PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

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[Letter From the President]

November 2007

Dear Members of the PDA Southeast chapter
I would like to start with thanking our members and sponsors for making the fall vendor show another successful meeting for the PDA Southeast chapter. I can report that the speakers and their presentations were well received and triggered some interesting questions and discussions. We have already received requests for information regarding next year's show from some vendors. You will find pictures of the show and a summary of the presentations in the articles included in this and the next newsletter.

The holiday season is around the corner, and the executive committee of our chapter has organized a one time special event to celebrate the success of our chapter, and to thank all of our members and sponsors for their support and participation in the chapter activities. Please see the flyer and registration form in this letter, which will also be posted and distributed in the next few days. Please register and return to the address on the form as soon as possible. The event is free, but space is limited; so do not miss out on this opportunity to be the first to see the winery's new facility.

I am also pleased to report that the chapter has awarded its first scholarship contribution to Campbell University. Their thank you letter is included in this issue. More philanthropy scholarships will be awarded in the next few weeks and will be presented at the Winter social and reported in the next newsletter.

I would also like to point out upcoming events in the RTP area:
*The first Biofilm Conference for the pharmaceutical industry will take place in RTP on November the 14th.
*The USP will be holding a customer day in Raleigh on November the 29th. This event is free.
Please see the flyers and registration forms in this letter and on the website.

The PDA has planned training courses for the first week of June:
Raleigh, NC Training Course Series
Held at Marriott Raleigh Crabtree Valley June 2 – 4, 2008
More details and the list and summary of the courses are available in this letter and on the chapter website: www.pdase.org, and the PDA website: www.pda.org.

Sponsors and vendors, the 2008 sponsorship form is available in this newsletter. Thank you again for your support.

Hope to see many of you at our special event in December.

Patrick Sabourin

Attention:

The PDASE web address has changed. Our new website is integrated into the PDA National website. There are many new features to the new website so please check it out. The current website (www.pdase.org) will redirect you to the new address: http://pdachapters.org/southeast/ . The new website will allow for online registration to upcoming events. It also has a forum section for you to discuss hot topics and any questions you may need help with. We are in the process of uploading information to our new website daily, so please check in on a regular basis for new information

Presentation made at the Fall PDA Meeting

Ongoing Stability Programs for Approved Drugs

Presented By Anthony J. Polletta, Anthony J. Polletta, Senior Operations Manager, Talecris Biotherapeutics, Inc.

Summary By Kathy Merold, GlaxoSmithKline

Mr Polletta presented the scope of the ICH Harmonized Tripartite Guideline, Q1A, Stability Testing of New Drug Substances and Products,(page 1), which states "The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a shelf life for the drug product and recommended storage conditions."

Mr. Polletta gave advice about making sure the guidance is followed. He suggested if you do not plan on following the guidance have sound reasons why the guidance will not be followed. It is important to talk with the Food and Drug Administration before you initiate studies if you plan to deviate from the guidance. He also went over three key questions to ask when developing a stability protocol: Is it meaningful? Is it reliable? Is it specific? Mr. Polletta explained that in order to operate in a state of control the following must be included: sound science, documentation, training, clinical, field reports, procedural, stability, and validation.

Mr. Polletta reviewed container closure systems for packaging human drugs and biologics and discussed examples of packaging concerns for common classes of drug products. For instance, inhalation aerosols and solution, injections and injectable suspensions fall into the category of the highest degree of concern associated with the route of administration with a high likelihood of packaging component-dosage form interaction. Ophthalmic solutions and suspensions, transdermal ointments and patches, nasal aerosols and sprays fall right behind the container closure systems already listed as a high concern associated with the route of administration. Sterile powders, powders for injection, and inhalation powders have the highest degree of concern associated with route of administration with a medium likelihood of packaging component-dosage form interaction. Topical solutions and suspensions, topical and lingual aerosols, oral solutions and suspensions fall into the category of the low degree of concern associated with route of administration with a high likelihood of packaging component- dosage form interaction. Topical powders and oral powders are a low degree of concern associated with route of administration with a medium likelihood of packaging component- dosage form interaction. Oral tablets and oral capsules have a low degree of concern associated with route of administration and a low likelihood of packaging component- dosage form interaction.

Mr. Polletta also emphasized the importance with patients abiding by the expiration dates on the product. An example was given using something most people use frequently, milk. He also used a common over-the-counter medication as a good example of a product that can produce toxic by-products when left at high temperatures such as the interior of a closed car. The importance of stability testing throughout the life of the product was also discussed. Areas of concern about a product during stability testing would be out of specification data, out of trend data, and uncharacteristic behavior.

