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Carolina-South Atlantic Chapter



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The 19th Annual ISPE CaSA Life Science Technology Show

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April 10, 2012



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President's Message



David Brande

It seems that it was just last week I was writing you about the upcoming events of February. Time seems to pass so quickly! For those of you who love green and all things Irish, I hope you had a happy St. Patrick's Day and the green beer didn't taste as bad as it looked. Easter is upon us and even if you do not celebrate the traditional Christian meaning of the holiday, it coincides with

the arrival of spring and a fresh new outlook on home, family and work.

Here at CaSA it's a new and fresh beginning with the **19th Annual Technology and Life Sciences Show** scheduled for April 10th. If you have not planned on attending, I urge you to check out the website (<http://www.ispe-casa.org/2012/>) which lists the educational opportunities available and the attending vendors. This year's show is remarkable in that Bruce Craven's committee has, for the first time, sold out the show. Yes, it is "sold out" already! This is the premier event of the year and it reflects a year-long planning effort by the Tech Show committee. Information, networking, contacts, and other opportunities are available to our Chapter Members thanks to the local chapter's efforts. Do not miss it!

Be sure to take advantage of the new Certified Pharmaceutical Industry Professional™ (CPIP™) study group that has just began meeting and join other peers that are preparing for the certification exam. The study group meets every other Wednesday, near Cameron Village, right after work. The exact meeting time and location for the study group is available from Casey Hinson at the

CaSA phone number—just another benefit of being actively engaged with the your local ISPE chapter.

May brings our CaSA scheduling year to a close as meetings begin to taper off through the summer and pick back up in August. Therefore be sure to sign up for the CaSA golf outing that will again be held at Prestonwood Country Club in Cary, North Carolina on May 7th. This is one of the oldest and most established annual events and this year should be better than last year's. Prestonwood has reserved two courses for us, ensuring plenty of space for anyone who wants to play. This is a very popular event so don't wait too late to register. Bring a foursome or just yourself; you will not be disappointed.

Again, see you at the 19th Annual Technology and Life Sciences Show on April 10th!

David Brande
Chapter President



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Chapter Event Highlights

Spotlight on the 19th Annual ISPE-CaSA Technology Show—APRIL 10

By Bruce Craven, Technology Show Committee Chair

At some point since my last article I must have blinked because I missed the transition from “winter” to “spring.” All of these blooms and flowers and yes, pollen, are telling me this year’s technology and vendor show is almost here. When we last talked, I told you about some of the changes for the 2012 Show and how the CaSA Technology Show Committee has been preparing and organizing for our event. I also gave you some clues or hints about these changes, so let’s recap.

Venue Name Change

Has anyone noticed the new name change of our venue location? If you are a die-hard hockey fan, you probably already know the answer to this; however, for those of you who do not normally travel down Edwards Mill Road, I will give you the answer. Our new venue location is now named the PNC Arena. As far as the temperature for our event, there may be a chance the arena will be less chilly than normal. It all depends if the arena no longer needs the “ice.” For that answer, we can all stay tuned to ESPN. Go Canes!

Don’t Forget to Register!

Have you registered yet? If you are a vendor, and you answered no — I must apologize and say that I hope to see you register next year as a vendor. We have completely sold all of our allowable space — that also includes the 5 extra booths we squeezed in back in early March. Let me take a moment to give a big thanks to all of you who have supported us through the purchase of booths and sponsorships. This show could not happen without you. Now if you want to be an attendee, you are still in luck. Registration for you is still open and “free.” Please take a moment and [register online](#). This way we can make sure there is plenty of “fun” for all, includ-

ing food and beverages. If you wait until the day of the show, that is ok. We will let you in, but there will be a small cover charge. Of course, all revenue received the day of the show will be donated to a local charity. When you register, remember to look at the details concerning course schedules, speaker bios, vendor representation, local HR representatives, and other useful information to help you plan your day with us. There are many events planned this year, so prepare to have a difficult time choosing.

