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PDA CHAPTER NEWS

DECEMBER 2003

UPCOMING MEETINGS / COURSES

February 4-6, 2004

The Lake Tahoe Course Series

PDA Training and Research Institute:

www.pda.org/PDF/TRI-Courses/TRI-04-Tahoe-Bro.pdf

February 16-20, 2004

2004 PDA International Congress, Courses and Tabletop Exhibition:

Congress and Exhibition: Feb. 16-18

Training Courses: Feb. 19-20

Messe Basel Convention Center
Basel, Switzerland

www.pda.org/PDF/Meetings/04Basel-Bro.pdf

March 8-12, 2004

2004 PDA SciTech Summit™

co-located with CleanRooms East:

PDA Conference/Exhibit: March 8-11

PDA Courses: March 10-12

CleanRooms East Conference/

Exhibits: March 9-11

Orange County Convention Center
Orlando, Florida

www.pda.org/calendar/index.html#scitechsummit04

HELPFUL LINKS & UPDATES:

- Missed an edition of *PDA Chapter News*? PDA members can read them all at www.pda.org

Want to learn about the Japan Chapter? See "Chapter Focus" in the December PDA Letter!

PDA INTEREST GROUPS FLOURISHING

Recently, there has been a groundswell in the number of "interest groups" organized by chapter members in various PDA regions. These groups are formed to better address specific needs of members.

The Delaware Valley Chapter, for example, supports four separate interest groups: Computer Systems; Environmental Monitoring, Disinfection and Media Fills, Quality Assurance and Inspection Trends, and Visual Inspection of Parenteral Products (VIPP).

The Delaware Valley Chapter VIPP interest group is particularly active. Meeting four to six times a year, the members primarily discuss manual and automated inspection systems for liquid and lyophilized parenteral products.

"There are about 20 members and we welcome anyone interested in this topic," explains VIPP Interest Group leader Jason C. Mattis, Associate Scientist, CTS Parenteral Manufacturing. The group's goals are "to have one

presentation a year from an industry expert" and "to provide an insight on visual inspection within industry standards," he says.

Chapter-sponsored interest groups like the Delaware Valley's VIPP are often subgroups of official PDA Interest Groups, which are important vehicles for PDA members to share common experiences and to learn from each other about specific topics. These groups generally facilitate the exchange of information, serve as good networking opportunities, and provide an excellent avenue for members to become involved in PDA. They also are the source of PDA Task Forces, which typically comment on regulatory guidances, develop PDA Technical Reports, perform studies/surveys, and/or produce other types of work products.

Any PDA member can join one or more interest group. Topics currently covered include: biotechnology, computer systems, contracting, delivery systems,

filtration, inspection trends and regulatory affairs, and visual inspection of parenterals. More information on PDA Interest Groups can be found at www.pda.org/science/IGs.html.

A Task Force on interest groups is forming to promote the coordination of efforts and information between the PDA Interest Groups and the chapter interest groups.

Persons interested in becoming involved with the Interest Group Task Force or with any of the interest groups, either at the PDA or the chapter level, should contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Story ideas, comments or

announcements? Contact KiKi

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NEW ONLINE CHAPTER LEADERS FORUM AIDS COMMUNICATION

In November, PDA launched an online Chapter Leaders Forum to assist chapter leaders administer their chapters with a specific focus on managing finances.

The forum allows invited chapter leaders to participate in an ongoing dialogue and to directly ask questions related to chapters.

PDA VP of Finance and Strategic Planning Lance Hoboy and Chapter Coordinator KiKi Coffman moderate the forum.

Additionally, the forum can be used to generate ideas for chapter activities, raising chapter funds and reducing chapter operating costs.

Chapter leaders are encouraged to take advantage of

this forum and to provide feedback on how it can be enhanced to serve them better.

The online forum provides a direct link from PDA headquarters to the regionally-diverse PDA chapters.

"I see the forum offering an excellent opportunity for chapters to exchange with each other ideas to improve chapter activities and administration," says PDA VP Hoboy, who was instrumental in creating the Chapter Leaders Forum.

The PDA Chapter Leaders Forum can be accessed at www.pda.org:8080/~pda.

PDA Fast Facts

Back by popular demand! Answer this quick PDA survey question for a chance to win a \$25 gift certificate:

Name the subjects, speakers, or courses that would make you want to attend a PDA event. (Must list at least three answers—detail is encouraged!)

