



The PDA Southeast Connection

Connecting People, Science and Regulation

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New Association Management Firm Chosen

The PDA Southeast Chapter Executive Committee recently chose Blue Star Services to manage the day-to-day activities of the PDA Southeast Chapter. Blue Star Services was chosen due to their knowledge of our industry and the services which they can provide to the organization. Blue Star Services is based in Chapel Hill, North Carolina. It is owned and operated by Debora and George Steenson. Debora holds a marketing degree and has been in the association management and convention planning field for over 24 years. Her experience provides organizations with a vast array of skills to accomplish their goals. She has managed over 22 associations during her association management career. Accolades and services include: Rotary International Four Avenues of Service Citation for Individual Rotarian, Volunteer Coordinator for Habitat for Humanity and the Susan G. Komen Breast Cancer Foundation Race. She was presented the ASID Carolinas Chapter Presidential Citation for Distinguished Service and The International Society of Pharmaceutical Engineers twice awarded the Excellence in Chapter Management Award.

George was president of ProActive Association Management, Inc. for over seven years. During that time, he managed the daily activities of the business and worked closely at developing synergistic relationships with the association's vendors. Additionally, George has assisted Debora in the management of events and the day-to-day operations of the various associations they managed. His analytical skills and attention to quality, have served those organizations well. Currently George volunteers as a project manager for "Helping Hands" a church based program which assists Chatham and Orange County residents in need of home repairs. George also works with Habitat for Humanity.

Blue Star Services staff members concentrate in the special areas of graphic design, trade show management, meeting management, event planning and financial management.

The Steensons' feel the best way to service their clientele is by addressing the specific needs of the organization, we can accommodate and expand our services to reach the mission and goals outlined by the leadership.

"We are very honored and pleased to be partnering with PDA Southeast and look forward to working with the leadership and membership of the organization to advance the mission of PDA Southeast", Debora Steenson commented.

To contact Blue Star Services, pdase@bluestarservices.net or call 919.418.1325.



Upcoming Events

Golf Social

June 13th

In this issue

*Golf Social Registration
Student Winners*

*Detection of Microbial
Contamination Article*

Committee Chairs

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Communications Committee Chair

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Philanthropy Committee Chair

Shelley Preslar
Invensys Validation Technologies
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If you would like to be a member of a committee, please contact the Committee Chair or the PDA Southeast Chapter Manager. Your involvement is encouraged.

***In the
Next Issue***

***Highlights of the
Spring Meeting***

Detection of Microbial Contamination by Rapid Quantitative RT-PCR

*Presented by Stephen Lovell, PhD, Lonza Bioscience at the Spring Meeting
Summary of presentation by Kathleen Merold, GlaxoSmithKline*

Stephen Lovell, PhD, from Lonza Bioscience, discussed how to detect total viable microorganisms, bacteria in one assay and yeast and mold in another assay, using the microCompass™ Method. The system works using extraction, amplification, and detection of nucleic acids from microorganisms using Quantitative RT-PCR technology. Ribosomal RNA is the target molecule using 16S rRNA for bacteria and 18S rRNA for yeast and molds. Ribosomal RNA is used because RNA sequences are highly conserved, the presence of RNA reflects protein synthesis and viability, and there are more target copies compared to DNA-based methods.

Sample preparation depends on whether a sample is filterable or non-filterable. The spin filtration method was reviewed. Using this method, the microorganisms are captured using a filter membrane. Then the microorganisms are resuspended in lysis buffer. A combination of mechanical lysis and lysis buffer breaks down cells and spores to free nucleic acid from the sample. The next step is RNA extraction. The samples are placed onto the rRNA Extraction Robot. Here RNA binds to the surface of the magnetic beads and is purified through a series of washes. Nucleic acids bind to the beads and are lifted out of the solution. The next steps are another wash step, a drying step, and an elution step, which strips PCR-ready RNA from the beads into the solution. The extracted RNA sample and PCR reagents are added to capillary tubes. The RT-PCR process includes a thermocycler and fluorometric optics. The Thermal Cycler generates a real-time PCR report for analysis.

