

## Carolina-South Atlantic Chapter

## **CaSA News**



Volume 20 • Number 2 APRIL 2013

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## President's Message



Jennifer Lauria Clark, CPIP

The last few weeks of Winter have been busy for our ISPE CaSA Chapter. We have held several exciting and memorable events for our Members. Thank you to all of our sponsors, volunteers and board Members for their commitment and dedication to our Chapter.

As we look back on the events we have held this year and look forward to what plans we are making to educate our Members and provide networking

opportunities, I ask that we reMember why we are doing what we do. Our ultimate goal, no matter where you are working in our industry, is to help provide the best services, manufacturing, research, quality, engineering, and compliance activities to our consumers, which are ultimately our patients. It is important to remember that our privilege to serve our industry comes with significant responsibilities. ISPE CaSA is committed to providing educational and networking opportunities to assist in these responsibilities.

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## President's Message

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Our Risk Management Seminar held at the NC Biotech Center was packed with people and information to help all the attendees understand and implement Risk Management more clearly. We hosted our first Therapeutic Tuesday in Charleston, South Carolina. We plan on continuing our networking events in SC, GA, and FL in the next few months. We held our 7th Annual CaSA Leadership Symposium and had a great turnout of students, young professionals and professionals. We followed the Leadership Symposium with our 4th Annual Casino night at the Capital City Club. It was an evening of fun and networking.

We were projecting an extremely successful 20th Annual ISPE CaSA Life Sciences Technology Conference and I believe we delivered. The new venue provided excellent opportunities for relevant educational sessions, a quiet room for those who needed to work or use the Internet, an exhibit hall full of vendors and attendees to learn about new companies. products and services, and excellent key note speeches from Mr. Bob Ingram and Mrs. Nancy Berg. Our changes this year improved the ability to network and converse with our existing friends and make new connections. Mr. Bruce Craven and Mr. Mike Putnam used their talents and the talents of their Technology Conference Committee with the help of our Chapter management to put on this outstanding event. Thank you to all the attendees and exhibitors for your support. Without your presence and support our event would not have been as successful.

Our sponsorship program is still available for the 2013 year. If you are interested please check out our website www. ispe-CaSA.org for more details.

Each newsletter I urge our members to share with us any concerns, compliments, or suggestions and would like you to let us know how we are doing and how we can better improve your membership.

Thank you again to our volunteer members who spend their time reviewing newsletters, cleaning up after events, or helping with whatever we need done to make the Chapter successful. The entire Board appreciates our good friends for staying involved and welcomes fresh ideas at our committee meetings. And now the To Do List:

- Get Involved. Let us know if you are interested in a
  volunteering with a committee or in active leadership of
  ISPE CaSA. Specific committees have stated they are in
  need of help. Membership and Education are two committees that are in the most need of volunteers. Please
  contact info@ispe-CaSA.org or the committee chairs if
  you are interested in any of the committees. Thank you
  to our new volunteers who have recently joined our committees.
- Share your ideas. Please send in some fresh ideas for 2013 educational programs and networking events. We will have a drawing that includes everyone who sends in an idea by May 1, 2013. The winner of a \$50 gift card will be announced in the next newsletter.
- Come see us...
  - —ISPE CaSA Golf Tournament, Monday, May 7, 2013 Prestonwood Country Club, Cary, NC
- —Medicago Plant Tour, Friday, May 17, 2013, RTP, NC We hope that you find our newsletter exciting and that you are motivated to continue to attend our events and share your experiences and vision with our Chapter. Together, we

can continue to put the patients first.

Jennifer Lauria Clark, CPIP
Chapter President





#### Carolina-South Atlantic Chapter

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- Jennifer Lauria Clark, CPIP, President
- David Brande, Past President
- Matt Gilson, Vice President
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- Jerry "Patch" Paciorek, CPIP, Membership Development
- · Jon Doyle, Young Professionals
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## **Membership Corner**

## **CPIP™: Something to think about ...**

Ensure career growth by pursuing our industry-recognized certification.

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Benefits of joining a CPIP Study Group:

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- Learn from others...
- Forum for discussions...
- Rely on the study group for future:
  - -Re-certification
  - —Problem solving in daily work
  - —Inspiration

For much more CPIP information: http://www.ispe-pcc.org/

For CaSA Chapter CPIP Study Group information contact:

Amy Lineberry, CPIP alineberry@manganinc.com
Jerry "Patch" Paciorek, CPIP paciorek@cagents.com



## Congratulations to CaSA's Newest CPIP!

Henry B. Bryant, CPIP



# 2013 Classroom Training

ISPE's in-depth courses cover the entire product lifecycle and are led by instructors who are active in the industry.

