PDA Parenteral Drug Association Southeast Chapter

The PDA Southeast Connection

Connecting People, Science and Regulation

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Upcoming Events

2008
Fall Conference
& Vendor Show
September 23
Awards Reception
December 8

From the PDA Southeast Chapter President...

Dear Members of the PDA Southeast Chapter,

With summer coming to a close, and 2009 approaching faster than some of us would like, I'd like to summarize some of the significant events that took place within PDASE so far this year.

In March of this year, Diane Williams chose to step down as our association manager. PDASE interviewed several management companies and chose Blue Stare Services out of Chapel Hill, North Carolina. Blue Star Services is owned and operated by George and Debora Steenson. Many of you have already met them as they were present at our Spring Conference this March, and they organized our Golf Social in June.

Our Spring Conference took place at the Biotech Center in RTP and, was well attended. Many vendors displayed their products and services. A sit down lunch was provided and sponsored by Accugenix, a proven supporter of PDA Southeast. I'd like to extend a big thank you to all the vendors that came out to support this function, as well as all the PDASE members, and Ta-Mela Jeffries from PDA national.

Our Golf Social took place at Lochmere Golf Club where on a beautiful sunny day; we had 69 golfers take to the links for a great day of golfing followed by a barbeque lunch. A drawing for prizes was conducted during lunch, and I'm pleased to say, everyone walked away with a gift, memo-

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In this issue

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Quality Processes in Manufacturing

Around the Job...

2008 Job Seekers Market

B y David G. Smith Area Manager Kelly Scientific Resources
Email: David_Smith@kellyservices.com

There is no doubt that the U.S. job market has softened considerably since the beginning of 2007. One does not have to look hard to see frequent announcements of plant closures, reorganizations, and layoffs. There are three specific factors affecting the pharmaceutical and biotech industries today.

1) An unstable investment atmosphere
2) The imminent expiration of several patents for blockbuster drugs, and
3) An increasingly demanding regulatory environment

Datamonitor states that drugs earning $140 billion in sales will lose patent protection by 2016. This fact, coupled with harder to obtain financing and the increasing cost of clinical trials, is forcing the industry into a period of change. During this change, the labor trends will be difficult to predict with precision, but we believe that the demand for talented scientists will remain generally high.

In the second half of 2008, the employment picture will continue to favor the job seeker. While job searches may take a bit longer, job seekers are apt to find a number of options available. Despite the fact that there may be more layoffs in the upcoming months, we are finding that most affected employees find new positions quickly. However, you will need to consider a few tips when looking for a job:

- Network, network, network
- Target industry specific job boards (i.e. PDA Website)
- Practice interviewing with a friend
- Spend the time to create a stellar resume
- Treat your job search as a full-time job

According to our customers, we will see a continued high demand for chemists (analytical, method development, polymer, and organic/synthetic), microbiologists, clinical research professionals, and regulatory specialists. Staffing in manufacturing and quality areas will continue to trend lower as many companies trim costs. While much of "Big Pharma" faces ongoing reorganizations, pharmaceutical companies specializing in generics are hiring in substantial numbers.

If you find yourself looking for a job or needing to increase staff, 2008 will prove challenging, but there is reason to be optimistic. Most candidates will need to be more flexible than in the recent past; but, they are likely to have a variety of job options. While there will be slightly more candidates on the market in 2008, employers will continue to struggle to identify skilled scientists. Because the national unemployment rate remains at a historically low 5 percent, overall, employment prospects remain solid.

