PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

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[Letter From the President]

August, 2005

This year has been very busy for the PDASE Chapter. We have already hosted 3 events in 2005. In February, we hosted a very successful

event with the United States Pharmacopeial (USP) Education Group. They brought their first course to the Research Triangle Park (RTP) area in February. The course was on Fundamentals of Microbiology Testing and was very well attended. In May, they brought their second course to RTP on Analytical Method Validations. Again, this course was very well attended. Since these events were so successful, the USP intends to bring more courses to RTP in the future.

In April, we had our PDASE Spring Meeting. Elaine Sartain and Dave Gallup gave excellent presentations that are summarized in this newsletter. We thank them for their service to the PDASE Chapter.

I would like to remind everyone that the PDA is hosting the 2005 PDA/FDA Joint Regulatory conference on September 12-16 in Washington, D.C. There is still time to register for this important event. They are also running membership promotions for new members of national PDA. Please feel free to contact me if you would like to find out more.

The PDA is also bringing courses to the RTP area in March 2006. There will be courses on Lyophilization, Process Validation, Visual SOPs, Environmental Monitoring, FDA Systems Inspections, cGMPS in Biotechnology, Continuous Quality Improvement, and Fermentation. Some brief course descriptions are presented in this newsletter. There will be more details in the future. We encourage you to take advantage of this valuable resource. These are courses that would be offered by the PDA-TRI group. It is an excellent opportunity for our members.

I would also like to announce that Hal Sanborn has joined the Sponsorship Committee as co-chair. He will be helping Steve Podolski and the entire Executive Committee. We are grateful to him for his offer of service.

At the end of 2005, we will be having elections for new officers. I encourage everyone to consider serving as an officer or committee chair/member. There are several opportunities that currently exist, and there will be even more for 2006. I know that all of you are busy in both your professional and personal lives. However, most activities are performed jointly by the Executive Committee. It only takes a few hours per month. The rewards far exceed the sacrifices. Volunteering is an outstanding way to meet new people and have input on what the chapter is providing to the members.

Fall Meeting and Vendor Show
September 28, 2005
Sheraton RTP, NC

Golf Social
October 21, 2005

Next year we will continue to work with local universities with our Philanthropy Committee. We also hope to pursue some kind of discount program for our loyal members who attend our meetings.

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

Fall Meeting and Vendor Show
September 28, 2005
Sheraton RTP, NC

Golf social
October 21, 2005
Hedingham Raleigh, NC

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

Lisa

Current Training and SOP Trends to Support Pharmaceutical Manufacturing

By David Gallup, Ed.D

Summary By Christine Cramer, Emory University / Office of Research Compliance

David Gallup is a Principal of the Training and Communications Group, Inc. Visiting 20 to 30 FDA regulated companies in a year as a consultant provides him an exceptional vantage for observing trends in training. At the spring meeting of the PDA Southeast chapter, Dr. Gallup shared from both his observations and his expertise how to best utilize written procedures to enhance personnel qualifications through job knowledge.

The old system of setting the trainee at a desk with a book of standard operating procedures (SOPs) to go through and sign off as "read and understood" has largely given way to the new self-instructional text of interactive learning modules (fortunately). On-the-job practical training and skill checklists supplement written evaluations. "Competency-based" training has been embraced for cGMP training needs because it works. Rather like a validation program, competency-based training gives you a verifiable product where the goals are identified, the pass/fail criteria are pre-set and the results are reproducible. The process to develop training material resembles a risk analysis or quality engineering approach: determine the needs of the task, set the objectives and consider the audience in the implementation and feedback iteration using outcomes evaluation.

FDA looks for the outcome based results, they don't inspect the training materials or methods. When FDA inspections consider training, it is generally a comparison of what is written in the SOP to the actual performance of the task. Use of job aids that are thoroughly illustrated with comprehensive checklists for step-by-step action renders consistent task performance. You now have operators performing in a state of control, which can be documented through your performance checklist. A bonus to this verifiably trained concept is that now if a person deviates from the process, the real cause may be addressed. Consider setting actual consequences for poor performance rather than just sending the errant operator for "retraining".

Now, consider how you may create SOPs to provide those detailed instructions required to support a consistently reproducible result of how a task is performed. An effective SOP will be clear, concise, accurate, readable, and available to enable the task to be consistently performed at the right time and place. The real subject matter experts are doing what they like, performing the task and are seldom inclined to write about the

continued on page 3

continued from page 2

task. These do-ers would need time to train in communications and the desire to write the SOP. So, produce SOPs that show the do-ers in action, illustrate the activity. The illustrated SOP will likely be more costly to produce, but the savings in training time and reduced errors more than compensate.

