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PDA CHAPTER NEWS

MARCH 2004

UPCOMING PDA EVENTS

April 15-16, 2004

Developing and Validating Cleaning and Disinfection Programs

TRI Lab Course

Baltimore, MD

April 19-21, 2004

Cleaning Validation

TRI Lab Course

Baltimore, MD

April 26, 2004

PDA EuroForum

"PAT from the Horse's Mouth"

UBS Ausbildungs-und Konferenzzentrum

Basel, Switzerland

May 3-5, 2004

PDA Training & Research Institute

San Diego Course Series

Sheraton San Diego Hotel & Marina

San Diego, CA

May 13-14, 2004

Environmental Mycology

Identification Workshop

TRI Lab Course

Baltimore, MD

May 17-21, 2004

2004 PDA Biennial Training

Conference, Courses and Vendor

Exhibit

San Juan, 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

Singapore

**Contact your local Chapter representative about special registration offers!*

PDA CHAPTER SCHOLARSHIP PROGRAM LAUNCHED

PDA Chapters now have something new to brag about—the PDA Chapter Scholarship Program. The program guidelines were updated to be consistent with the dollar levels specified in the Chapter Financial Policies and based on a proposed scholarship description sent to PDA by the Capital Area Chapter president, **Dr. Barry Friedman**, Director for Quality Control at Cambrex.

PDA wishes to thank the Capital Area Chapter for leading the way on this initiative that will benefit all Chapters and PDA.

The PDA Chapter Scholarship guidelines have been sent to all PDA Chapter officers. The guidelines are also posted under "Chapter Leader Resources" in the Members Only section of the PDA Web site.

Included in the guidelines: PDA Chapters are encouraged to sponsor and offer scholarships to students of pharmaceutical, biopharmaceutical and related disciplines attending accredited institutions of higher learning within the PDA Chapter's geographical region; the PDA Chapter will require written

approval from PDA to make a commitment in excess of \$5,000.00 (U.S.); the scholarship shall be promoted as a PDA Scholarship sponsored by PDA and the PDA Chapter; and the PDA Chapter will make a public presentation of the scholarship to the recipient.

PDA will prominently cover the PDA Chapter Scholarship Program and recipients in the *PDA Letter* and will work to generate interest in each participating PDA Chapter's geographic region.

PDA CHAPTER REPORT: ISRAEL CHAPTER

On March 2, 2003, over 60 attendees attended a one-day course hosted by the Israel Chapter at the Tel Aviv Hilton. The course was titled, "How to Prepare for an Inspection by European Authorities" and was taught by expert German Inspector Dr. Joerg Neuhaus, Bezirksregierung Koln.

Dr. Neuhaus provided an instructive overview of how the European Union functions and explained the differences between the European Union and The European Economic Area. He discussed how the European Parliament operates, its legislation and the status of "Directives," "Decisions," "Regulations," and "Recommendations." The legislative power of The Council of Ministers was clarified, and participants were introduced to the lesser known Council of Europe and the EDQM, the body responsible, amongst other things, for issuing the European Pharmacopoeia and Certificates of Suitability. The Pharmaceutical Inspection Convention (PIC) and its evolution into Pharmaceutical Inspection Cooperation Scheme (PIC/S) were also discussed.

Next, Dr. Neuhaus engaged participants with a presentation concerning European Inspections, triggers for inspections and different techniques for conducting inspections. Products manufactured once a year or once every two years are subject to intense scrutiny, while cancelled and out-of-specification batches will almost certainly be reviewed. He provided insight into how, when inspecting manufacturers, he seeks entrance to "technical areas" which are often used to store machinery that the company doesn't want the inspector to find in production during the inspection. He also discussed his technique of using binoculars to view clean rooms when firms deny him permission to enter for fear of contaminating product.

Dr. Neuhaus provided pointers on process validation. He addressed process variables including employee behavior (a factor that is seldom taken into consideration) and a

validation strategy that eliminates as many variables as possible by converting them to constants or demonstrating that they have negligible impact on the process, e.g. single vendors, specifically defined equipment, process defined in detail and conditioned environment.

The Israel Chapter wishes to express its gratitude to PDA, Gautam Maitra, PDA European Headquarters Director, and to Dr. Neuhaus.

— compiled by the Israel Chapter officers



PDA Israel Chapter Executive Committee with lecturer (L to R): Raphy Bar, Dr. Joerg Neuhaus, Sigalit Portnoy, Karin Baer, Karen Ginsbury and in the back row: Benny Klener and Mordechai Izhar.

CHAPTER REPORTS FROM AROUND THE WORLD

Mountain States Chapter will hold a dinner meeting called "An Approach to Risk Management in Validation," April 1, in Longmont, Colorado.

The meeting, sponsored by Amgen, will feature presentations by Mark P. Roache and Howard Becker, both Associate Directors, IT Consulting Services, from KMI, a division of PAREXEL International.

