



# *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



***Earlybird  
rate extended  
until  
September  
10th***

***To Register Online  
[www.pdachapters.org/southeast/](http://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 Chapter 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 21<sup>st</sup> 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 operations 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 Xantho (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

## **The NEW Raleigh Marriott City Center**

**Directions to the NEW Raleigh Marriott City Center**  
**500 Fayetteville St.**  
**Raleigh, NC 27601**  
**Telephone 919.833.1120**

*From Wilmington, NC*

Take I-40 West

At exit 300B, take Ramp (RIGHT) onto Rock Quarry Rd  
Turn LEFT to stay on Rock Quarry Rd  
Bear LEFT (West) onto E Davie St  
Turn LEFT (South) onto Fayetteville St

*From Charlotte, NC*

I-40 East

At exit 298A, turn RIGHT onto Ramp  
Bear LEFT (East) onto Local road(s)  
Turn LEFT (North) onto US-401 [US-70]  
Turn RIGHT (East) onto W Davie St  
Turn RIGHT (South) onto Fayetteville St

# Attendee Registration

Earlybird registration is \$100/person (payment by September 10, 2008) \$ \_\_\_\_\_

Attendee registration is \$125/person after September 10, 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

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

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**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**