Visual SOPs are shorter, simpler and clearer than long written descriptive narratives. Visual SOPs act as job aids, prompts for task completion, placed at the job site for use when the time is now to use it. Visual SOPs are simple, easier for operators to use independently. They drastically reduce training needs, simply add a test and you now can evaluate the training result.; Create a leader's guide and you've completed the training materials, and have a system whereby the lead operator can be the lead trainer. Visual SOPs lower the reading level required of the user and the SOP utilizes multiple learning styles.

Did those in the audience review their SOPs when they returned to work? Did you find your SOPs to actually be a training aid and performance enhancement tool, rather than just an uninspired response to an FDA requirement for written procedures?

PDA Southeast Chapter Spring Meeting, 2005

MARK YOUR CALENDARS

Fifth Annual PDA Southeast Chapter

Golf Social

(NOT for the serious golfer!)

Friday, October 21, 2005

10:30am Shot-gun Start

Hedingham Golf Club
Raleigh, NC

Entry Fees:

★ Chapter Member with Paid Attendance to BOTH the Spring and Fall 2005 Meetings	**NO CHARGE**
● Chapter Member With Paid Attendance to EITHER the Spring or Fall 2005 Meetings	**$35**
● Individual (no meetings attended in 2005)	**$45**

- **18-holes golf, Captain's Choice Format**
- **Team Prizes**
- **Hole Prizes (longest drive, closest to the pin, etc)**
- **Door Prizes**
- **Complimentary Roving Beverage Cart**
- **Catered Meal**

Vendor Sponsorships $150

- **Contestant prize presented in your company's name**
- **Signage recognizing sponsorship**
- **Bar-B-Que dinner for two company representatives**

VENDOR SPONSORSHIPS Available Now!! See pages 10 and 11 in the newsletter.

PDA Southeast Chapter Fall Exhibitor Show & Meeting

Wednesday, September 28, 2005
9:30 am-4:00 pm
Sheraton Imperial Hotel and Convention Center

Join PDA Southeast Chapter for our Fall 2005 Exhibitor Show and Meeting at the Sheraton Imperial Hotel and Convention Center in RTP, North Carolina. The event will be held on Wednesday, September 28, 2005. Registration begins at 9:30 AM and the day concludes at 4:00 PM

Schedule of Events

9:30 am	Registration
9:30 am	Exhibitor Show Opens (Continental Breakfast in Exhibit Hall)
10:30 am	PDA SOUTHEAST CHAPTER Business Meeting
11:00 am	**Non-Destructive Headspace Gas Analysis: Applications to Container Closure Integrity** ***Jim Veale,*** *Light House Instruments*
12:00	Lunch- Dessert in Exhibitor Area
1:30 pm	**Aseptic Vial Inspection System using NMR, A PAT Approach** ***Chris Fee,*** BOC Edwards
3:00 pm	Refreshments in the Exhibit Hall
3:30 pm	Door Prizes Awarded
4:00 pm	Exhibitor Show Closes

About Our Speakers

Jim Veale is the president and founder of Lighthouse Instruments. He holds a PhD in physics from the University of Virginia. He spent 6 years as a researcher at GTE Laboratories in Boston, MA. His research interests are in developing laser spectroscopy methods and his business interests are in applying laser spectroscopy to unmet needs in the pharmaceutical industry.

Chris Fee, is the General Manager of BOC Edwards' Tonawanda operations. Previously Chris was a Sales Manager, North America. Chris has 9 years of Pharma industry experience and a diverse background which includes management responsibility for Sales/Business Development, Project Engineering, Quality/Validation, Health/Safety/Environment, and Organization Development.

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 Sept. 15, 2005	$80 per person (includes lunch)
After Sept. 15, 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 _____

Card number _____

Type of card _____ Expiration Date _____

Signature _____

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

Return this form:
By Fax: 919.463.0588
(check must be received by September 15, 2005)
By Mail: PDA Southeast Chapter, 302 Versailles Drive, Cary, NC 27511

Deadline: **September 15, 2005**
Questions: Diane S. Williams
919.463.0615 fax: 919.463.0588
Email: proflink@aol.com
www.PDASE.org

PDA Southeast Chapter/ USP Joint Training Program is a Success

by **Mary Carver**, **Eisai**

On May 24, 2005, fifty-three people participated in the USP training course titled Analytical Methods Validation at the McKimmon Center in Raleigh. The course was considered a huge success due to the incredible response. PDA worked with Rob Tyler, National Account Manager, to distribute information about the course. Thanks to all who participated. Another training course is planned for November 15, 2005, and will also be held at the McKimmon Center. The PDA Southeast Chapter and the USP will again work to publicize the course.