Mr. Polletta's presentation about ongoing stability programs for approved drugs touched on the basics of stability requirements and gave insight to other issues to take into consideration when developing a stability program. It is important to have the required data as stability testing is important to patient safety and to the company manufacturing the product.

CAMPBELL
UNIVERSITY

Institutional Advancement

October 24, 2007

Southeast Chapter of PDA
105 Jennings Way
Morrisville, NC 27560

Dear Friends:

I would like to add my heartfelt appreciation to those of Dr. Wallace and others for your recent contribution to Campbell University's Pharmacy School Direct Aid Scholarship Fund.

You have joined many other committed and motivated donors who have so generously invested in the future of Campbell University and the future of our students. Thank you for your support and please remember your gift will help make a difference in the lives of young people!

With warmest regards,

Sincerely,

Jack Britt
Vice President
Institutional Advancement

Thank you!

International Association for Pharmaceutical Science and Technology

pdase.org

PDA Southeast Chapter Winter Social

"A Toast to our Chapter"

Thursday, December 6th, 2007
4pm-7pm
Chatham Hill Winery
3500 Gateway Centre Blvd
Morrisville, NC 27560
(919) 380-7135

In appreciation for all our members for the success of the chapter and their continuous support, the PDA Southeast Chapter is hosting a wine tasting at the Chatham Hill Winery near RTP!

Come enjoy hors-d'oeuvres and a glass of wine while we tour the winery and see more than the efforts of PDA SE coming to fruition!

This event will be the first of its kind in Chatham Hill's new facility. This sneak peak is only being offered to you, our wonderful PDA members and guests.

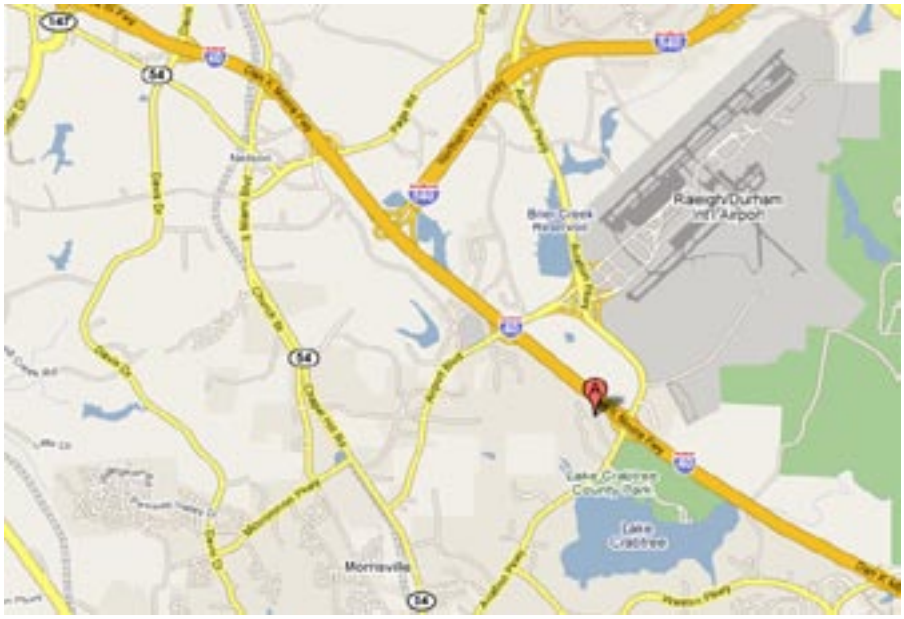
If you know someone who may be interested in joining the PDA SE Chapter this is a great event to bring them along to mingle and network with the members of the chapter!

Schedule of Events

4:00pm	Meet and mingle
4:30pm	First Tour
5:15pm	Second Tour
5:45pm	Wine 101
6:30pm	Sampling

PDA
An International Association For Pharmaceutical Science And Technology

We know most of our guest will be coming from work, and although it may be a no brainer, dress is business casual. Don't worry about your attire, just join us for an evening of fun!



Directions:

From RTP: Head northeast on Aviation Parkway toward Southport Dr. Turn Left on Gateway Center Blvd.

From Raleigh :Take I40 West to exit 285 Aviation Parkway turn Left at the end of the ramp. The Gateway Center is about 0.3mls on your right.

From Durham: Take I40 East to exit 285 Aviation Parkway turn Right at the end of the ramp. The Gateway Center is about 0.1mls on your right.

