PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

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[Letter From the President]

August 2007

Dear Members of the PDA Southeast chapter,

I hope you all had a nice summer and had a chance to enjoy some vacation.

I am pleased to report that

the interest for our chapter is growing and that we have received several offers to get involved in chapter committees over the last few weeks, and several of you have joined the team. Thank you for your support, and remember, we always need volunteers to make our chapter live and grow. Do not hesitate to call any member of the committee if you would like to get involved.

Our next main event is the fall vendor show. You should have received a registration form by now. We have a very exciting program and we hope to see many of you there. For more information, please see the event page on the PDASE website at www.pdase.org. The registration form is posted there and you can register on line.

We are also planning to have a holiday social, gathering members for fun, food and drinks. Stay tune for more information to come soon.

You will find in this issue the presentations of the spring meeting and a report on the golf social, which was a fun event, as shown by the pictures.

I would also like to take this opportunity to bring to your attention the new student program introduced by PDA. There are 3 student programs that were developed to promote applied research in areas of study relevant to the scientific foundations of pharmaceutical and biopharmaceutical product development, drug manufacturing and quality assurance technologies. So, if you know students that might be interested (some funding will be available), make sure to let them know. Complete information is available on the PDA website under Professional resources. We will have brochures on the program available at the Fall Vendor show. Please make sure to pick one.

Hope to see many of you very soon.

Patrick Sabourin

If your contact information has changed, please let us know so you will not miss any of the upcoming events.
email:
dwilliamsinc@bellsouth.net

Presentation made at the Spring PDA Meeting

Process Risk Assessment to Ensure Microbial Contamination Control and Q & A

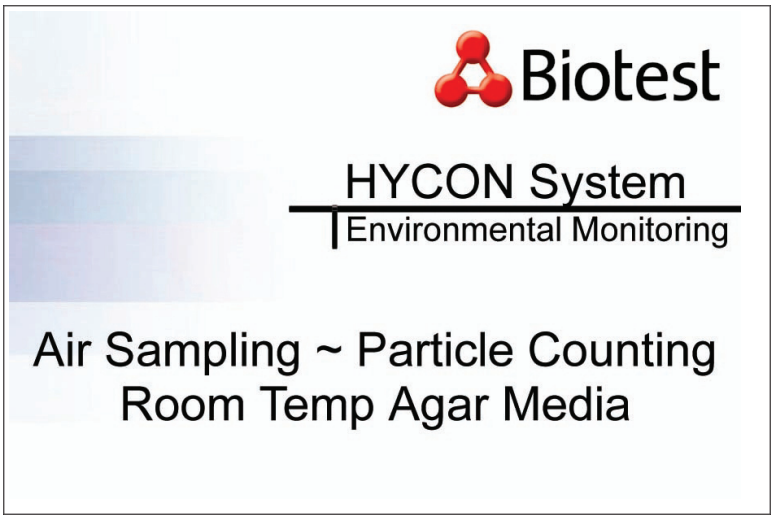
Presented By Lucia Clontz, Director of Microbiology at Diosynth Biotechnology

Summary By Kathy Merold, GlaxoSmithKline

Lucia Clontz's presentation allowed the audience to acquaint themselves with a variety of regulatory requirements and industry standards. Vendor qualification programs must be considered as well as specifications to include requirements for microbial quality and bacterial endotoxin (where applicable). Other important requirements are no cardboard boxes in controlled areas, effective cleaning and disinfection procedures for materials and containers, validated cleaning and sanitization cycles for water systems, and effective monitoring program for water systems. Equipment should be easily disassembled and cleaned, sanitary equipment/parts used, clean equipment stored in sanitary conditions, product contact surfaces resist corrosion, qualified cleaning and sanitization cycles, and use of disposable materials, whenever possible. Lucia also pointed out that facilities and disinfectants or sanitizers should meet industry standards. Air pressure, microorganisms, dust, humidity, and temperature should be in control in the facility. This includes the manufacturing, packaging, and holding areas. Surfaces must be resistant to chemicals, abrasion, and flaking. Floors should be cleaned daily and sloped toward the drain. Traffic patterns and personnel room capacity should be established. Disinfectants and sanitizers should have vendor qualifications. There should be a procedure for product acceptance and rejection and Standard Operating Procedures should detail documentation for the preparation and use of the disinfectants and sanitizers. Contamination control is the science and applied technology that involves processes, environment, materials, equipment, and personnel associated with product manufacturing. This includes microbial contamination, cross-contamination, and particulates and other impurities. The risk of microbial contamination must be assessed in order to ensure product quality and safety. Lucia suggests understanding the processes and sources of microbial contamination. Potential sources of microbial contamination could be raw materials and excipients, equipment, environment, facility design, or personnel. It was suggested to consider the components on the raw materials such as whether or not it is a natural or synthetic, the water activity level, and what type of containers are used. Water systems also fall under the raw material section. Lucia did point out that biofilms can be a problem with water systems.