The Cat’s Still Not Out of the Bag

Remember my other clue concerning one of our speakers? Did you guess? If you have registered, you probably discovered who I was referring to. I am still not telling the name, but his office is located in Clayton, NC. As far as more information, the show date is too close to let the proverbial “cat out of the bag,” but I will say that I hope to see each and everyone one of you there. We have over 160 vendors, more than 20 speakers and presenters, discussing topics in 5 different knowledge tracks, and one of the best venue locations for this year’s show. There will be great food and beverages and many social event opportunities. Don’t miss the chance to see all of your colleagues and friends on April 10; and remember to bring someone new to ISPE.





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Chapter Event Highlights

Leadership Symposium Overview

By Jennifer Lauria Clark, CPIP and VP of CaSA ISPE

The CaSA Young Professionals hosted a Leadership Symposium February 17, 2012 in Raleigh, NC. There were about 100 people in attendance between speakers, facilitators, students, young professionals, and our seasoned professionals. Four panel topics provided excellent feedback from Hiring Managers of big pharmaceutical companies, directors, young professionals, and more. The four panel topics were as follows:

1. **Hiring Managers:** What do we need to know to get past corporate resume submissions,
2. **Career Path to Leadership:** How did you get where you are today,
3. **Young Professionals:** What can you share with others since you have recently entered the work force, and
4. **Owner vs. Consultant:** What are the biggest differences in working for an owner company versus a consultant/vendor company.

Overall, the day was extremely successful with great discussions, networking, food, and sponsors. Thank you to all who participated. If you are interested in more information regarding the event, please contact Jennifer Lauria Clark. (jennifer.clark@cagents.com)




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Chapter Event Highlights

4th Annual CaSA Casino Night a Big Win!

By Sheri Davis, Membership Committee

The 21st floor of the Capital City Club was filled with excitement as over 100 people enjoyed our 4th Annual Casino Night on February, 11th. While some were busy at the Craps table, others tried their luck at Roulette, Black Jack, Triple Shot or Texas Hold 'Em. As with any casino, our high rollers enjoyed great food with a heavy hors d'oeuvres menu that included Mediterranean shrimp, vegetable tempura, roast beef and pasta stations, plus an assortment of fruit, cheeses, and desserts.

The gaming competition was fierce but friendly. Congratulations to our top 3 winners Lisa Payne, Pharma Pham, and Scott Billman who traded their 'fake money' for the chance to draw Visa Gift Cards and celebrate their good fortune!

Of course, this evening of fun would not have been possible without the generous support of our sponsors. We extend a special thanks to Premiere Sponsors: PCI, CRB, and Commissioning Agents, as well as our Table Sponsors: RoviSys, McDonald York, Mangan, IPS, Bahnson Environmental Specialties, and Avid Solutions.



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Chapter Event Highlights

Young Professionals' Update

By Blake Derrick, YP Chair

(photos continued from previous page)



The Young Professionals and Programs Committees are holding a joint educational event on Wednesday, April 25th. The speaker will be Ray Miller of Eisai Pharmaceuticals, and he will be giving a seminar on “Fundamentals of IT Systems Validation,” which will serve as an introduction to a topic that should benefit young professionals looking to scratch the surface in that area of expertise, but also may be of interest to seasoned professionals looking to expand their knowledge base. We hope to be doing a series of “Intro” seminars this year, so we hope you can come out and join us for this first installment. Registration is required, so be sure to look for announcement emails in the near future containing more information and the website registration link. The event will be held at BTEC’s auditorium on NCSU’s Centennial Campus, and will include a sandwich dinner catered by Jimmy John’s.

We look forward to seeing you then!



Technical Section

Simulations for Improved Production Cycles Using a Lean Supply Chain Postponement Strategy

By Jim Curry, Opstat Group Inc.

Background

A supply chain postponement strategy is a valuable lean design concept for the biopharmaceutical industry that has applicability particularly because of the typical multi-stage production processes involved in the conversion of raw materials through to final customer fulfillment. The computer industry has been using this strategy for assembly postponement for many years, such as in the mass customization of computers. The computer industry stores inventory of assemblies, and produces a uniquely configured computer to a customer specification.

Any industry which requires unique labeling of final products such as biopharma does for country specific labels can have significant benefits from geographic postponement, i.e. postponing committing inventory to its final form, by storing inventory of unlabeled products, and then labeling to order or to kanbans for individual country requirements. Like computer assembly, this allows more predictable estimation of aggregate demand across markets.

