PDA Southeast Chapter

SOUTHEAST CHAPTER
www.pdase.org

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[Letter From the President]

July 2006

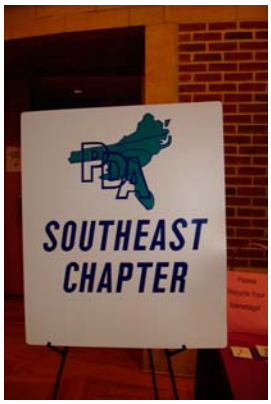
Summer is here, and the PDA Southeast Chapter is planning our annual Fall Meeting & Vendor Show. Additionally, we're planning our Golf Social for the upcoming cooler weather. Mark your calendars for October 10 as we host the Fall Meeting and Vendor Show at the Sheraton Chapel Hill. Soon we will announce the date of our golf social to be held this Fall.

Our website, www.pdase.org, is a valuable source of information for upcoming events, Executive Committee contact information, sponsorship opportunities, and newsletter archives. Registration forms for attendees and exhibitors for the Fall Meeting are already posted on the web under Events & Meetings.

It has been a great year so far, and I would like to thank everyone who has contributed to making our chapter very successful. We rely on the support of our members, sponsors, and our Executive Committee to enable our chapter to thrive. At the Spring Meeting, we had 3 speakers that generated a lot of interest and enthusiasm. Our program was well attended by over 125 people, and we had our first Exclusive Sponsor for a PDA Southeast Chapter event.

> Our website, www.pdase.org, is a valuable source of information for upcoming events

I have been President for the last 2 ½ years, and I am extremely proud of the efforts of our chapter. At the end of this year, we will hold elections for our upcoming 2 year terms. I encourage everyone to consider participating in a broader role next year. We have opportunities for officers (President, President-Elect, Secretary, and Treasurer), for committee chairs (Program, Membership), and for committee members. All of these activities are extremely rewarding, and the time commitment is minimal as compared to the benefits. I have met hundreds of people over the last few years, and I have been privileged to have served as the leader of this chapter. The knowledge that I have gained from the chapter events is secondary to the friendships that I have made.



I am fortunate to have a great group of people helping me to lead this chapter. Next year we hope to continue hosting chapter events that are both informative and interesting. Please feel free to contact me anytime if you have questions or concerns about the chapter.

Lisa

Lean Manufacturing Concepts for Pharmaceutical and Biotech Manufacturing

Presented by Daniel Zajac Process Excellence Leader, Centocor

Summary by David Yaffe, Project Manager for Commissioning Agents

Daniel Zajac, Process Excellence Leader at Centocor, presented a

talk on these concepts to the PDA Southeast Chapter members on May 16, 2006 at the North Carolina Biotechnology Center in Durham, NC. The discussion included a summary of how the quality strategy has changed through the years at Johnson and Johnson, the parent company of Centocor. From standardized work in the 1920's through all of the improvements up to the 1990's and including the Process Excellence Program in the 2000's, Quality Assurance has come full circle.

Next Dan laid out the basic principles of Process Excellence and the differences between Lean and Six Sigma Practices. Both sets of tools may be required depending on what problems need to be addressed. Six Sigma tools are used to improve a process that has variability and Lean tools are used to address processes that impact cycle times or issues that can affect aspects of inefficiencies in a department of the business.

Metrics and dashboards are used to measure efficiencies and allow the company to focus on what's important, identify gaps in performance, and align resources to solve problems using sound methodologies. The Lean concept can be summarized from the text Lean Thinking as follows, "it provides a way to do more and more with less and less – less human effort, less equipment, less time, and less space – while coming closer and closer to providing customers with exactly what they want." The idea in the pharma environment is to transform processes to deliver customer VALUE faster, improve work FLOW and eliminate waste. The 7 key fundamental principles of Lean Thinking were discussed: Value, Value Creation, Pull, Flow, Roles, Responsibilities, and Culture, Goal Alignment, and

Continuous Improvement. Waste was defined in Lean Thinking as, "Any human activity, which absorbs resources but creates no value."

Dan finished with a presentation of a case study of a Batch Record Review process that was modified using the Lean techniques. The historical review period was 2 to 4 weeks of these batch records. The project goal was to reduce this cycle time by 50%. The work flow for the review process was analyzed with a fine toothed comb and various inefficiencies were revealed. This resulted in changing the methods for this review cycle, including changing the location of the Quality personnel to the manufacturing suites where the batch records were filled out. The result was a reduction in the review cycle to one week and more importantly, a reduction in the errors on the batch records overall.

Did any of you ask management about using Lean Concepts in your manufacturing facility when you returned to work?

Execution Excellence (or Lack Thereof)/ Recent FDA Audit Trends and Solutions

Summary by Kathy Duensing, Senior Scientist, GlaxoSmithKline

Presented by Amy Peterson, MS, Senior QA Specialist, Wyeth Biotech and John Schaeffer, Training Consultant, Wyeth Biotech and Founder, Individual Consulting, Inc.

