

PDA Southeast Chapter



SOUTHEAST CHAPTER
www.pdase.org

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[Letter From the President]

March, 2005

Happy New Year! I hope everyone can look forward to a happy and prosperous 2005. Last year was a challenging year for everyone. Many of us were faced with budget cuts, reduced personnel, and increased demands on our time. However, the PDA Southeast Chapter Executive



Committee hopes that we have continued to provide a valuable service to our members.

The national chapter of the Parenteral Drug Association has given the regional chapters the following missions (brief summaries):

- to foster and advance the art and science of pharmaceuticals, biotechnology, etc.
- to provide information to our members
- to encourage cooperative spirit and cultivate relations between members, companies, and government agencies
- to encourage scientific and technical advances
- to promote high standards of manufacturing
- to encourage education and training of our members

The Executive Committee strives to continue improving our chapter and our meetings. We try to make improvements at every event. Your comments are welcome because they really help us provide the best service to you. The PDA Southeast Chapter hopes that we are meeting your needs and the mission given to us by the national chapter.

The year 2004 was a transition phase for the Executive Committee. We had several new officers and committee chairs last year. We would like to thank Pam Webb (Programs), Christine Cramer (Communications), and Nancy Wisniewski (Philanthropy) for their service to the chapter. They will be stepping down to pursue other opportunities. Thanks for your help!

In 2005, we need some volunteers for the Communications Committee, the Program Committee, and the Sponsorship Committee. The Communications Committee members

The Executive Committee strives to continue improving our chapter and our meetings.

write speaker summaries for the newsletter. The Program Committee obtains speakers and coordinates the presentations. The Sponsorship Committee tries to keep the meeting costs down for the members by obtaining sponsors for our events. Please let me know if you have any interest in helping with these activities.

We look forward to seeing you at our events this year.

Spring Meeting
April 19 2005 at the NC Biotechnology Center

Golf social **TBD**
Fall Meeting and Vendor Show **TBD –**
Probably October 2005

Please visit our website, www.pdase.org for updated event information for the Southeast Chapter and the national PDA.

Lisa

Pharmaceutical Trends in Microbial Identification Technologies

By Michel Nogueras

Summary By Christine Cramer, Research Compliance Specialist at Emory University

Michel Nogueras is currently the lead specialist and member of the QAL-Microbiology Department at AMGEN Rhode Island, and involved in development of their microbial identification laboratory. He gave his viewpoint of currently available identification methods; useful timing as the USP is completing the harmonized chapter on Microbial Limits testing, and starting work on other microbial compendial methods. Besides that, the microbial test methods and environmental monitoring needs of GMP facilities continue to require frequent evaluation for compliance, in-house trends and self-assessment to ascertain if the right questions are being adequately answered by the methods employed.

I found the talk both dynamic and thought provoking. Its concepts were basic enough to understand by those like me with only rudimentary microbiology education yet invoked sufficient detail to arouse a lively discussion (throughout the talk and) at the Q&A time. He succinctly presented both the strong points and limitations of not only several identification methods but of more than a half dozen commercial systems in a refreshingly candid manner. It isn't often that a speaker actually tells an audience what he found that worked, and what didn't, and why. He used the platform not to push a specific agenda, but to encourage his listeners to ask the right questions.

First ask what do you want to test? How do you distinguish and follow trends in order to demonstrate control of the facility? What Alert and Action levels are really necessary – are yours practicable, are they useful? Just because a technology makes an answer possible to discover doesn't mean that it is worth knowing.

So before looking at available technologies, your team must define what is needed. Delineate your user requirements and user specifications. Then look for the system that

will work for the parameters you have set. Will the system identify organisms endemic to your process? Will it identify to the level that you need? Does its identification library come pre-programmed or will you be required to set it up? Most commercial systems come with IQ/OQ validation procedures, but you will need to include your own isolates in a good PQ, as well as demonstrating that your operators can run it consistently.