Members In The News

Accugenix, Inc. is proud to announce the September 4 release of its 2008 Bacterial Library! The leader in genetic microbial identification, Accugenix has tested and analyzed over 300,000 environmental isolates common to pharmaceutical and other manufacturing sites. Our library update includes organisms recently discovered and/or previously unidentifiable at the species level. Accugenix boasts the industry's most comprehensive validated DNA sequence library, and the new Bacterial Library marks our continued commitment to providing customers with the industry's best microbial identification services. FDA-registered, cGMP compliant, competitive global standards. Accugenix—the leader in genetic microbial identification. Please visit www.accugenix.com/pdase

Griffin Engineering recently has moved into their new office in Morrisville, NC. The new office is centrally located in RTP, near RDU airport. The location provides RTP clients with immediate support. Their design, commissioning, validation, LEED, energy studies, and NEBB® Certified Test, Adjust, and Balance divisions operate from this office. They have added a production area for process skid development and testing, as well as, a specialized area and equipment for training and procedure development for their TAB division. Contact Info: JimGriffin@Griffin-Engineering.com

If you would like to contribute to the Members in the News, send information to pdase@bluestarservices.net

From the PDA Southeast Chapter President...*(continued)*

ries of a great day, and a photo of their foursome. Another Thank You is in order. PDASE would like to thank all of our sponsors for helping with this special event. Without them it could not take place, so if in your daily activities you see one of them, please take a moment to thank them for their continued support, and let them know you look forward to seeing them next year.

Please mark your calendars for the PDASE Fall Vendor Show to be held on Tuesday, September 23rd at the new Marriott City Center in downtown Raleigh. This promises to be a special event you won't want to miss. Information regarding the Fall Conference & Vendor Show should have been received. I am looking forward to seeing you and your colleagues there.

In closing, I'd like to remind you that your chapter is dependent on the support of its vendors, sponsors and members like you. If you'd like to volunteer for a committee, please contact our Management Company at: PDASE@bluestarservices.net. You can also contact Blue Star Services with any updated information, or questions you may have.

I sincerely hope you have a safe and happy summer, and I look forward to seeing all of you at our remaining 2008 events!