The first three respondents will win a \$25 gift certificate. Send your answers to KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

CHAPTER REPORTS FROM AROUND THE WORLD

Southern California Chapter reported that their event, “An Evening with FDA at the Disneyland Hotel,” on “Pre-Approval Inspections: How to Prepare for a Successful PAI” was a great success! The event brought in 115 attendees—a record for the chapter. Demand for the event exceeded availability.

The speakers were **Caryn McNab**, an FDA Investigator with the Los Angeles District Office and **Jeff Yuen**, President of Jeff Yuen & Associates. Chapter President Kikoo Tejwani recognized the efforts of chapter officers Tarra Roshan and Bob Mitchell. PDA Global Headquarters helped promote the event. For more information about the PDA Southern

California Chapter, please visit the Chapter’s Web site at www.pdasc.org and see “Chapter Focus” in the November *PDA Letter*.

New England Chapter is proud to report on its last event of the year: “Disinfectant Regulation, Technologies, Sterility and Validation,” which took place on December 4th in Cambridge, Massachusetts. The seminar covered: antimicrobial regulations and technologies; validation for cleanrooms; disinfectants; and sterilants. Common questions regarding antimicrobial products were answered in conjunction with presentations of ‘real world’ examples of validation and sanitization

programs. Manufacturers, QA/QC scientists, and regulatory professionals benefited from the event. Steris Laboratories was the event sponsor.

Capital Area Chapter sponsored a meeting on Dec. 10, entitled “Rapid Microbiological Methods and Product Quality Microbiology—the NDA Scientific Review Process.” The featured speaker was FDA’s Peter H. Cooney, Ph.D., Associate Director for New Drug Microbiology, Office of Pharmaceutical Science, CDER.



Upcoming Chapter Meetings & Events

January 13, 2004

Southeast Chapter & North Carolina Pharmaceutical Discussion Group: “Software Solutions to Meet Part 11 Requirements in Pharmaceutical Manufacturing”
6:00 p.m.- 9:00 p.m.
Embassy Suites
Cary, North Carolina



ATTENTION:

Chapters that would like to get involved in the planning for the PDA Pharmaceutical & Biopharmaceutical Manufacturing Science & Technology Congress, Training Courses, and Exhibition (May 17–21) in Singapore, please contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

ITALY CHAPTER UPDATE

John W. Mitchell, President of Pfizer Global Manufacturing and Senior Vice President of Pfizer, Inc., presented a strategic approach for establishing a global quality vision at PDA’s 2003 Taormina International Conference in Taormina, Italy.

Mr. Mitchell examined how a successful organization like Pfizer must continually gauge the level in which it is realizing its vision and identify how the firm will be viewed once the vision has been achieved. The elements of Pfizer Global Manufacturing’s mission are to:

- Obtain the best quality performance in the industry
- Satisfy their customers 100% of the time
- Achieve the best environmental, health, and safety performance in the industry
- Bring new products to market faster than their competition
- Improve product cost continually
- Integrate globally

Mr. Mitchell explained how Pfizer utilizes their mission as a “stretch goal” and a focal point

that drives the organization. The mission is used to provide the focus for their strategic business planning and goal setting, and it drives the overall business. All of their sites receive objectives related to the mission elements. The mission is integral to individual performance, serving as the basis for employee performance objectives, and it is discussed at all review meetings and budget presentations.

Mr. Mitchell is responsible for one of the world’s largest manufacturing operations in the healthcare industry. Pfizer produces pharmaceutical, consumer healthcare and animal health products. Pfizer Global Manufacturing operates plants and logistics centers at more than 140 sites in 40 countries with approximately 35,000 employees. Mr. Mitchell also serves on Pfizer’s Pharmaceutical Group Leadership Team.

Mr. Mitchell addressed the diverse audience of 65 delegates from 15 countries attending this Conference in historic Taormina. Senior level executives from the pharma-

ceutical manufacturing industry met with preeminent global health authorities to discuss issues pertaining to managing quality in a cost-focused environment.

This article was first published in the November issue of the Italy Chapter Newsletter.



PDA President Neal Koller presented Antonino Giannetto, Ph.D., Technical Director for SIFI (Lavano Catania, Italy) with a Certificate of Appreciation for his leadership in organizing the Taormina conference.

PDA Leader of the Month



We need nominations for next month’s Chapter Leader of the Month!

PDA Chapter News—a monthly electronic publication for PDA members

Walter Morris, Senior Editor
Kiki Coffman, Chapter Coordinator

Neal Koller, President
Matthew Clark, Director, Marketing Services