*****Follow Gateway Center Blvd approximately 0.3mls and follow the signs to the winery's new location.**

PDA Southeast will be the first to tour the new Chatham Hill facility. Be there as we cover Wine 101 and enjoy the fruits of our chapter's labor!

Please RSVP by fax or email at (919)781-3502 or emoniuszko@pci-llc.com by November 26th, to reserve your spot at this exclusive event.

Member Attendees: _____

Non-Member Attendees:_____

Member Numbers:_____

_____

Company:_____

Phone:_____

Fax:_____

Email:_____

This event is free for members and guest, but space is limited. Please notify us immediately if you can not attend to allow waitlisted members the opportunity. For more information contact: Evan Moniuszko at 919-781-7787 x221 or emoniuszko@pci-llc.com or visit us on the web at www.pdase.org.

Biofilm Meeting Agenda

Biofilm Conference 2007

This is the first public event sponsored by the Biofilm Networking Group (BNG). Aimed at the pharmaceutical professional, the event will cover the basics of biofilms, including their harmful effects on pharmaceutical manufacturing.

When:
November 14th 2007

Where:
Campbell University, RTP Campus
808 Aviation Parkway, suite 1100
Morrisville, NC 27560

Meeting Agenda

8:00 - 8:30	Registration and Refreshments
8:30 - 9:00	Introduction - Biofilm Networking Group and its members/sponsors
9:00 - 10:45	Biofilms Basics
10:45 - 11:00	Networking Break
11:00 - 12:00	Biofilm in High Purity Water Systems: Detection and Control
12:00 - 13:00	Lunch
13:00 - 13:45	USP Perspectives on Contamination Control and USP Chapter <1072>
13:50 - 14:30	Biofilm Prevention and Remediation for Biopharmaceutical Manufacturing Equipment
14:30 - 15:00	Networking Break
15:00 - 15:45	Case Study on Disinfectant Efficacy for Equipment Cleaning
15:45 - 16:30	FDA Perspective on Equipment Biofilms and Impact on Product Quality and Safety
16:30 - 17:30	Panel Discussion
17:30	Meeting Adjourned

Meeting Information

Who Should Attend?

Professionals responsible for any aspect of microbial control, including QA, QC, RA, Validation, Engineering, product development scientists and cleaning validation experts.

Learning Objectives:

- Discuss the fundamental aspects of biofilms as applied to pharmaceuticals
- Recognize the tools available to manage and control biofilms
- Understand the regulatory and business implications of equipment biofouling

The cost for this event is $425.00/person.
To obtain the registration form, visit:
www.sci-nc.com

For more information, contact:

Lucia Clontz
(919) 345-1522
lucia.clontz@diosynth-RTP.com

Speaker Bios page 2

REGISTRATION IS LIMITED TO 50 PARTICIPANTS!

Mark Your Calendar for USP Customer days

USP Customer Days Schedule

10 a.m.–3 p.m.

- ❑ **October 30, 2007**
  East Brunswick, NJ
- ❑ **November 29, 2007**
  Raleigh, NC
- ❑ **February 28, 2008**
  Irvine, CA
- ❑ **May 14, 2008**
  St. Louis, MO
- ❑ **June 4, 2008**
  Montreal, Canada

Beginning this fall, the USP Account Management Team will be traveling across the U.S. and Canada. At each stop, we'll be presenting **one-day, free seminars** to discuss timely issues regarding USP initiatives and how you can use them to your best advantage. Seminar topics include

- **USP Publications**
- **Reference Standards**
- **USP Verified Services**
- **Pharmacopeial Education**
- **Opportunities to get involved with USP**

All events will include a Q&A session and take-home materials. Lunch will be provided.

Register Online Today—It's FREE!!
www.usp.org/goto/USPCustomerDays

MS207F

U.S. PHARMACOPEIA
The Standard of Quality℠

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Raleigh, NC Training Course Series
Held at Marriott Raleigh Crabtree Valley June 2 – 4, 2008

JUNE 2

Achieving cGMP Compliance During Development of a Biotechnology Product – PDA #286

This interactive lecture is designed to provide guidance on how Current Good Manufacturing Practices (cGMP) regulations and principles should be interpreted and applied from product development through the final stages of biotechnology drug manufacture and approval (preclinical through phase III and validation lots). The course will cover all aspects, from the foundations necessary for early stage cGMP and Quality Programs, to cGMPs applied in development labs, application to early manufacturing phases, QC and QA responsibilities and how a cGMP program can be applied and grow along with the process and the business.