What will your throughput capability need to be? Can the system operate efficiently for both the slow and the peak sample traffic volumes? What will the reagent costs and availability be? What manpower is needed keep the system

operating? Is the data system compatible with your current software? Can you trend your findings? Will the security be maintained if the identification system uses an Internet query system?

Critically review your procedures and your filings. Are you claiming a specific system in your licensing application? Wouldn't you rather just claim that you will ID an organism? Be general when you can to permit flexibility in your approach, specify only what you must.

Mr. Nogueros reminded us of the questions to ask, then provided broad guidance of methodology capabilities and specifics to look for in particular systems in order to answer the questions.



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USP Pharmacopeial Education Group

By Lucia Clontz

On February 17th, the USP Pharmacopeial Education group held its first class in the RTP/Raleigh area. The course Fundamentals of Microbiological Testing was presented by Dr. Dave Porter, Associate Director of Complex Actives and Dr. Ian Deveau, Senior Scientist. The PDA Southeast Chapter was instrumental in helping the USP bring courses to our area.

There were about 50 students at Wednesday's

class, a great turnout according to USP



Lisa Eklund, Lucia Clontz, and Robert Tyler (Senior National Account Manager, USP)

representatives. Most of the students were from local companies. However, there were people from the Wilmington area and even from Georgia. Given the success of the class and interest in the Pharmacopeial Education programs, the next class on analytical method validation has already been scheduled for May, 2005. Make sure to check our website for details.

Follow PDASE.org to keep up with all Southeast Chapter Events.



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Recent USP Pharmaceutical Water Developments

Presented by T.C. Soli, PhD

Summary Written by James F. Cooper, M.S. Pharm. D; Endotoxin Consulting Services

Dr. T. C. Soli presented a timely discussion on important USP revision activity regarding waters. To encourage innovation in water purification, USP 27 opened up the option of WFI production to methods other than distillation and reverse osmosis (RO). Less expensive and small scale options may be used for WFI provided they are equivalent to distillation for removing chemicals and microbes. Dr. Soli was skeptical that Europe would agree with this proposal.

The USP addressed the serious problem of water quality for hemodialysis by introducing a new monograph for Water for Hemodialysis and a new information chapter for Water for Health Applications. Hemodialysis water is primarily made by a cold RO process and appears on the waste side of the dialysis membrane, so more permissive specifications exist, such as 2 EU/mL (Endotoxin Units).

Dr. Soli distributed a comprehensive handout for participants that contained proposed in-process revisions regarding water affecting four compendial chapters and four monographs; see

Pharmacopeial Forum 30(5), Sept.-Oct. 2004. The <643> Total Organic Carbon chapter was revised to make the test quantitative, eliminate exact standard weighings and add performance criteria. Types of waters were expanded to 4 bulk water and steam monographs and 5 packaged water monographs. The importance of pure steam led to a monograph where purity aspects are measured on the condensate. Bulk WFI differs from SWFI because packaging in plastic and glass containers introduces contaminants into the water. Therefore, chemical attributes of packaged waters are primarily defined by wet chemistry. Both TOC and Conductivity in packaged water is permissive in comparison to WFI.

Chapter <1231> Water for Pharmaceutical Purposes was essentially rewritten with new and expanded, existing sections to make it more informative and contemporary. The section on validation and qualification of water purification, storage, and distribution systems was expanded and proposed a 10-step validation plan. Levels should be used, rather than limits, because the latter is a specification. Highlights of Chapter <1231> include enhanced discussions of purification steps, sterilization, sampling and biofilm. The history and rationale of conductivity and TOC specifications was added to address misinformation issues. WFI endotoxin level is revised as not more than to less than 0.25 EU/mL to facilitate harmonization.

Harmonization efforts for WFI were reviewed, including progress to date and nine contentious issues such as conductivity methods and limits, chemistry tests and micro specifications. Agreement on packaged water will require reduction in the number of wet chemistry tests.

Dr. Soli closed by urging participants to get involved in the USP revision process by completing a questionnaire regarding the critical revisions under consideration for waters.