The top 10 drug observations (FDA) were presented and it was noted that the majority of the citations were procedural citations. Amy and John discussed errors versus events. Error rates can be reduced by having checks in place to avoid errors; events are the consequences from errors. According to a survey of 26 leading organizations, the majority of performance problems stem from environmental causes rather than individual causes. Companies should take an active role to determine where error precursors exist in order to reduce the possibility of an event.

Companies should have defenses in place to minimize events. This would include policies, procedures, and job aids. Alarms, warning signs, labels, and floor markings are valuable defenses. A company should also consider error precursors. Amy and John suggest using the TWIN (task demands, work environment, individual capabilities, and nature) analysis process. Each section of TWIN offers specific error precursors. By analyzing these precursors, errors could be reduced.

Three work operational modes were discussed: skill based, rule based, and knowledge based. When employees work in the skill based operational mode, errors are reduced substantially. The error rate is increased when working in the rule based operational

continued on page 4

continued from page 3

mode, and errors are even more prevalent in the knowledge based operational mode. Companies should promote an environment that instills the skill based operational mode to reduce employee errors.

When a company is regulated by outside sources, the company tends to have polices that are more restrictive than the regulations. When investigations arise, personnel revise the company policies, which incorporate more restrictions. Eventually, the personnel within the company have difficulty performing their jobs because the procedures have become too restrictive. The internal regulatory groups within an organization should try to focus on corrective actions which eliminate organizational issues, eliminate flawed defenses and error precursors, and provide preventative actions for the individual who initiates the action. Corrective action tools should focus on the development of the individual, (skill based errors), leadership (rule based errors), and the organization (knowledge based errors).

Execution Excellence depends on the alignment of individual behaviors, leader behaviors, and organizational processes/values. Individuals need to create a shared understanding, anticipate possible error situations, confirm integrity of defenses, and improve personal capabilities. Leadership behaviors should include open communication, promote teamwork to eliminate possible error situations and strengthen defenses, identify and eliminate organizational weaknesses, reinforce desired job behaviors and value prevention of errors. The organization should foster a culture that values prevention of events, strengthens integrity of defenses to prevent errors, precludes development of possible error situations, and creates a learning environment that promotes continuous improvements.

Mark YOUR Calendars!
The PDA Southeast Chapter Golf Tournament will be held on Friday, November 3, 2006. Details to follow...

PDA Southeast Chapter Fall Exhibitor Show & Meeting

SOUTHEAST CHAPTER

Tuesday, October 10, 2006
9:30 am-4:00 pm

Sheraton Chapel Hill Hotel, Chapel Hill, NC

Join PDA Southeast Chapter for our Fall 2006 Exhibitor Show and Meeting at the Sheraton Chapel Hill Hotel, Chapel Hill, North Carolina. The event will be held on Tuesday, October 10, 2006. Registration begins at 9:30 AM and the day concludes at 4:00 PM.

Schedule of Events

9:30 am	Registration
9:30 am	Exhibitor Show Opens (Continental Breakfast in Exhibit Hall)
10:30 am	PDA SOUTHEAST CHAPTER Business Meeting
11:00 am	**ICH Q8, Q9 and Q10** *Dr. Ron Tetzlaff, Vice President of PAREXEL Consulting*
12:00 Noon	Lunch Dessert in Exhibitor Area
1:30 pm	**The Use of Quality by Design Principles to Define Design Space** *Dr. Tom Garcia, Associate Director in Regulatory CMC, Pfizer Inc.*
2:30 pm	**Q & A Panel Discussion** *Dr. Tom Garcia and Dr. Ron Tetzlaff*
3:15 pm	Refreshments in the Exhibit Hall
3:45 pm	Door Prizes Awarded in the Exhibit Hall

Registration Form (please print)

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

Email _____

Company _____

Address _____

City, State, Zip _____

Registration Fee:

Before Sept. 26, 2006	$85 per person (includes lunch)
After Sept. 26, 2006	$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 September 26, 2006, in order to receive the pre-show discount)
By Mail:	PDA Southeast Chapter, 302 Versailles Drive, Cary, NC 27511
Deadline:	**September 26, 2006**
Questions:	Diane S. Williams 919.463.0615 fax: 919.463.0588 Email: dwilliamsinc@bellsouth.net www.PDASE.org

Interested in Being an Exhibitor at the Fall Meeting and Exhibits Show?

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, 2006. The event will take place at the Sheraton Chapel Hill Hotel in Chapel Hill, North Carolina on Tuesday, October 10, 2006.

8' Table Top Exhibit (Includes lunch for 2)		$450.00
Lunch Registration	x	$80.00
Meeting Break Sponsor Recognition during meeting/name listed on table plaque and on meeting publications and at registration table (Limit 3 am and 3 pm sponsors)		$150.00
Fall Meeting Lunch Sponsor (Limit 2 sponsors)		$500.00
Logo Bag Sponsorship Your logo will appear on the canvas conference bag (Deadline September 19, 2006) Recognition during meeting/name listed on table plaque and on meeting publications and at registration table.		$100.00

Go to www.pdase.org under events for the Show Exhibitor Registration Form

Register today! DEADLINE IS September 19, 2006

Don't miss any of the PDA Southeast Chapter Events. Make sure you email dwilliamsinc@bellsouth.net when your contact information changes. Thank you!

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