JUNE 2-3

Practical and Effective Application of Design Review as a Risk Management Tool (NEW COURSE) – PDA #112

Design Qualification/Review is a new concept being applied to facilities, equipment and systems in the drug manufacturing industry. The FDA is enforcing this component of the *Quality by Design* approach through the application of the new guideline on Quality Systems and the ICH Quality guidelines such as Q7A and the future Q10. It is a concept that makes business common sense – review the design to meet your specifications and avoid exponentially larger costs by detecting problems/discrepancies earlier. This concept must be applied using a risk-based decision in terms of which systems and at what level to apply the Design Review requirements.

Root Cause Investigation for CAPA – PDA #576

Root cause investigation for corrective and preventive actions (CAPA) is a proven methodology to investigate and identify the root cause when there has been a shift in the performance of a product, machine, equipment, work process, or system. The methodology identifies the change(s) that have occurred so that they can be eliminated and the performance can return to its previous level. A template is used to guide the participants through the CAPA investigation and suggest appropriate tools. After each step is presented, the participants immediately apply their learning on a case study of a real problem. A great part of the second day is devoted to strengthening that knowledge and practicing the skills on a second, more complex, real issue so that the participants are prepared to immediately apply the learning back on the job.

JUNE 2-4

Pharmaceutical Water Systems Design and Validation – PDA #387

This course is structured to address the design, operation, maintenance, microbiology and validation of pharmaceutical water systems. An overview of raw feedwater characteristics, basic theory of water purification unit operations and the evolution of emerging technologies will be presented. Water purification systems ultimately used as an ingredient - particularly for parenteral products for production of bulk pharmaceuticals - will be addressed. A discussion of USP Purified Water and Water for Injection Systems will also be presented. Discussion associated with USP Purified Water Systems will address potential substitution of purified water meeting the chemical, bacterial and bacterial endotoxins for USP Water for Injection (WFI) as a substitute in various manufacturing operations, and prior to final rinses with WFI. Several state-of-the-art USP Purified Water designs will be presented. Important considerations for pre-treatment to WFI systems will be discussed, particularly the effect of chloramines, trihalomethanes and ammonia on final product water quality. A thorough discussion of Supplement 5 of USP 23 will be presented, and validation considerations for new and existing systems will be addressed.

JUNE 3-4

Preparing for an FDA Pre-Approval Inspection – PDA #455

This course presents a brief review of FDA inspections that are conducted in accordance with the FDA pre-approval inspection (PAI) program and highlights certain activities that are normally carried out well in advance of the PAI. Described, are systematic steps that may be followed to assure that development activities are suitable (i.e., provide scientific support), and to ensure personnel are able to provide the information that is commonly addressed during pre-approval and post-approval inspection programs (e.g., FDA Compliance Programs 7346.832 and 7346.843).

Preparation for PAIs is broken into three phases (*Before*, *During* and *After* the inspection). For each of these phases, information is provided for what each employee may do to get ready, and what the company should do to prepare.

JUNE 4

Fermentation Scale-Up and Biologics Production (NEW COURSE) – PDA #203

This course will cover the basic principles of biologics production through the application of fermentation, cell culture, separations and purification techniques. Concepts of scale-up will be illustrated through practical manufacturing scenarios. Processing equipment, control systems and overall process design will be described and illustrated with many practical examples. Creation of model manufacturing processes by the use of selected and properly sized unit operations will be discussed.

Bioassay Development and Validation (one-day version) – PDA #227

This course covers the fundamental concepts needed to understand bioassay, bioassay development and validation of bioassays, and reviews the statistical issues and concepts in calibration. Substantial time is devoted to basic statistical concepts and how they are relevant to the practical limitations of bioassays, particularly when performed in 96 well cell culture plates. Statistical terms which will be introduced include blocks, experimental units, analysis of variance and analysis of covariance. The course develops tools for bioassay development and enables participants to place bioassay validation in the larger context of bioassay development. The rationale behind each of the requirements in USP 23 <111> is explained and several approaches to meet these requirements are discussed. The specific methods presented in the USP 23 <111> and the European Pharmacopeia are explained and compared. Validation of bioassays are developed in detail in the context of satisfying both USP 23 <111> and <1225>.

The course also includes in-class drills on the statistical concepts as they apply to bioassay. Those who have some relevant experience stand to gain the most from the material presented, the drills and the discussion.