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Mark Your Calendars! PDA



Southeast Chapter Spring Meeting

Tuesday, April 19, 2005

9:30 am-4:00 pm

NC Biotechnology Center,
Research Triangle Park, NC

*Join PDA Southeast Chapter for our 2005 Spring Meeting
at the NC Biotechnology Center in RTP, North Carolina.
The event will be held Tuesday, April 19, 2005.
Registration begins at 9:30 AM and the day
concludes at 4:00 PM.*

Schedule of Events

9:30 am	Registration
10:00 am	Business Meeting
10:30 am	Recent Training and SOP Trends to Support Pharmaceutical Manufacturing Dave Gallup, Ed.D
12:00	Lunch
1:00 pm	Disinfectant Validation: Current Regulatory Trends and Industry Practices Elaine Sartain
2:45-4:00 pm	Round Tables

About Our Speakers

David A. Gallup, Ed.D., co-founded the The Training and Communications Group, in 1981. David has 25 years' experience conducting compliance training audits, developing and implementing compliance training plans and designing, producing and evaluating training programs. His background includes conducting needs analyses and task analyses as well as designing and implementing training programs for client firms. Dr. Gallup is a member of the Faculty of the PDA and currently teaches and advises in Penn State's Training Design and Development Graduate program at the school's Great Valley campus.

Elaine Kopis Sartain is the Director of the Technical Services Department for the Life Sciences Division of STERIS Corporation, manufacturer of contamination control and prevention equipment and products. In this position her focus area is microbial control in cleanrooms and other critical environments, and selection and validation of CIP cleaning agents. Elaine is responsible for providing assistance to STERIS customers in selection and application of disinfectants and cleaners and for providing educational seminars and literature to customer groups. Elaine has lectured on microbial control in cleanrooms throughout North America, Europe and Asia, and has numerous published articles on contamination control related topics.

Elaine is a member of the Association of Official Analytical Chemists, the American Chemical Society, the Institute of Environmental Sciences and Technology, and the Parenteral Drug Association. Additionally, Elaine is on the editorial advisory board of *CleanRooms* magazine and is a faculty member of the PDA Training and Research Institute. She has a B.S. degree in Chemistry from Southern Illinois University.

Registration Form (please print).

Name _____
Your first name as you wish it to appear on your nametag

Email _____

Company _____

Address _____

City, State, Zip _____

Registration Fee:
Before April 11, 2005 \$80 per person (includes lunch)
After April 11, 2005 \$100 per person (includes lunch)
Students \$35 per person (includes lunch)

No. of people x \$80.00 each= _____
No. of people x \$100.00 each= _____
No. of people x \$35.00 each= _____

TOTAL _____

Payment: **CHECK** made payable to: **PDA Southeast Chapter** OR
CREDIT CARD

(If using a credit card, please add \$5.00 to each registration and complete the form below.)

Name _____

Type of card _____ Expiration Date _____

Signature _____

Please feel free to make multiple copies of this registration form)

Payment: Check made payable to: **PDA Southeast Chapter**

Return this form:

By Fax: 919.463.0588 (check must be received by April 11, 2005)
By Mail: PDA Southeast Chapter, 302 Versailles Drive, Cary, NC 27511
Deadline: **April 11, 2005**
Questions: Diane S. Williams, Diane S. Williams Marketing Inc.
919.463.0615 fax: 919.463.0588
Email: proflink@aol.com
www.PDASE.org

PDA SE Chapter Golf Tournament Friday, October 8, 2004





PDA SOUTHEAST CHAPTER 2005 SPONSORSHIP OPPORTUNITIES

The Southeast Chapter of the PDA has now been in existence for over 8 years! During this time, we have seen our Chapter grow in membership and participation. We are grateful to our dedicated members and sponsors for their continued interest, participation, and support. At present, there are **over 1900 Chapter members across NC, SC, VA, TN, GA and FL. The Chapter Spring Meeting and Fall Vendor Show each routinely attracts over 100 attendees.** The Chapter produces a series of newsletters every year and hosts other special events such as **Annual Golf Outings, Summer Dinner Meetings, and local PDA-TRI or USP training courses.** All of these activities provide a unique setting for our sponsors to interact with our members. We truly appreciate the generosity of our sponsors over the years, for without you, we could not provide this level of activity for our members. This year, we would like to offer you a variety of ways to be involved with our Chapter. We have provided a “menu” of sponsorship opportunities below. Please consider participating in as many ways, as possible, this year!

