑ VISA ❑ AmEx ❑ Diners Club

Account Number: _____ Exp. Date: _____

Name *(exactly as on card)*: _____

Signature: _____ Date: _____

Billing Address: _____

Federal Tax I.D. #52-1906152

5. **Return completed form with check or bank draft made to:** PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA **Fax Credit Card Payments to:** +1 (301) 986-1093 (credit cards only)

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

Calendar of Events, from back cover

June 28, 2004
PDA EuroForum
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
Location TBA
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 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

September 27, 2004
PDA EuroForum
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

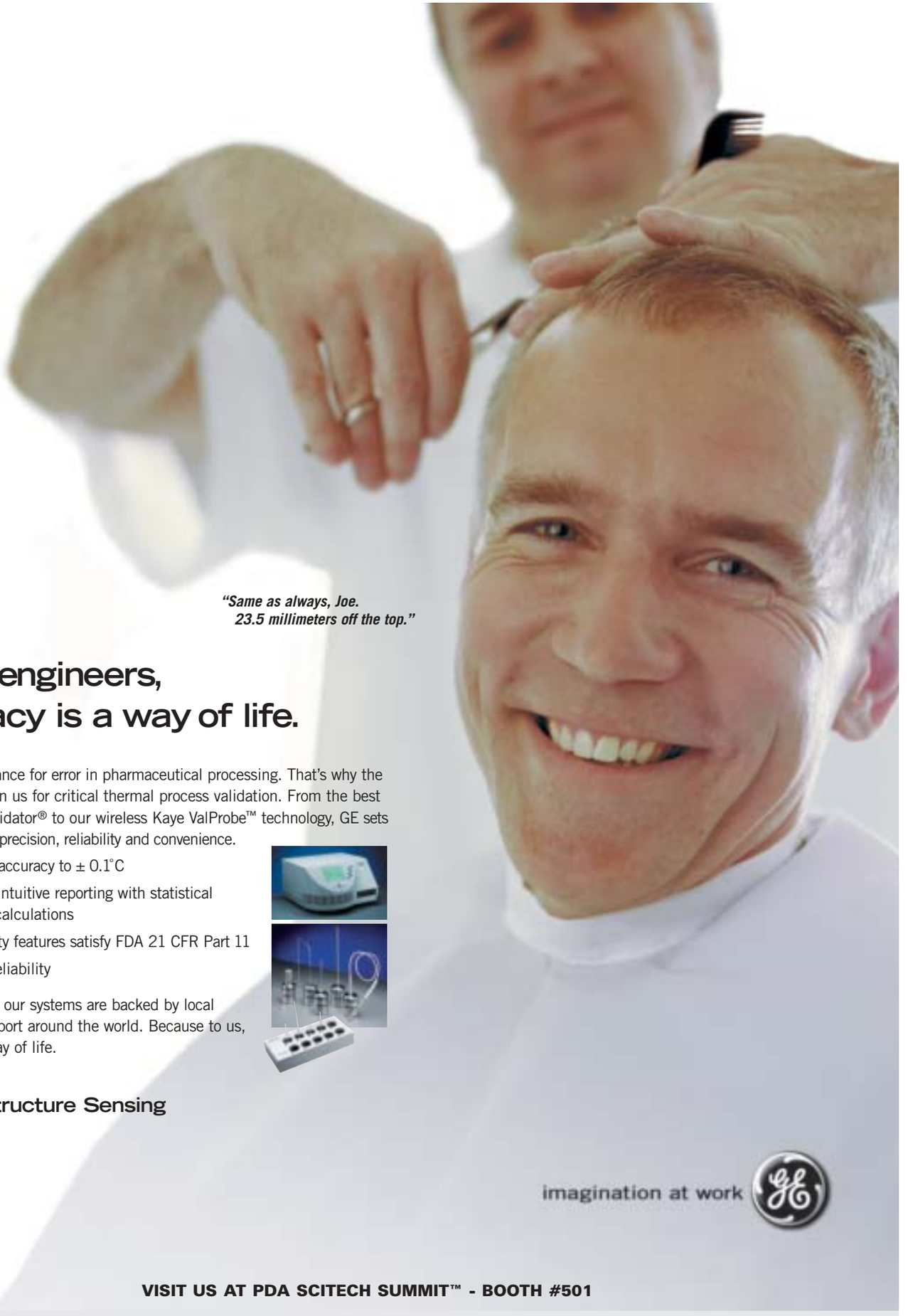
October

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

October 14–15, 2004
PDA Training and Research Institute Laboratory Course
Fundamentals of D, F, and z Value Analysis
PDA Training and Research Institute, Baltimore, MD

October 18–22, 2004
PDA Training and Research Institute Laboratory Course
Rapid Microbiological Methods
PDA Training and Research Institute, Baltimore, MD

October 25–27, 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



"Same as always, Joe.
23.5 millimeters off the top."

To our engineers, accuracy is a way of life.

There's no tolerance for error in pharmaceutical processing. That's why the industry relies on us for critical thermal process validation. From the best selling Kaye Validator® to our wireless Kaye ValProbe™ technology, GE sets the standard for precision, reliability and convenience.

- Measurement accuracy to ± 0.1˚C
- Powerful, yet intuitive reporting with statistical and lethality calculations
- System security features satisfy FDA 21 CFR Part 11
- Unmatched reliability

Of course, all of our systems are backed by local service and support around the world. Because to us, accuracy is a way of life.

GE Infrastructure Sensing

imagination at work

VISIT US AT PDA SCITECH SUMMIT™ - BOOTH #501

Formerly GE Kaye
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

March

March 8–12, 2004
PDA SciTech Summit™
Conference: March 8–12
Courses: March 10–12
Exhibition: March 9–11
Orlando County Convention Center, Orlando, FL
PDA Training and Research Institute Lecture Courses:
March 10:
Achieving CGMP Compliance During Development of a Biotechnology Product
Design and Validation of a Cleaning and Disinfection Program
Designing, Monitoring and Validation of HVAC Systems
Environmental Monitoring in Pharmaceutical Manufacturing
March 11–12:
A Practical Approach to Aseptic Processing & Contamination Control
Bioassay Development and Validation
Compliance Auditing of Cleanrooms and Controlled Environments
Computer and Network Infrastructure (CNI) Qualification
Using C3Q™ Sterile Pharmaceutical Dosage Forms: Basic Principles

March 15, 2004
PDA EuroForum
Implementation Challenges of CTD
Hilton Barcelona Hotel, Barcelona, Spain

March 16–17, 2004
PDA Training and Research Institute Laboratory Course
Validating a Steam Sterilizer
PDA Training and Research Institute, Baltimore, MD

March 22–26, 2004
PDA Training and Research Institute Laboratory Course
Aseptic Processing Training Program—Week 1
PDA Training and Research Institute, Baltimore, MD

March 29, 2004
PDA EuroForum
Principles and Practical Aspects of Steam Sterilization and Aseptic Processing
UBS Ausbildungs-und Konferenzzentrum
Basel, Switzerland

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 19–21, 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 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 & Golf Club, Puerto Rico

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

May 24, 2004
PDA EuroForum
Location TBA
Amsterdam, The Netherlands

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

June

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

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

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

continues on page 46

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