PDA SOUTHEAST CHAPTER
2008 SPONSORSHIP OPPORTUNITIES

The Southeast Chapter of the PDA has now been in existence for over 10 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 attract over 100 attendees**. The Chapter produces a series of newsletters every year and hosts other special events such as **Annual Golf Outings**, **Special Events**, and co-sponsors **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.

- The PDA Southeast Chapter Executive Committee

My company would like to support the PDA Southeast Chapter in 2008 in the following ways:

Company Name:	
Contact Name:	
Contact email:	
Company Address:	
Phone:	
Fax:	
Web site:	

Opportunity	Sponsorship Description	Contribution
Year Long Support Opportunities		
Newsletter Recognition & Web Site Link	Your 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.	- website link included - $200 Business Card Size $250 ¼ Page $400 ½ page $500 full page _____
Year Long Support Opportunities	**Subtotal**	

Spring Meeting March 2008		
Meeting Exhibitor	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. Table space is limited to 6 vendors	$400 for 6' Table Space, 1 representative with lunch
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 on fliers on the registration table. Limit 3 for AM break and 3 for PM break	$150 AM Break $150 PM Break _____
Lunch Sponsor	This helps defray the expense of the luncheon and your company will be recognized verbally and on table plaque and on fliers on the registration table. Limit 2 for Lunch Sponsor	$500 Lunch Sponsor _____
Exclusive Sponsor	Your company will receive special recognition as the key sponsor of the meeting. In addition to verbal and printed recognition, your company representative will be able to briefly address the members at opening of meeting. Limit 1 – First Come First Served	$600 Spring Exclusive Sponsor with brief address of members. _____
Door Prize	The Chapter always appreciates donations of door prizes at our meetings and items for goody-bags at the Golf Social. Check here if you would like to make a door prize donation. Your company's name is announced as the gift is awarded.	Yes, We will be supplying a Spring Meeting Door Prize _____
Spring Meeting Support Opportunities	**Subtotal**	

Fall Meeting & Vendor Showcase TBD -		
Meeting Exhibitor	Your company will have an exhibit table at the vendor show, 2 representatives for lunch, and a 50-word company description in the program. ___ Yes, We need Electrical Service	$500 for 2 exhibitors, table and lunch _____

MARK YOUR CALENDARS

Eighth Annual PDA Southeast Chapter
Golf Social
(NOT for the serious golfer!)

Friday, June 13, 2008
9:30am Shot-gun Start

(NOTE: start time one hour earlier than last year)
Lochmere Golf Club
Cary, NC

Golfer registration and sponsorship information to follow

Additional Representative	Additional representative for the Fall Meeting, includes Lunch.	$85 for additional rep, includes luncheon _____
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 on fliers on the registration table. Limit 3 for AM break and 3 for PM break	$150 AM Break $150 PM Break _____
Lunch Sponsor	This helps us defray the expense of the luncheon and your company will be recognized verbally and on table plaque and on fliers on the registration table. Limit 2 for Lunch Sponsor	$500 Lunch Sponsor _____
Exclusive Sponsor	Your company will receive special recognition as the key sponsor of the meeting. In addition to verbal and printed recognition, your company representative will be able to briefly address the members at opening of meeting. Limit 1 – First Come First Served	$750 Fall Exclusive Sponsor with brief address of members. _____
Fall Vendor Show Logo Tote Bag	Your company's logo will be printed on the canvas tote bag given to meeting attendees.	$100 _____
Door Prize	The Chapter always appreciates donations of door prizes at our meetings and items for goody-bags at the Golf Social. Check here if you would like to make a door prize donation. Your company's name is announced as the gift is awarded.	Yes, We will be supplying a Fall Meeting Door Prize _____
Fall Meeting Support Opportunities	**Subtotal**	

Golf Social June 2008		
Golf Social Sponsor	Sponsor a hole on the course of our "Not for the serious golfer" social! Your company will be recognized verbally when hole prize is awarded and with a sign on the tee.	$200 per hole _____
Golf Social Goody Bag Donation	The Chapter always appreciates donations of door prizes at our meetings and items for goody-bags at the Golf Social. Check here if you would like to make goody-bag donation for the golf outing. Contact us for counts approximately 3 weeks ahead.	Goody Bag Donation _____
Golf Social Support Opportunities	**Subtotal**	

PDASE SPONSORSHIP 2008 **Total**	

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:
(Suggestions include donation of computer projector, overhead projector, flip charts, meeting program printing and binding expenses or administrative services)

Please send completed forms and checks to:

Diane Williams
302 Versailles Dr.
Cary, NC 27511
919-463-0615
fax: 919-463-0588
dwilliamsinc@bellsouth.net