Patrick Sabourin, President
PDA Southeast Chapter

PDA
Parenteral Drug Association
Southeast Chapter

Quality Processes in Manufacturing

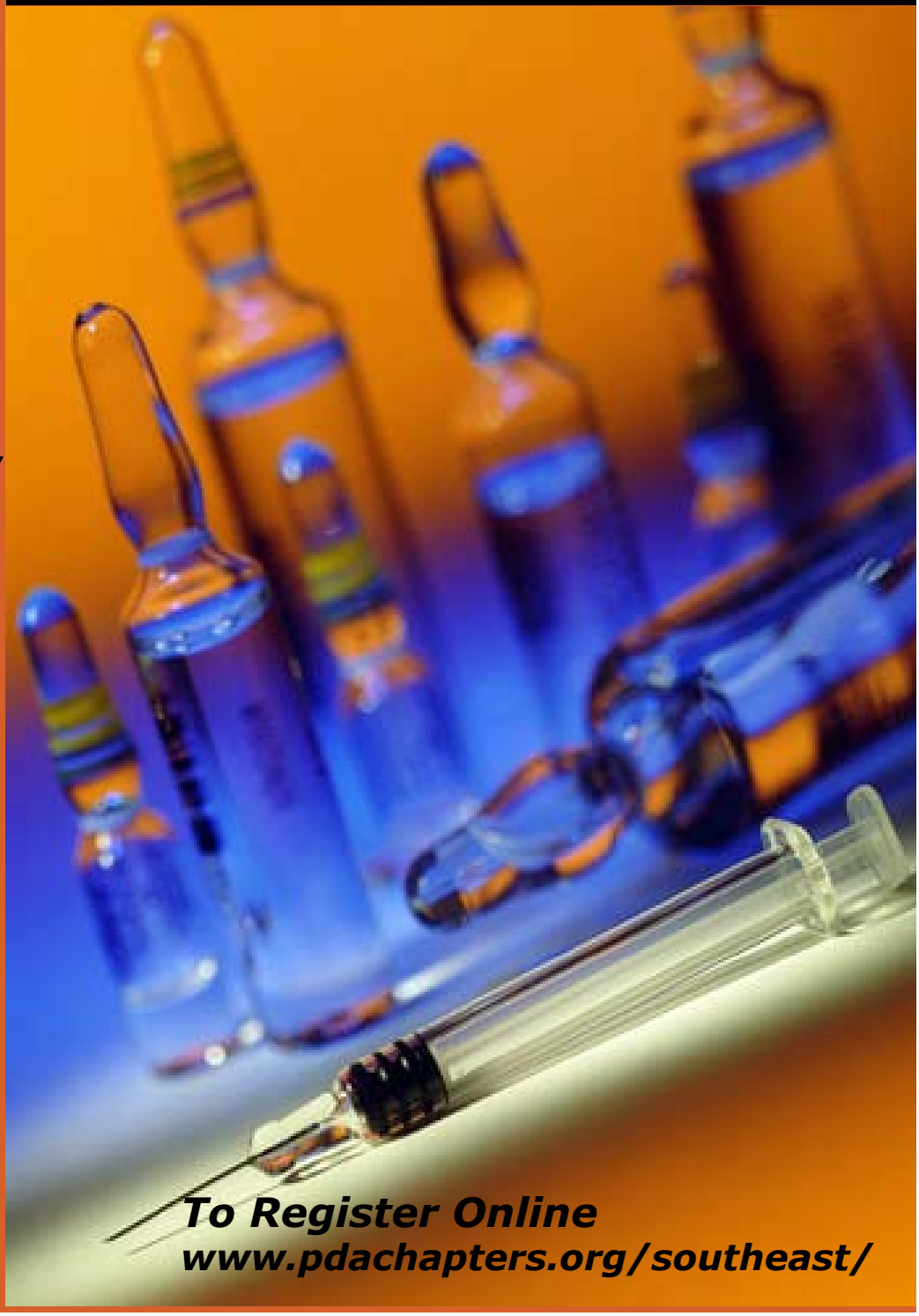
PDA Southeast Chapter

2008 Fall Conference & Vendor Show

Tuesday
September 23

The New Raleigh Marriott City Center
located in Downtown Raleigh

- Educational Sessions
- Latest in Technology
- Networking Opportunities
- Free Parking Tokens for Attendees



To Register Online
www.pdachapters.org/southeast/

2008 Fall Conference & Vendor Show

Tuesday, September 23, 2008
The NEW Raleigh Marriott City Center
Downtown Raleigh, North Carolina

You are invited to attend one of the most important events of the year as our special guest, at the PDA SOUTHEAST CHAPTER Fall Conference & Vendor Show. The event will take place at the ***NEW*** Raleigh Marriott City Center in downtown Raleigh, North Carolina on Tuesday, September 23, 2008.

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.

AGENDA

6:00am-7:30am Exhibitor Setup

7:30am–8:30am Registration/ Exhibitor Hall Opens

8:30am–9:30am ***Leveraging Statistical Methods and Analysis for Validation***
Stephen M. Perry, PMP - President, Kymanox

The premise of "n=3=validated" is not consistent with the FDA's 21st Century approach to quality and new global quality systems such as Q10. Adopting the principles of QbD also means adopting practices that are rooted in sound science - which includes statistics. It is imperative that validation efforts utilize statistical methods to help determine sample sizes, acceptance criteria and related data evaluations. With proper awareness and training, both technical and quality individuals should be able to use the most common statistical tools and know when situations require consultation by a trained statistician.

Stephen M. Perry, PMP is the founder and president of Kymanox – a diversified company specializing in technical project management for the pharmaceutical, biotechnology and medical device industries. He has a well over decade of cGMP manufacturing experience as a process engineer, technical project manager and quality advisor. Stephen has led three multi-million dollar capital projects and has contributed to five major facility installations which began at the conceptual design phase. Before starting Kymanox, Stephen had various leadership roles supporting scale-up, start-up and commercialization initiatives at Abbott Laboratories, Covance Biotechnology Services, Diosynth Biotechnology and Human Genome Sciences.

