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PDA CHAPTER NEWS

FEBRUARY 2004

UPCOMING PDA MEETINGS/COURSES



March 8-12, 2004

PDA SciTech Summit™
PDA's NEW Annual Meeting
Combines the PDA Annual Meeting
and Spring Conference
*Co-located with CleanRooms East
Orlando, FL

March 15, 2004

PDA EuroForum
"Implementation Challenges of CTD"
Hilton Barcelona Hotel
Barcelona, Spain

March 29, 2004

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

April 19, 2004

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

Laboratory Courses at the PDA Training and Research Institute Baltimore, Maryland

March 16-17, 2004

Validating a Steam Sterilizer

April 1-2, 2004

What You Need to Know to Select
Adequate Thermal Validation
Equipment

April 15-16, 2004

Developing and Validating Cleaning
and Disinfection Programs

April 19-21, 2004

Cleaning Validation

PDA CHAPTER POINTS PROGRAM UPDATE

This month, Chapters received their first **PDA Chapter Points Program** balance statements. Questions regarding the program poured into PDA Global Headquarters, and several strong initial leaders emerged based on Interest Group and Task Force involvement, alone.

It is important for Chapters to remember to use the **PDA Chapter Points Tally Form** to report to PDA Headquarters the **PDA Points** accumulated on a monthly basis. Chapter leaders should ensure that the information is received by PDA no later than the 15th of each month. The form includes a checklist of the activities completed in the past 30 days and a space to total the **PDA Points** earned.

Currently, Chapters have a great opportunity to earn **PDA Points**! Earlier this month, PDA

requested input from the Chapters on two draft documents issued by the World Health Organization (WHO): "WHO Good Manufacturing Practices (GMP): Water for Pharmaceutical Use (WPU)" and "Good Distribution Practices (GDP) for Pharmaceutical Products." Both documents may be found at the WHO Web site, www.who.int.

Chapters have the opportunity to comment on these drafts and earn **PDA Points** (50 **PDA Points** for each comment document!) The deadline for comments on the guidelines is Friday, February 27.

Comments on how to improve the drafts, including alternative wording and/or alternative approaches are welcome and Chapter leaders are asked to submit the **PDA Chapter Points Program Tally Form** and comments at the same time. The

form may be found in the **PDA Chapter Points Program Manual** posted under "Chapter Leader Resources" in the Members Only section on the PDA Web site.

PDA Fast Facts

Answer this quick PDA question for a chance to win a \$50 (U.S.) gift certificate:

PDA Chapters offer a lot of different services to local PDA members and nonmembers. What services provided by your Chapter do you appreciate most?

Send your comments to KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Each of the first three respondents will win a \$50 (U.S.) gift certificate.

PDA CHAPTER FOCUS: CANADA CHAPTER

When PDA first considered the formation of Chapters outside the U.S. in the late 1980's, the association immediately thought of Canada, which was a growing source of PDA membership, as the logical place to start.

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

newsletter, entitled the Canadian Information Letter, a French and English publication.

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

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

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

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

CHAPTER REPORTS FROM AROUND THE WORLD

Metro Chapter will hold a meeting covering "Environmental Monitoring" on March 3. This meeting will be held at the Crown Plaza Hotel, in Clark, New Jersey.

The speaker will be Ken Muhvich, Ph.D., Principal Consultant, Micro-Reliance.

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

The meeting, sponsored by Amgen, will feature presentations by Mark Roche and Howard Becker, both from KMI, a division of PAREXEL International.

New England Chapter will hold a dinner seminar titled, "Corrective and Preventative Action Systems," on Feb. 26, in Cambridge, Massachusetts.

Speakers are: Mike Cross, Manager of Quality Engineering, Biogen/dec and Tonya White-Salters, QA Team Leader for Clinical Development Services, Avecia Biotechnology.

The seminar, sponsored by Steris, will address aspects of Corrective and Preventive Action Systems (CAPA) that will be of interest to manufacturing, quality and regulatory professionals. Approaches used for both external and internal system management related to CAPA will be investigated.

Prague Chapter held a planning meeting on Jan. 24, to discuss topics and potential meetings for the year. Particular subjects of interest include: Annex 13, filtration management and sterile validation. The Chapter is planning a forum on "The Impact After Six Months of Joining EU," possibly in November.

Puerto Rico Chapter held a planning meeting on Jan. 22 at Wyeth in Carolina. The Chapter is still looking for PDA members in Puerto Rico who want to help with the Chapter newsletter and Web site.

PDA CHAPTER ANNOUNCEMENTS, BRIEFS

Have you made your reservations for SciTech Summit™ yet? Plans are well underway for the Chapter Council Meeting being held during SciTech Summit March 8–12 in Orlando, Florida. The current meeting for Chapter leaders is scheduled 2:30 - 3:30 p.m. Monday, March 8, in Room 108B.

This will be Chapter leaders' opportunity to ask questions regarding the **PDA Chapter Points Program**, **PDA Chapter News**, Chapter events publicity, and Chapter-related financial issues. It will also provide leaders an opportunity to report on Chapter activities and goals for the upcoming year.

An agenda will go out to Chapter leaders before the meeting in preparation for the discussion.

Chapter leaders who plan to attend and have any questions or items they feel need to be added to the agenda may use the online "Chapter Leaders Forum" in the Members Only section at pda.org or contact KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

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.

Thank you to all the Chapters that have already submitted the required yearly financial data to PDA. Lance Hoboy, Vice President of Finance and Strategic Planning, expects to receive part or all of the reports and/or summaries from the international Chapters, which were granted an extension for financial reporting submissions.

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

Chapter Leaders:

Support PDA by wearing your PDA Chapter officer shirt! All PDA Chapter leaders are requested to submit shirt sizes (S, M, L, XL, or XXL) by February 25, 2004, to KiKi Coffman, Chapter Coordinator, at coffman@pda.org.

Fast Facts Quiz Winners:

The winners from January's Fast Facts quiz question are: Maria Elena Cortes, QA Manager for RJ Consulting Corp. - \$50 (U.S.) Gift Certificate; Susan Polizzotto, for Aventis Pasteur - \$50 (U.S.) Gift Certificate; and Anthony Pavell, Director of Operations for Cardinal Health - \$50 (U.S.) Gift Certificate.

If you didn't win last month, please try again with this issue!



Upcoming Chapter Events

February 26, 2004

New England Chapter
"Corrective and Preventative Action Systems"
Cambridge Marriott Kendall Square
Cambridge, Massachusetts

March 2, 2004

Israel Chapter
One-day course on Inspection
Tel Aviv, Israel

March 3, 2004

Metro Chapter
"Environmental Monitoring"
4:00 p.m. – 7:00 p.m.
Crown Plaza Hotel
Clark, New Jersey

March 15, 2004

Spain Chapter
PDA EuroForum
"Implementation Challenges of CTD"
Barcelona, Spain

March 25, 2004

Midwest Chapter
"Ask the Experts Night and Vendor Show"
Northbrook Hilton
Chicago-Northbrook, Illinois

April 1, 2004

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

April 28-29, 2004

UK & Ireland Chapter
"What to Do When Things Go Wrong"
London, England

April 26, 2004

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

Story ideas, comments or announcements?

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