St. Louis, Missouri USA 20 – 23 May

- Basic GAMP® 5, Including Revised Annex 11 and Part 11 Update (T45)
- Cleaning Validation (T17)
- Facility Project Management (T26)
- Pharmaceutical Water Generation (T04)
- Quality Risk Management (T42)
- Science and Risk Based Commissioning & Qualification (T40)
- Storage, Delivery and Qualification of Pharmaceutical Waters (T23)

Brussels, Belgium 22 – 23 May

- Basic GAMP® 5, Including Revised Annex 11 and Part 11 Update (T45)
- Clinical Trial Materials (T13)
- Facility Project Management (T26)
- Oral Solid Dosage Forms (T10)
- Quality Risk Management (T42)
- Risk-MaPP (T41)
- Science and Risk Based Commissioning & Qualification (T40)







Baltimore, Maryland USA

- 11 12 June
- Practical Application of CSC GAMP® 5 (T11)
- Turning QbD into a Practical Reality (T43)

Durham, North Carolina USA 26 – 28 August

- HVAC for Pharmaceutical Facilities (T14)
- QbD (T46)



## Membership Corner

## Member Spotlight: Dr. Daniel Shin

By Wendy Haines, Newsletter Chair

Q: What is your full name?

A: Ildong Daniel Shin

Q: Birth Place?

A: Pusan, South Korea

Q: College?

A: : NC State University: PhD in Analytical Chemistry

Western Illinois University: MS

Korea University: BA

#### Q: Tell me a little about your personal life.

A: I live with my lovely wife, Sonok, in Fuquay Varina, NC. We have two sons, a daughter, and two granddaughters. Our two sons are married and living in Salt Lake City, Utah and Seattle, Washington. My daughter is living with us currently. My wife and I like to travel around. We love small towns in NC.

## Q: What is your present position? What do you do at your job?

A: As a professor in the Pharmaceutical Sciences department at Campbell University College of Pharmacy & Health Sciences, I am having fun teaching analytical instrumentation and pharmaceutical analysis. It has always been a great pleasure for me to participate in ISPE and CaSA meetings as a faculty advisor of the ISPE Campbell University Student Chapter. I've never seen a boring ISPE meeting; all have been energetic, fun and provided great opportunities to meet wonderful people. I serve in various departmental and college committees and conduct various research projects.

#### Q: How long have you been with your current employer?

A: I have worked for 12 years at Campbell University.

## Q: Tell me about your career path and how you ended up where you are today.

A: After my Bachelor's degree, I worked for a pharmaceutical company in Korea and later as a chemistry instructor. I fell in love with teaching and guiding students, so I pursued a higher degree in the States to become a teacher. While I was



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in graduate school, I loved teaching as a TA. After receiving my degree, my main areas of work were teaching, research, advisement and helping the students. I have received outstanding teaching awards a few times as a TA as well as a professor.

## Q: What is your favorite part of your job?

A: The greatest rewards of my job are when my

students are successful in their careers. Their success gives me strength and encouragement.



## Q: How long have you been a Member of ISPE? When did you first join ISPE?

A: In 2002, I joined ISPE and became a faculty advisor for the ISPE Campbell University Student Chapter. I felt welcomed by all other ISPE Members and leaders at the meetings, tech shows, events, conferences, career fairs, etc. Those who greatly helped in strengthening our student Chapter are Mark Yates, Jane Brown, Bo Crouse, Wendy Haines, Jennifer Clark, Amy Lineberry and many more. Thanks to all these people, Campbell Student Chapter won the "Student Chapter of the Year" award in 2007. Thank you, Thank you, Thank you...

## Q: What benefits have you realized from being a Member of ISPE?

A: The energy you get whenever you attend meetings. Positive energy is flowing thanks to all of the good people. It is second to none for me and my students to be able to network with them!!! The website and publications have updated, relevant knowledge.



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## Membership Corner

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#### Q: Why are you still involved with ISPE?

A: The opportunities ISPE brings to the students are amazing – jobs, networking, updated knowledge and news about the pharmaceutical industry, etc.

## Q: Any Mentors/Role Models that have helped to shape your life?

A: There was always someone who stepped up to guide me in the right direction in every stage of my life. Friends, colleagues, and many people have helped me, shaping my life. My parents, my wife and even my children have had a big influence in my life. My mentors who helped me the most are Ed Stejskal (deceased in 2012) and Al Tonelli.

## Q: If you weren't involved in teaching/mentoring, what business do you think you'd be in?

A: I cannot think of any other vocations than the current one. But if opportunities directed me otherwise, then I probably would have worked in computer related jobs.