Stephen has a liberal education background with a high-honors bachelor's degree in Chemical Engineering from the University of Notre Dame and studied at the graduate level at Purdue University. Stephen is member of the International Society of Pharmaceutical Engineering (ISPE) and is a certified Project Management Professional (PMP) by the Project Management Institute

9:30am-10:00am Business Meeting

10:00am–10:30am Break with Exhibitors

10:30am–11:30am ***Early Trials Manufacturing and Product Consistency in the Biotech Industry***
Tatyana Touzova-Senior Director of Quality Assurance-Biolex Therapeutics, Inc

Biolex' Lemna Expression System (LEX ™ System) uses aquatic plant Lemna (duckweed) to produce transgenic proteins for therapeutic applications. Biolex currently has company's leading product an interferon alfa-2b in Phase 2 clinical development and is faced with the challenges of Phase 3 Investigational Medicinal Products. This presentation will discuss:

- Biolex resolution of the challenges offered by the novel production system in the production of GLP and early phase clinical trials.
- Integrating regulatory considerations at the early stage of development to avoid setback and adjustments at the time of filling the applications with the regulatory authorities.
- Scientific based and Risk based approaches to provide the flexibility in transitioning from GLP to GMP clinical manufacturing. Implementation of a tiered quality system at the pre-clinical stage of development to leverage the consistency of product features throughout the developmental phases.

Mrs. Touzova joined Biolex Therapeutics in 2003 as a Director of Quality Control. She was responsible for establishing QC capacity within the organization and later managing all QC opera-

tions related to microbiology, chemistry, bioassay, in-coming raw material and stability program. More recently, she became the Director of the Quality Assurance department and now serves as Senior Director of Quality Assurance. In this role, she oversees all QA operations at Biolex Therapeutics including drug substance and drug products release for pre-clinical and clinical studies, QA Compliance activities, QA Engineering, and validation functions. She is also the CMC reviewer for regulatory submission and is in communication with the agencies. Her experience includes management responsibilities within the QA organization at Diosynth (biotechnology) and earlier at Xanthon (medical device). She also held major responsibilities within the QC department at Biogen previously. Mrs. Touzova received a Master of Science degree in Bioengineering from Mendeleyev Institute of Chemical Technology, Moscow.

11:45am–1:00pm Lunch in Exhibit Hall

1:00pm-2:30 pm ***Mitigating Raw Material Risk for Supply Chain Continuity***

John Hollenbach, MBA- Director of Sales and Marketing-Doe & Ingalls of NC

The rise of lean operations has forced companies to consider both efficiency and risk when making supply chain decisions. Important corporate goals to improve productivity, eliminate redundancies, reduce waste and squeeze costs from operations impact supply chain security.

This presentation will give an overview of the major risks and discuss a framework for assessing those risks. It will also provide recommendations from Doe & Ingalls of North Carolina's experience on how to mitigate risk to avoid supply chain interruptions while being mindful of operational efficiency.

The presentation will help the audience become savvier in managing its supply chain, will expose the audience to a framework for evaluating risk, discuss market-wide versus product-specific risks and will get audience to consider how lean manufacturing and risk mitigation can impact each other

John has worked in the biotechnology industry for over 18 years, spending the past 14 years at Doe & Ingalls of North Carolina in sales and marketing management. He specializes in advising customers on ways to change, improve and secure their raw material supply chains to prevent supply chain interruptions. John received his BS in Chemistry and MBA from the University of North Carolina at Wilmington.

Solutions for Addressing Bacterial Spore and Mold Spore Excursions in Pharmaceutical and Biotech Operations

Jim Polarine Jr, MA-Formulated Chemistries Technical Service Specialist-STERIS Corporation

The industry has seen an increase in the number and species of bacterial endospores and mold spores found in their facilities. This presentation will focus on ways to limit bacterial and mold spore contamination from incoming items into cleanrooms and limit other sources of spore contamination. Sporicidal products will be discussed and data will be presented which can be used to address bacterial spore issues. Current industry regulation in the US and Europe will be discussed related to sporicides. Additionally, the presentation will convey a robust approach to addressing bacterial spores by covering personnel practices, incoming items into cleanrooms, facility design and conditions, and the products used to address bacterial and mold spores as well as more resistant bacterial spore species.