Again, we appreciate your overwhelming support, as we strive to achieve our mission in support of our members from the Pharmaceutical, Medical Device and Biotech industries.

My company would like to support the PDA Southeast Chapter in 2005 in the following ways:

Company Name: _____

Contact Name: _____

Contact email: _____

Company Address: _____

Phone: _____

Fax: _____

Web site address: _____

Check all that apply:	Sponsorship Description	Amount To Be Contributed
	<p>Newsletter Recognition & Web Site LinkYour company information will appear in each issue of the newsletter for an entire year and your company's web site will be linked to the PDASE web site's sponsors page. Amount: \$150 for business card size, \$200 for ¼ page, \$300 for ½ page, \$450 for full page.</p>	
	<p>Spring Meeting Sponsor, April 19, 2005 Your company will have an exhibit table to display products and 1 representative may attend meeting and lunch. The company will be recognized verbally and in the meeting program. Amount: \$325 Table space is limited to 6 vendors</p>	<p>Limited space: <i>First come first serve.(note: payment due by April 4th)</i></p>
	<p>Spring Meeting Break Sponsor, April 19, 2005 This covers all or part of morning or afternoon refreshments, and your company will receive recognition verbally and on table plaque, during the break and on fliers on the registration table. Amount: \$150 Limit 3 for AM break and 3 for PM break</p>	<p><i>(note: payment due by April 4th)</i></p>
	<p>Fall Golf Social Sponsor: Oct. *TBD, 2005 Your company will be recognized verbally when hole prize is awarded and with a sign on the tee. Amount: \$ 150 per hole</p>	<p><i>(note: payment due by Sept. 23rd)</i></p>
	<p>Fall Vendor Show, September 28, 2005 Your company will have an exhibit table at vendor show, 2 representatives for lunch, and a 50-word company description in program.Amount: \$ 400 (plus \$25 electrical fee, if needed)</p>	<p><i>(note: payment due by Sept. 2nd)</i></p>
	<p>Fall Vendor Show/ Meeting Break Sponsor This covers all or part of morning or afternoon refreshments, and your company will receive recognition verbally and on table plaque, during the break and in fliers on the registration table. Amount: \$150 Limit 3 for AM break and 3 for PM break</p>	<p><i>(note: payment due by Sept. 9th)</i></p>
	<p>Fall Vendor Show Logo Tote Bag Your company's logo will be printed on the canvas tote bag given to meeting attendees. Amount: \$100</p>	<p><i>(note: payment due by Sept. 9th)</i></p>
	<p>Exclusive Meeting Sponsor – Your company will receive special recognition as the key sponsor of the Fall or Spring meeting. In addition to verbal and printed recognition, your company representative will be able to briefly address the members for a few minutes Limit 1 for Spring Meeting: \$500 Limit 1 for Fall Meeting: \$750</p>	<p>Limit 1 per meeting: First Come First Serve</p>
	<p>TOTAL ANNUAL SPONSORSHIP :</p>	

	<i>(note: the Chapter always appreciates donations of door prizes at our meetings and items for goody-bags at the Golf Social)</i>	
Sponsorship Committee:	Other ideas?? If your company wants to contribute to the Chapter in another way, please specify here or contact a member of the Sponsorship Committee: <i>(Suggestions include donation of computer projector, overhead projector, flip charts, meeting program printing and binding expenses or administrative services)</i>	

Please send completed forms to:

PDA SE Chapter Sponsorship Committee Chair

Phone: 919-754-7280

Fax: 919-854-7926

Email: stephen_podolski@pall.com

Please mail completed form and payment to:

Stephen Podolski

1904 Freewood Court

Raleigh, NC 27606