Some examples for use of the microCompass™ system are Preservative Efficacy Test (PET), testing cell cultures, and water testing. A case study was presented for each of these applications.

PDA Southeast Chapter

c/o Blue Star Services

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Visit www.pdase.org

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PDASE Student Awards

The PDA South East Chapter is contributing towards the future of drug development through the establishment of the PDASE Student Awards. What better way to show students that the drug development industry cares about their career development, than by contributing to their scholastic future? Shelley Preslar, Philanthropy Committee Chair; Wendy Haines, Philanthropy Committee member; and Bruce Craven, PDASE Chapter Treasurer visited 4 local universities this Fall to present each with the PDASE Student Chapter Award. The following universities/programs now have an endowed PDASE Student Award:

Campbell University School of Pharmacy,
Pharmaceutical Sciences Program

North Carolina State University, BTECH
(Biomanufacturing Training and Education Center) Program

North Carolina Central University, BRITE
(Biomanufacturing Research Institute and Technology Enterprise) Program

University of North Carolina, Chapel Hill

The student winners were presented engraved business card holder/pen sets at the PDASE Winter Social on December 6, 2007. Below you will find a list of the inaugural student award recipients:

1. Lam Nguyen
Campbell University
2. Ogechi Ihenatu
North Carolina Central University
3. Ikechukwu Ihenatu
North Carolina Central University
4. Nicole Seabrook
North Carolina State University
5. Stacey Foti - Graduate Winner
University of North Carolina,
Chapel Hill
6. Jessica Steve
Undergraduate Winner
University of North Carolina,
Chapel Hill

Additional information about these and other PDA sponsored Student awards can be found at www.pda.org. You can learn more about some of the inaugural PDASE student award recipients below.

Stacey Beth Foti is in her final year at the University of North Carolina, Chapel Hill pursuing her PhD in Neurobiology in the labs of Jude Samulski and Thomas McCown. Stacey's thesis work revolves around generating novel Adeno-Associated virus (AAV) vectors to deliver therapeutic neuropeptides that will reduce the occurrence and severity of seizures. While in graduate school, Stacey generated and then used viral vectors for gene therapy, and as a tool to elucidate brain function. Stacey would like a challenging and team-oriented job, perhaps for a small biotechnology company. In this environment, Stacey would be able to explore what types of work she will enjoy and determine how she can best contribute to the drug industry.



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PDASE Student Awards *Continued*



Ogechi Ihenatu is a senior and in the charter class of the Biomanufacturing Research Institute and Technology Enterprise, BRITE, Program at North Carolina Central University. Ogechi is number one in her class and will graduate in May 2008 with a BS degree in Biology with a Concentration in Biotechnology. She would like to attend Pharmacy School upon her graduation, this May. She envisions herself working for a biotechnology company in the future.

Ikechukwu ("Ike") Inhenatu is a senior and in the charter class of the Biomanufacturing Research Institute and Technology Enterprise, BRITE, Program at North Carolina Central University. Ike is number two in his class will graduate in May 2008 with a BS degree in Biology with a Concentration in Biotechnology. Ike would like to pursue an MD/PhD combined degree upon his graduation, this May. He is very interested in staying in the lab and performing research for either the FDA or NIH.

Lam Nguyen is a senior in the Pharmaceutical Science Program, at Campbell University, School of Pharmacy. She attended Georgia Perimeter College in Lawrenceville, GA her

freshman year of college, and then transferred to Campbell University. Lam is very interested in careers in molecular biology. After obtaining her BS in Pharmaceutical Sciences in August of 2008, she plans to get a MS in Pharmaceutical Sciences, with a concentration in Biotechnology. In the future, she would like to work in cancer therapeutics research.

Veltek Associates, Inc.

Brent Watkins
Southeastern Sales Manager
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Sterile Chemicals
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Eighth Annual PDA Southeast Chapter Golf Social

(NOT for the serious golfer!)