The presentation will provide troubleshooting skills and experiences for bacterial spore contamination issues. Current industry sporicides will be discussed in detail along with efficacy data against spores. The audience will obtain a better understanding of how personnel practices, transferring items into cleanrooms, facility design, construction, and sporicidal chemistries are critical to developing a successful contamination control program.

Mr. Polarine is a technical service specialist at STERIS Corporation, where his current technical focus is microbial control in cleanrooms and other critical environments. He has lectured globally on issues related to disinfection and sanitation in cleanrooms. He has worked on several book article publications related to cleaning and disinfection and contamination control. He is currently co-authoring several articles and is an author on the PDA technical report on cleaning and disinfection. He is also currently active on the PDA task force on cleaning and disinfection. Mr. Polarine graduated from the University of Illinois with a Master of Arts in Biology, and he previously worked as a clinical research coordinator with the Department of Veterans Affairs and as a biology and microbiology instructor at the University of Illinois.

Human Factoring Application to Electronic Production Record Systems: Error Reduction and Efficiency Gain

Amy Peterson, MS - Sr. QA Specialist II-Wyeth Biotech

John A. Shaeffer, Training Specialist III- Wyeth Biotech

Take Home Benefits:
Human factoring techniques
Human factoring resources
Tools to utilize in operation to gain efficiency and reduce errors

Session Objectives:
What is human factoring?
What are human factoring deficiencies?
How do human factoring deficiencies affect operation cycle-time?
How to overcome human factoring deficiencies and improve operation cycle-time?

Rationale: Understanding and applying human factoring techniques to a process, manual or automated, will modify the human system interaction to improve human performance (efficiency gains of approximately and error reductions of approximately 30% to 40%).

Amy M. Peterson, MS is a Sr. QA Specialist for Wyeth Biotech and has over 12 years of pharmaceutical industry experience. Amy has designed, implemented and evaluated CAPA and CAPA effectiveness measurement systems. Her background also includes evaluating and improving quality and manufacturing processes using principles and tools from Six Sigma, Lean Manufacturing, Human Factoring and Execution Excellence.

John A. Shaeffer also from Wyeth Biotech has over 28 years in industrial operations spanning both the nuclear and pharmaceutical/biotechnology industries. He has designed, produced and implemented manufacturing, quality, engineering, management and training systems using Human Factoring and Execution Excellence principles. John also has developed CAPA and CAPA effectiveness measurement systems and has experience using Six Sigma and Lean Manufacturing tools.

2:30pm–2:45pm Break

2:45pm–3:45pm ***Using Enhanced Commissioning and Qualification Strategies to Deliver a Multi-Product Bioprocess Plant on Time, on Budget and Fully Qualified***
Amnon Eylath, MA-Director of Quality-Ariad Pharmaceuticals

Anyone who has had experience with the construction, qualification and start-up of a GMP manufacturing facility is familiar with a series of too-common outcomes: The facility start up is delayed to difficulties in qualification and validation of equipment and systems; equipment and systems do not perform as expected; delays due to inability to validate computer-based systems, and large cost overruns due to extensive remediation efforts. The K360 cross-departmental project team evaluated the root cases of these typical failures and decided to take an "Enhanced Commissioning' approach to the design, construction and qualification of this $300 million plus multi-product biotech pilot plant. By applying these concepts, we were able to identify and remediate facility and system failures and deficiencies early-on, eliminating delays to the critical path and significant costs to the project sponsor. This presentation details the concepts applied and the beneficial results obtained.