We have all seen operations that focus on “when will that batch be released?” with production frequently breaking into its schedules to meet a short term requirement. When final country labeled products are produced right from the final production step, it creates many more items in the schedule, and many more inventory items to monitor. Postponement can be a design technique in an optimized supply chain in which all the functions and operations are synchronized.

This presentation uses an actual case study to focus on two things:

1. Postponement as a supply chain design strategy, and how to develop the design process, and
2. The benefit of using simulation to test a new design, including one such as postponement, prior implementing it in practice.

Approach & Methodology

The biopharma industry has some unique challenges to manage. Production campaigning required due to both pre- and post-production changeovers/cleaning activities make scheduling complex. Quality testing and QA documentation add to the lead times for the end-to-end process, which in turn impacts inventory management. In addition, demand variability is increased when every country labeled product is an inventory stock-keeping unit.

This is a case study of a biopharma company in Europe that had some typical symptoms we see in many companies including high inventory levels and deficiencies in service levels, i.e., missing customer orders. The company sold vials of its products through country affiliates. Inventory levels were not known or understood; nor were the number of missed orders. The vials were labeled and packaged after the batch was created and then shipped to country affiliates. The affiliates had country distribution centers that stored all products sold in the country. Root causes of these symptoms included organizational disconnects such as country affiliates operating at arm’s-length from the plant, which led to throwing orders “over the wall” to the plant.

Conceptually there is ample evidence that any supply chain operation will benefit from reduced demand variability, consistent production and reduced lead times. However, many lean projects tend to focus only on the high volume products, which usually do not have the complexity and variability of lower volume ones. They also tend to require less effort per unit and cause disruption to the overall supply chain. Two design concepts to keep in mind in a lean improvement effort are:

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Technical Section

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- One size does not fit all, meaning a solution that fits the high volume products and customers may not fit all products, and
- Keep inventory as far back in the supply chain as possible, i.e., give your operation more flexibility by not committing resources and products to their final form or geography before you need to, and particularly, not utilizing constrained resources before you need to.

In this case, there were significant differences in the demand and supply patterns of products in terms of demand variability and lead-time. For each finished country specific product, the coefficient of variation of the demand (standard deviation / mean weekly demand), and the supply lead-time plus variability, was computed. These are both drivers of the amount of safety stock required to fulfill customer demand.

The following table shows the comparative differences for the amount of safety stock required.

**WEEKS OF SAFETY STOCK REQUIRED FOR
98% SERVICE LEVEL**

Lead Time (weeks)	CofV = .5	CofV = 1.0	CofV = 2.0
0	2	3	4
4	2.5	5	9
8	3	6	12
14	5	8	15
26	6	11	21

An analysis of the total business revealed that of approximately 200 finished labeled products, 14 accounted for 66% of demand volume and 26% of the inventory value, and 98 contributed 18% of demand but 63% of inventory value. These typically had higher unit costs and also higher demand variability. The remaining products consisted of lower volumes and inventory. All three categories were included in a design as follows:

- High volume products with level, frequent supply to be produced on a biweekly level cycle
- High cost products with postponement which would produce “white label” product every 4 weeks with kanbans for country labeled stock. The 98 labeled country items were comprised of 21 finished products in vials without the country labels.
- Low volume/low cost products with level supply to be produced twice per year on a regular schedule.

The high cost products with postponement had the most potential for both service improvement and lower inventory. For example, one product was typical of the 21 total in this high cost group. It was sold and labeled for seven countries; on average each labeled item was produced at the plant and supplied to the country warehouses about every six months. The demand in each country was highly variable, so the combination of lead-time and demand variability required high levels of safety stock to be maintained.