Lochmere Golf Club

2511 Kildare Farm Rd

Cary, NC

Ref. www.Lochmere.com for directions

Friday, June 13, 2008

9:30am Shot-gun Start

(Registration begins at 8:30am)

- Captain's Choice Format
- Entries may be individual or in pairs (team pairings will be random, arranged by Organizing Committee)
- Teams are not handicapped – for fun and networking
- Team Prizes
- Hole Prizes (longest drive, closest to the pin, etc)
- Door Prizes
- Complimentary Roving Beverage Cart
- Catered Bar-B-Q Dinner

Entry Fees:

Individual \$35

Paired 2-some (will play together) \$70

NOTE: Each golfer must supply their own golf shoes (soft spikes) and golf clubs

To Register: Complete and return attached registration form **before June 6, 2008** to:

PDASE
c/o Blue Star Services
1829 East Franklin Street – Ste 600
Chapel Hill, NC 27514

919.418.1325 Phone

Payment Must Accompany Registration - Two Payment Options:

1. By check payable to 'PDA Southeast Chapter'
2. By credit card – complete required information on the registration form



2008 PDA Southeast Chapter Golf Social
June 13, 2008
Lochmere Golf Club

Registration
(please print legibly)

Player #1 (Please Provide ALL Requested Information, \$35.00 entry fee)

Name _____

Company _____

Daytime Phone _____

Approx. score for 18 holes _____ (required)

email address _____
(optional, if you would like registration confirmation)

Player #2 – Complete ONLY if you are registering as a 2-some (\$70 entry fee)

Name _____

Company _____

Daytime Phone _____

Approx. score for 18 holes _____ (required)

email address _____
(optional, if you would like registration confirmation)

Complete and return attached registration form before June 6, 2008 to

PDASE
c/o Blue Star Services
1829 East Franklin Street – Ste 600
Chapel Hill, NC 27514

919.418.1325 Phone

Indicate Method of Payment:

_____ **CHECK** Enclosed (\$35 individual/\$70 for 2-some, Payable to ‘PDA Southeast Chapter’)

_____ **CREDIT CARD** – Provide the following required information:

Type of Card _____ Name as it appears on card _____

Card Number _____ Exp Date _____

Signature _____



‘FORE’ Vendors



Sponsorships available for the Eighth Annual PDA Southeast Chapter Golf Social

Friday, June 13, 2008

9:30am Shot-gun Start

(Registration begins at 8:30am)

Lochmere Golf Club

2511 Kildare Farm Rd

Cary, NC

Ref. www.Lochmere.com for directions

\$200 Sponsorship Includes:

- 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 items (golf balls, tees, markers, bags, huggers, golf towels) **received by June 9** will be included.

To register as a sponsor – **Must be received before June 1, 2008**

Complete and return the attached form by US Mail to:

PDASE
c/o Blue Star Services
1829 East Franklin St. – Ste. 600
Chapel Hill, NC 27514

919.418.1325 Phone

Payment must accompany registration – Two Payment Options

1. By check payable to ‘PDA Southeast Chapter’
2. By credit card – complete required information on the attached registration form



PDA Southeast Chapter Golf Social
June 13, 2008
Lochmere Golf Club

Vendor Sponsorship Registration
(please print legibly)

Company _____
(As you would like it to appear on signage)

Contact Name _____ Phone _____

E-mail _____

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

(2) _____

Note: this is for sponsor registration ONLY, separate registration and entry fee required to register as a player

Item(s) for goodie bags _____

Complete and return attached registration form before June 1, 2008 to

PDASE
c/o Blue Star Services
1829 East Franklin St. – Ste. 600
Chapel Hill, NC 27514

919.418.1325 Phone

Indicate Preferred Method of Payment:

_____ **CHECK** Enclosed (\$200 sponsorship, Payable to 'PDA Southeast Chapter')

_____ **CREDIT CARD** – Provide the following required information:

Type of Card _____ Name as it appears on card _____

Card Number _____ Exp Date _____

Signature _____