Location: NC State University, Jane S. McKimmon Conference and Training Center, Raleigh, NC

Course: Effectively Using the USP-NF

This condensed 1-day class provides a thorough overview of the US Pharmacopeia, its publications and its Reference Standards.

The USP organization, its regulatory status, public standards development process, and revision process. Learn how to effectively use the USP-NF and Pharmacopeial Forum. Build your understanding of USP Reference Standards: determining the current lot, valid use dates, presumption of suitability, proper storage and proper use. Understand General Notices, General Chapters, and their importance to USP-NF monographs. Learn how to use USP General Notices and Requirements and General Chapters. Build your understanding of the elements of a USP-NF monograph and the included tests which assess the identity, strength, quality and purity of drug substances, drug products and excipients.

For information concerning this class, contact:
Steven Paul, Manager, Pharmacopeial Education
US Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852
301-816-8210 or email, stp@usp.org

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PDA, Raleigh, NC Course Series
March 13-15, 2006

March 13, 2006

NEW! Approaches to Performing Self Inspections as Part of a Total Quality System for Pharmaceutical Product Development and Manufacture

Joseph Habarta, Ph.D.

J. Habarta Consulting

This course will provide the basis for tools and techniques for performing self-inspections from pre-clinical development through commercial manufacture of a pharmaceutical drug product. The lecture and discussion will describe the role self-inspections play in assessing a company's compliance to GLP and cGMP regulations and in the development of a Quality System. Formats for providing feedback, writing reports and assuring compliance to observations will be presented. An abbreviated mock self-inspection audit role-play will be staged with attendees.

March 14, 2006

NEW! Validation of Biopharmaceutical Processes

Antonio Moreira, Ph.D., Vice Provost for Academic Affairs and Professor of Chemical and Biochemical Engineering, University of Maryland Baltimore County

This course presents a detailed description of the approaches that a biopharmaceutical company can take in order to implement process validation strategies that will achieve the ultimate goal of complying with the regulatory requirements for validation in an evolving environment. Examples from real case situations will be used to demonstrate such approaches and to guide participants through lessons learned.

March 15, 2006

Principles & Applications of CGMPs in Biopharmaceutical Manufacturing

Antonio Moreira, Ph.D., Vice Provost for Academic Affairs and Professor of Chemical and Biochemical Engineering, University of Maryland Baltimore County. Through lecture, discussion and case studies, this interactive course presents practical instruction of the steps an organization can follow in order to achieve and/or maintain compliance with the CGMP regulations during biopharmaceutical manufacturing

March 13, 2006

NEW! Visual SOPs

David Gallup, EdD, Principal, Training and Communications Group, Inc.

The purpose of this course is to provide information on how to develop and write visual SOPs. Participants will be given an exercise where they will have a concept, SOP template and camera. Participants will be asked to develop a visual SOP on the concept.

March 13, 2006

NEW!! Fermentation Biotechnology

Edward Sybert, Maryland Technology Enterprise Institute, Biotechnology Industry Program

This one-day course will provide an overview of the techniques used during manufacturing of pharmaceutical and biological products from microbial and host cells. All aspects of production will be covered, from cell bank creation and media development through bulk, API purification. The scientific and engineering principles that support the production techniques will be explained as they relate to the process.

March 14, 2006

***NEW!* Continuous Quality Improvement**

Daniel H. Gold, PhD
D.H. Gold Associates, Inc.
(Description to follow)

March 15, 2006

***NEW!* FDA Systems Inspections**

Daniel H. Gold, PhD, D.H. Gold Associates, Inc.
(Description to follow)

March 13, 2006

Environmental Monitoring in Pharmaceutical Manufa cturing

Joseph Kirby Farrington, Ph.D
Eli Lilly

This one-day course will be a combination of lecture and discussion centered on the topic of environmental monitoring with an emphasis on viable monitoring. The subject matter will be approached from an applied standpoint using as a guide various FDA issued warning letters, 483 observations and other published sources. The objective of the course will be to review the current issues involving environmental monitoring and provide tools and solutions to address those issues.

March 13-15

Cleanroom Microbiology Workshop

David Matsuhiro, Cleanroom Compliance, Inc.

This two and one-half day "hands-on" course will provide an overview of microbiology for professionals operating in and/or auditing pharmaceutical and biopharmaceutical cleanrooms. Microbial contamination can be a costly nuisance resulting in the loss of materials, product, production time and regulatory actions. This course will consist of lecture, demonstrations, case studies and exercises designed to provide attendees with knowledge and technical skills required to control microbiological contamination in clean rooms.