On the other hand, the Europe-wide aggregated demand for the product showed lower variability and there was enough volume that a batch of unlabeled vials could be produced every six weeks. The comparative demand variability for the individual countries and the aggregated total is:

COEFFICIENT OF VARIATION

Aggregate Demand All Countries	.65
Spain	1.03
Germany	.95
Sweden	1.98
France	2.85
Netherlands	2.28
Italy	1.20
Great Britain	2.11

Simulation results

After the design analysis, all three product-set designs were simulated with actual patterns of demand and the production constraints. Adjustments for safety stock were made as needed to address the variability patterns of individual products / countries. It also included the kanban approach for country specific labeling that included a country quarantine lead-time. Simulation allowed a virtual implementation of the design prior to it physically being implemented.

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Technical Section

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The simulation showed that implementing postponement of labeling, the company could provide a 97+% service level for their customers for the 21 products included, with a 30% reduction in overall inventory.

Summary

This case study demonstrates the benefits of methodically analyzing the patterns of demand and supply for biopharma supply chains. The operation described is fairly common in our industry, and offers an opportunity for improvement. Specifically, it highlights that there are measurable benefits from using the reduced variability of aggregated demand wherever possible. The aggregated demand combined with shortened supply lead-times and increased consistency in those lead-times, combine to improve the management of the supply chain. The measurable benefits result are higher, predictable service levels and reduced safety stock requirements to achieve them.

Jim Curry is CEO of the OpStat Group Inc. He has been a management consultant for large multi-national companies in operations and supply chain improvement since 1987. His clients include companies in the pharmaceutical, chemical, high tech, consumer, and transportation industries. He is also an Adjunct Professor at Fairfield University, teaching graduate courses in supply chain design and lean manufacturing. He serves on the Steering Committee for the ISPE's Operations Management Community of Practice and has written material for ISPE's Pharmaceutical Engineering.

The link to the original presentation is on the ISPE Carolina So. Atlantic Chapter website *APICS-ISPE Joint Event - Operational Management: Simulations for improved production cycles -- 17 January 2012*



Welcome New Members

New Members who joined
February 1, 2011-March 26, 2011

Brittany Alston
Sandeep Araveti
Christopher Bartlett
Georg Beilinson
Richard Bennett
Emily Blackwell
LeAnne Brozovsky
Jason Chancey
Matthew Clark
Peter Clothier
David Culver
Charles Daniels
Arinc Demir Leishear
Jessica Ewy
Kevin Flanagan
Judith Ford
Michael Ford
Brian Gaudaur
Sherri Gerepka
Bunn Gray
Katrina Hultgren
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Daniel Ludwig
Walter Manger
Mitchell Montgomery
Anthony Nero
Kirk Nielsen
Lisa Pendergraph
Courtney Phillips
Roberto Quinones
Joseph Reardon
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John Ritter
Wilfredo Rivera-Baez
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Upcoming Events

CaSA ISPE Student Corner

By LeAnna Pearson, Student Committee Chair

There was a total of 425 candidates that were hand selected by multiple companies in the RTP area to attend the career fair on February 24, 2012. This is a joint effort by NC State's BTEC School and the ISPE CaSA Chapter. Along with the multiple companies that were conducting interviewing sessions there was also an opportunity for ISPE CaSA to set up a booth for membership recruitment. Three CaSA Board members including LeAnna Pearson, Jennifer Lauria-Clark, CPIP and Amy Lineberry, CPIP, discussed the benefits of an ISPE Membership with students and young professionals. A laptop was made available and this allowed them to recruit 15 new members and aid several others with membership renewal.

2012 ISPE CaSA Poster Competition

The 2012 ISPE CaSA Poster Competition will be held on Tuesday April 10th, 2012 during the Technology Show. The graduate and under-graduate winners will be awarded with a full expenses paid trip to the 2012 ISPE Annual Meeting in San Francisco to compete at the International Poster Competition. Winners of the competition will be announced in the next news letter.

Student Chapter Elections

Student Chapters are holding their spring elections! The new members of each student chapter board will be announced in the Summer newsletter.



MARK YOUR CALENDARS!

CaSA Chapter Events

- **April 10, 2012**
19th Annual ISPE CaSA Life Science Technology Show (and Student Poster Competition)
PNC (formerly RBC) Center, Raleigh, NC
9:30 am til 6:30 pm
- **May 7, 2012**
Golf Tournament
Prestonwood, Cary, NC
- **Last Thursday of the month**
Therapeutic Thursdays
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