Lucia defined the Microbial Risk Assessment as a process using a systematic approach to evaluate the likelihood of microbial contamination so that measures to correct and prevent contamination can be implemented. Lucia introduced using Hazard Analysis Critical Control Point (HACCP) methodology to pharmaceutical and biotechnology processes to reduce risk of microbial contamination. The assessment is done during product and process development so that potential risks are designed out. The assessment is planned and carried out for specific products. Differences between pilot and scaled-up processes should be considered. If there are any significant changes a re-assessment must be completed. A flow diagram of the process should be prepared. It was suggested to develop a list of potential risks and key questions to determine the level of risk. Lucia described some considerations during an assessment such as the qualitative and quantitative evaluation of risks, possibility of survival or proliferation of organisms, potential for production of microbial toxins, evaluation or materials and ingredients, equipment and process steps, equipment sanitization procedures, and personnel involvement.

In summary, Lucia Clontz's presentation detailed regulatory requirements and expectations, potential sources and types of contaminants, and a risk analysis tool that can be applied to contamination control.



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2007 Golf Event

By Teri Polson, GlaxoSmithKline

The Annual Southeast Chapter Golf Social was held June 14 at Lochmere Golf Course in Cary. It was a perfect day to be outdoors, meeting and networking with other Chapter members, chasing the little white ball around to qualify for some amazing prizes and give-aways, and enjoying a catered bar-b-que and fried chicken dinner. Prizes were awarded to the following teams/individuals:

Lowest Score
Todd Sanders, Wyeth Laboratories
David Brewer, Sequence Validation
Craig Morgan, Pharmasys Inc

Best Effort (The 'No One Got Hurt' Award)
Rob Orazi, PCI
Shelley Preslar, Invensys Validation Technology
Lisa Hodes, Cardinal Health

Longest Drive, women	Connie Pilkington
Longest Drive, men	Darold Hill
Closest to Pin	Ron Backman, Mike Putnam, Todd Sanders
Straightest Drive, women	Jackie Scialabba
Straightest Drive, men	Craig Morgan
Longest Putt	Patti Glynn, Rob Orazi

A very special 'thank you' to the sponsors for this year's tournament, without whom this event would not be possible:

BioTech Logic
Doe & Ingalls
Hydro Services
ITW Texwipes
Millipore
Pharmaceutical Calibration & Instrumentation
PharmaSys
Sequence Validation
Steris

Have you registered for the PDA Southeast Chapter Fall Meeting and Vendor Show? Registration Forms are included with this newsletter. Deadline is August 24, 2007 so register TODAY!

2007 Golf Event Photos

Your Objectives: Aggressive Schedule
Cost Control
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Your Resource: Commissioning Agents, Inc.

CAI

Local Contact: David Yaffe
david.yaffe@cagents.com
919.696.3721

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COMMISSIONING AGENTS, INC.

PDA Southeast Chapter Fall Exhibitor Show & Meeting

SOUTHEAST CHAPTER

Wednesday, September 5, 2007
9:00 am-4:00 pm

Sheraton Imperial Hotel and Convention Center
RTP, NC

Join PDA Southeast Chapter for our Fall 2007 Exhibitor Show and Meeting at the Sheraton Imperial Hotel and Convention Center, RTP, North Carolina.
The event will be held on Wednesday, September 5, 2007.
Registration begins at 9:00 AM and the day concludes at 4:00 PM.

Schedule of Events

9:00 am	Registration
9:00 am	Exhibitor Show Opens (Continental Breakfast in Exhibit Hall)
10:00 am	PDA SOUTHEAST CHAPTER Business Meeting
10:15 am	**Ongoing Stability Programs for Approved Drugs** ***Anthony J. Polletta,*** *Senior Operations Manager, Talecris Biotherapeutics, Inc.*
11:15 pm	**EU Directive of APIs compliance with GMPs** ***Kathy Wessberg*****,** *Corporate Quality Program Manager at Abbott Labs*
12:15	Lunch Dessert in Exhibitor Area
2:00 pm	**FDA CAPA Compliant Root Cause Investigation and Documentation** ***Wade Speir,*** *Managing Consultant, Life Sciences, PA Consulting*
3:00 pm	Refreshments in the Exhibit Hall
3:45 pm	Door Prizes Awarded in the Exhibit Hall
4:00 pm	Exhibitor Show Closes

Registration Form (please print)

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

Email _____
Directions and registration information will be sent by email.
Please include this important information.