Midwest Chapter will hold its first "Ask the Experts Night and Vendor Show" March 25, in Northbrook, Illinois.

Come have your questions answered by industry experts, see what's new in the PDA Midwest Chapter or get more information about what participating vendors have to offer! The panel will present educational case-studies taken from industry experiences.

Attendees will be encouraged to volunteer their own real-life experiences or problems to stimulate discussion. Guest speakers will include: Ballard Graham, DVP Global Compliance, Abbott Laboratories; Daniel Osterby, Senior Consultant, Vectech Pharmaceutical Consultants; and Dan Hoch, Senior Director of Project Services, Protocol Link.

Puerto Rico Chapter will hold its first official meeting on March 30, in Carolina, Puerto Rico.

Attendees will have the opportunity to learn more about PDA and how the Puerto Rico Chapter can contribute to their day-to-day activities. Also, participants will have the opportunity to share expectations about the Chapter and volunteer to participate in committees.

UK & Ireland Chapter will hold a one-day conference featuring speakers from the U.S. FDA, MHRA, and multinational pharmaceutical and biopharmaceutical industry leaders titled, "What To Do When Things Go Wrong," on April 28, in London, England.

Hear views from the U.S. FDA and the MHRA on "what to do when things go wrong" and take home expert advice on prevention by design. If you have ever encountered a problem in your manufacturing process, this conference will be invaluable to you and your organization!

For more information, contact Gautam Maitra, PDA European Headquarters Director, by E-mail at maitra@pda.org.

PDA CHAPTER ANNOUNCEMENTS, BRIEFS

PDA Chapter Officers to Receive Meetings Discount—

A new program offering Chapter officers a standing invitation to attend any PDA program, meeting, or conference at half-price registration was announced by the PDA Membership and Chapters Department this month.

Chapter officers will receive the discount as a benefit of regular volunteer service to PDA.

For more information, please contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Remember to Mention the PDA Volunteer Corps to Chapter Attendees!

Do you promote the PDA Volunteer Corps discount to the attendees of regular Chapter meetings?

The Volunteer Corps is a program offering half-price registration in exchange for volunteering six hours at any PDA program, meeting, or conference. The hours chosen for volunteer work (e.g., monitoring an interest group room, helping with registration, sitting at the PDA welcome desk) are up to the individual volunteering.

For more information about either of the two discount

programs mentioned above, contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Case Studies Wanted!

PDA wants to continue to include case studies in the *PDA Letter* each month. Any Chapter member who submits a qualifying case study will earn 25 **PDA Points** for his or her Chapter and will be recognized in the *PDA Letter*.

For more information, please contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Attention International Chapter Officers!

Please remember to contact Lance Hobby, Vice President of Finance and Strategic Planning, if you have outstanding financial reports and/or summaries. International Chapters were granted an extension for financial reporting. Please send all financial submissions by April 1.

If you have questions regarding the Chapter financial reporting requirements to PDA, please contact Lance Hobby at hobby@pda.org.

Chapter Officers — Support PDA by wearing your PDA Chapter officer shirt!

All PDA Chapter officers are requested to submit shirt sizes (S, M, L, XL, or XXL) by **April 15, 2004**, to KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

The shirts will be distributed in June and in time for the Chapter Council Meeting at the PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits, September 20–24, Washington, D.C.

Fast Facts Quiz Winners:

The winners from March's Fast Facts quiz question are: Andrea Chamblee, Regulatory Affairs Manager for Cambrex BioScience - \$50 (U.S.) Gift Certificate; Michael Anisfeld, President for Globepharm - \$50 (U.S.) Gift Certificate; and Nancy Blaszkowski, Lab Operations Manager, Sterigenics Analytical Laboratory - \$50 (U.S.) Gift Certificate.



Upcoming Chapter Events

March 25, 2004

Midwest Chapter
"Ask the Experts Night and Vendor Show"
Northbrook, IL

March 30, 2004

Puerto Rico Chapter
"Information Sharing Forum"
Carolina, Puerto Rico

April 1, 2004

Mountain States Chapter
"An Approach to Risk Management in Validation"
Longmont, CO

April 7, 2004

Capital Area Chapter
"Designing a Cleaning and Disinfection Program in GMP Controlled Environments"
Gaithersburg, MD

April 20, 2004

Southeast Chapter
Annual Spring Meeting
Research Triangle Park, NC

April 21, 2004

Delaware Valley Chapter
"Cleanroom Velocities, Airflow and Media Fill Case Studies from the PDA-TRI"
Malvern, PA

April 26, 2004

Canada Chapter
"Current Regulations and Compliance"
Holiday Inn - Midtown
Montreal, Quebec, Canada

April 28, 2004

UK & Ireland Chapter
"What To Do When Things Go Wrong"
Gatwick Hilton, Gatwick Airport
London, England

Story ideas, comments or announcements?

Contact KiKi Coffman, Chapter Coordinator:

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