Amnon Eylath is Director of Quality at Ariad in Cambridge, Massachusetts. He is responsible for global QA/QC oversight of clinical supply, pharmaceutical alliances, and GxP compliance. Amnon has over 20 years of experience in medical research, process & assay development, facility and process validation, QA audits, development and deployment of quality systems, as well as disposition of clinical materials for US and global use. Amnon also originated Amgen's Isolator Technology Group, and Filling and Packaging Engineering Projects team. Amnon has lectured at various PDA events and training courses. Prior work experience includes Eli Lilly, Amgen, ImmuLogic, Cellcor, Mass. General Hospital, and consulting. Eylath has a Masters Degree in biology from Harvard University, and a BS in Biology from University of Mass-Boston.

3:45pm Refreshments in Exhibit Hall

4:15pm Door Prizes Awarded

4:30pm Exhibits close

4:30pm–5:30pm Exhibit Breakdown

Attendee Registration

Earlybird registration is $100/person (payment by September 8, 2008) $_____

Attendee registration is $125/person after September 8, 2008 $_____

Student registration is $35/person $_____

Attendee #1 **(Please print)**

First Name _____ Last Name _____

Company _____

Address _____

City/State/Zip _____

Telephone _____ Fax _____

E-mail _____

Attendee #2 **(Please print)**

First Name _____Last Name _____

Company _____

Address _____

City/State/Zip _____

Telephone _____ Fax _____

E-mail _____

PAYMENT INFO

Please add Registration Fee for all individuals Total Payment $_____

Payment Method _____Check (Preferred Method) ____VISA ____ M/C ____ AE ____ Diners Club

Name as it appears on card _____

Address where card statement is sent _____

Card Number _____Exp. Date _____ Security Code _____

Authorized Signature _____

To register online: www.pda.org/southeast/

Complete and fax this form with payment info to: PDA Southeast Chapter FAX #919.933.9233

Or mail this form with payment to:

PDA Southeast Chapter
c/o Blue Star Services
1829 East Franklin St. - Suite 600
Chapel Hill, NC 27514

Questions? Call Debora Steenson at 919.418.1325

Golf Social Highlights

The PDA South East Chapter held their annual Golf Social on Friday, June 13, 2008, at the Lochmere Golf Club in Cary NC. There were a total of sixty-nine golfers and fourteen sponsors. It was a best ball game, and prizes were given out to the top three teams. Not only did the top teams walk home with a prize, there were prizes given out on four holes for closest to pin. Rick Mineo received the top prize for the closest to the hole, an IPod provided by Accugenix, Inc.

After golf, everyone enjoyed a Southern style barbecue lunch while a drawing was held for golfing gifts. Everyone received a gift, two of which were free rounds of golf generously donated by Lochmere Golf Club.

The day was a hit, everyone fully enjoyed themselves, and even left with a commemorative photo of their foursome.

Thank you to all our sponsors, volunteers, and members for making this social such a success. We look forward to seeing you on June 12th at Lochmere Golf Club for the PDA-SE 2009 Golf Social!

A Special Thank You to our Sponsors

Accugenix, Inc.
Azopharma Product Development Group
BioTech logic
Biotest Diagnostics USA
Clarkton Consulting
CRB Engineers-Builders
Doe & Ingalls
Hydro Services
Invensys
ITW Texwipes
PCI (Pharmaceutical Calibrations and Instrumentation)
PharmaSys Inc.
Sequence Validation
Veltek

Congrats to our 2008 Golf Winners

1st place Team

David Brewer	Todd Sanders
Mike Putnam	Mark Levanites

2nd Place Team

David Roth	Brad Hall
Gray Norris	Jack Dalziel

3rd Place Team

Rich Costamzo	Mark Eryich
Ron Backman	Ray Costamzo

Closest to the Pin Winners

Pin #3	Tom Parmelee
Pin #7	Ray Blaner
Pin # 17	Brent Watkins
Pin # 11	Rick Mineo

To view photos of the 2008 Golf Social visit:
http://pdachapters.org/southeast/content/view/15/28/