Company _____

Address _____

City, State, Zip _____

Registration Fee:

Before August 24, 2007	$85 per person (includes lunch)
After August 24, 2007	$105 per person (includes lunch)
Students	$35 per person (includes lunch)

No. of people x $85.00 each= _____
No. of people x $105.00 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 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 August 24, 2007, in order to receive the pre-show discount)

By Mail: PDA Southeast Chapter, 302 Versailles Drive, Cary, NC 27511

Deadline: **August 24, 2007**

Questions: Diane S. Williams
919.463.0615 fax: 919.463.0588
Email: dwilliamsinc@bellsouth.net
www.PDASE.org

Exhibitor Registration

PDA Southeast Chapter
Fall Meeting and Exhibits Show 2007
Wednesday, September 5, 2007
Sheraton Imperial Hotel and Convention Center
RTP, NC

You are invited to attend one of the most important events of the year as our special guest, at the PDA SOUTHEAST CHAPTER Fall Meeting and Exhibits Show, 2007. The event will take place at the Sheraton Imperial Hotel and Convention Center in RTP, North Carolina on Wednesday, September 5, 2007. Below is a tentative agenda for the conference.

Wednesday, September 5, 2007

8:00 am	Exhibitor Setup
9:00 am	Member Registration/ Exhibitor Hall Opens
10:00 am	PDA SOUTHEAST CHAPTER Business Meeting
10:15 am	**Ongoing Stability Programs for Approved Drugs** *Anthony J. Polletta, Senior Operations Manager, Talecris Biotherapeutics, Inc.*
11:15 am	**EU Directive of APIs compliance with GMPs** *Kathy Wessberg, Corporate Quality Program Manager at Abbott Labs*
12:15 pm	Lunch (dessert served in exhibit hall)
2:00 pm	**FDA CAPA Compliant Root Cause Investigation and Documentation** *Wade Speir, Managing Consultant, Life Sciences, PA Consulting*
3:00pm	Refreshments in Exhibit Hall
3:45 pm	Door Prizes Awarded
4:00 pm	Exhibits close

PAYMENT METHOD: CHECK MADE PAYABLE TO:
PDA SOUTHEAST CHAPTER or CREDIT CARD

Credit Card # _____

Expiration Date _____

Type of Credit Card _____

Signature _____

The PDA Southeast Chaper serves the states of North Carolina, South Carolina, Georgia, Florida, Virginia and Tennessee. The chapter works to foster and advance the art and science of pharmaceuticals/medical devices/ biotechnology by providing the membership with practical, technical lecture and laboratory education and training in pharmaceutical technology.

Please include a 50 word company description for inclusion in conference brochure. This must be received by *Friday, August 24, 2007.* Use additional attachment if necessary.

☐ ***Yes,*** *I'd like to donate a door prize! Please include a description of your door prize with your registration.*

Register today! DEADLINE IS August 24, 2007
ALL PAYMENTS MUST BE RECEIVED BY THIS DATE
Mail or fax this form to:

PDA SOUTHEAST CHAPTER
Attn: Diane S. Williams, Marketing, Inc.
302 Versailles Dr., Cary, NC 27511
E-Mail: dwilliamsinc@bellsouth.net

Tel: (919) 463-0615 Fax: (919) 463-0588

Name _____

Company _____

Address _____

City/State/Zip _____

Phone _____ Fax _____

E-Mail _____

Is there any company you would **not** like to be placed near?

_____
Complimentary Exhibitor(s) Name (PLEASE PRINT)

1.) _____

2.) _____

Additional representative's names ($80 each)

_____

A. Exhibitor Selections

8' Table Top Exhibit $500.00 ☐
(Includes lunch for 2)

Lunch Registration _____ x $85.00 ☐
(each additional rep. includes lunch)

Electrical service yes ☐ no ☐

Meeting Break Sponsor $150.00 ☐
Recognition during meeting/name listed on table plaque and on meeting publications and at registration table (Limit 3 am and 3 pm sponsors)

Fall Meeting Lunch Sponsor $500.00 ☐
Recognition during meeting/name listed on table plaque and on meeting publications and at registration table. (Limit 2 sponsors)

Logo Bag Sponsorship $100.00 ☐
Your logo will appear on the canvas conference bag (Deadline August 17, 2007)

Total from A _____
Payment due by August 24, 2007

No refunds after August 24, 2007