March 14-15

NEW! Lyophilization – Fundamentals of Validation

Anthony Cannon
(Description to follow)

March 14-15, Raleigh, NC
& September 21-22 – Baltimore, MD

UPDATED! Computer Products Supplier Auditing Model: Auditor Training

Charles Waite
ProDesCon, Inc.

This two day course will provide specific auditor training in all phases of the audit cycle outlined in the PDA process model ***PDA Technical Report #32*** "Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations". The participant will learn about:

- Audit Initiation
- Preparation and Pre-work
- Conducting the Audit
- Observations and Reporting
- Decision Making

Follow-up and Close-out

'FORE' Vendors

Sponsorships available for the Fifth Annual PDA Southeast Chapter Golf Social

Hedingham Golf Club
Raleigh, NC

Friday, Oct 21, 2005 **10:30am Shot-gun Start**
(NOTE change in start time from previous years)

$150 Sponsorship:

- **Contestant prize presented in your company's name (Chapter Organization Committee will select and purchase)**
- **Signage recognizing sponsorship**
- **Bar-B-Que dinner for two company representatives**

Each golfer will receive a 'Goodie' bag containing golf paraphernalia. Vendor donations of items (golf balls, tees, markers, bags, huggers, golf towels, etc) for these are also needed by Oct 15, 2005.

To register as a sponsor, complete and return the attached form with sponsor fee ($150/sponsorship) before Oct 7, 2005 to:

Mary Carver
Eisai
900 Davis Dr
RTP, NC 27709

ph: (919) 474-2149
fax: (919) 941-6934
mary_carver@eisai.com

Make checks payable to 'PDA Southeast Chapter.'

PDA Southeast Chapter Golf Social

October 21, 2005
Hedingham Golf Club

Vendor Sponsorship Registration
(please print legibly)

Company _____

Rep(s) attending but not golfing (1)_____

(2)_____

**(Note: separate registration and entry fee required to play in tournament)

Address _____

City _____ State ____ Zip _____

Daytime Phone _____

Item(s) for goodie bags _____

_____

Complete and return attached registration form with $150 before Oct 7, 2005 to:

Mary Carver
900 Davis Dr
RTP, NC 27709

(Make checks payable to 'PDA Southeast Chapter')

Disinfectant Validation, Regulatory Requirements, Practical Approaches, and the X-Factor

By Elaine Kopis Sartain, Director of Technical Services, STERIS Corporation

Summary by Pam Webb, STERIS

Elaine Kopis Sartain, Director of Technical Services at STERIS Corporation presented to the Southeast Chapter PDA at the April Meeting. The presentation was titled "Disinfectant Validation, Regulatory Requirements, Practical Approaches, and the X-Factor." The X-Factor is items such as facilities and personnel which can be a variable in disinfectant validation. All facilities are different. The traffic flow (entry and exit areas) varies. The surface integrity such as rusting, pitting, paint flaking, etc. varies. The water sources and placement varies. The personnel vary. The amount of and type of training varies. All of these things must be taken in consideration during disinfectant validation. The components of disinfectant validation include in vitro testing such as the suspension or carrier tests, in situ testing, and environmental monitoring which displays data trending and identification of in house organisms.

Laboratory efficacy studies must consider the suspension vs. carrier tests and substrates used during the testing. How is the disinfectant prepared? How is the disinfectant applied (e.g. sprayed, wiped, fogged)? What interfering substances such as residues from other disinfectants might be present? What is the contact time? The FDA is getting tighter about making sure that all of these things are considered during an efficacy study. The FDA expects the testing to reflect actual use conditions. Here are some examples of 483 observations:

"The qualification study only evaluated stainless steel and not other surfaces in the APA such as glass, plastic, and epoxy painted surfaces. "

"The qualification study used a longer exposure time to the sanitizing agent than that time specified in the cleaning SOPs."

"The qualification study immersed the test surface in the disinfectant for …..instead of wiping the surface as specified in the SOPs."

GMP Trends May 1, 2003

In addition, the environmental in house isolates must be considered and laboratory studies must demonstrate that the agent used can achieve a certain log reduction depending on the agent used and the microorganism tested. General recommendations for suspension testing acceptance criteria on a disinfectant efficacy study is a 4-5 log reduction while the carrier acceptance criteria for the same study is a 2-3 log reduction.

Remember disinfectant efficacy testing and disinfectant validation is not the same thing.

Fall Meeting and Vendor Show
September 28, 2005
Sheraton Imperial, RTP

Registration Form included in this newsletter.

Address change?
Email proflink@aol.com to update your contact information.

Follow PDASE.org for updated meeting information.