#### Q: What is one skill you wish you had that you don't?

A: I wish I had a good persuasion skill, among many that I lack. Some people command good and logical ways of presenting their ideas such that everybody, or at least the majority of people, would agree or follow while making them feel happy. I do not have that skill.

#### Q: Any hobbies? What are they?

A: Yes, I do enjoy calligraphy. When I concentrate on writing and am absorbed in the beauty of the nature of calligraphy, it gives me a moment of Zen experience. Everything else fades away except my pen, ink, paper and me.

#### Q: Do you collect anything?

A: I try not to. But still many things accumulate in my house. I try to get rid of them. I know you are not talking about junk....

#### Q: Finish this sentence - "I need more...."

A: I need more love developed in me. I need to show more love toward my family, extended family, friends, students, coworkers, and so on. As I mature, it is clear that human relationship is one of the most important things in my life.

#### Q: Favorite Food?

A: It used to be my mother's dishes, now it is my wife's - whatever she cooks for me.

## Q: What is something that people would be surprised to learn about you?

A: I am a Vietnam veteran. I served from 1971 to 1972 in the White Horse Battalion of the Korean (ROK) Army. We joined operations with the US military. I couldn't find any humanity in war. We all became beasts. That is why I hate wars.

#### Q: Last movie you saw?

A: I don't even remember. However, two movies are my

all-time favorites – 'Fiddler on the Roof' and 'The Sound of Music.'

## Q: For those in the early stage of their careers, what advice would you give them?

A: Do what you love. Love what you do.



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#### **BEST Fest Committee**

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#### **Student Affairs Committee**

LeAnna Pearson

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# Take Control of Your Career — CaSA Leadership Symposium Highlights

By Blake Derrick, Event Organizer

Despite icy weather forecasts on February 22, 2013, we are happy to report that the 2013 CaSA Leadership Symposium began on time and completed on schedule at the NCSU McKimmon Center. We certainly appreciate NCSU not announcing any delays that morning. The weather didn't detract from attendance either, since by mid-morning there were only 6 name tags not picked up of the approximately 91 pre-registered event attendees. Including a number of additional attendees, there were nearly 100 guests over the course of the day.

#### Highlights of the Day

This year's focus was "Take Control of Your Career!" Attendees gained perspective from a variety of panelists and guest speakers on the topic of career growth and development in the pharmaceutical development, manufacturing and services industries. Our morning sessions included an HR & Staffing Panel Discussion in which staffing partners and recruiters from Biogen Idec, Novartis, Novo Nordisk, and PCI gave insights into the characteristics most desirable in potential candidates. It was great to hear suggestions on what to do and what not to do when following up or interviewing for new roles in your career. Following this panel, Jerry "Patch" Paciorek, CPIP, gave an excellent overview of the CPIP Certification and provided some best practices for preparing for the exam and the potential benefits for your career.

One of the highlights of the day was a talk given by Associate Director of Regulatory Affairs at Biogen Idec, Brian Nunnally, Ph.D. His topic was "Leadership Lessons In Literature," in which Brian compellingly gave several anecdotes while summarizing several business books that have had the biggest impact for guiding his career. One of our seasoned professionals summarized it well: "Wow. This presentation should be given to most corporate organizations. Definitely energized me." If you missed this presentation, don't worry as we hope that this won't be the last time we are able to ask Brian to give this talk!

Following a networking lunch, we were provided some additional food for thought for "Avoiding the Career Fiscal Cliff," by Neil Jones, VP of Scientific Operations at Kryosphere. Through a creative slide deck illustrating career development wisdom obtained from the behaviors of dung beetles to butterflies, Neil gave an engaging and witty presentation while having a great time interacting with the audience. Following his presentation, we had our final panel discussion of the day, complementing our earlier HR panel by learning from scientific and technical professionals from Novozymes, Medicago, Pfizer, and Metrics, Inc. Our panelists covered topics from how to balance work and professional life, to the career paths and skill sets necessary for success in R&D, Manufacturing,







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Engineering, and Quality. It was also great to see two CPIP certified professionals on the panel reinforcing some of the benefits mentioned in an earlier presentation.

Overall the day was a great success, and we look forward to providing more career development and networking opportunities at next year's symposium. We hope the following quotes about 2013's success will be the theme for years to come:

- "Thank you for putting together such a great and informative career event. I gained a lot of valuable info and made a few new contacts as well."
- "Thank you and I cannot wait again for the event next vear!"
- "I had an amazing time and learned numerous essential points about my future career. Thank you so much."
- "I enjoyed the networking and presentations. I wouldn't change a thing."
- "It was a great opportunity to be exposed to professionals in the network. Would love to be a part of it next year."
- "Overall, a very excellent event. I loved the panel discussions."

### Thanks again to all of our sponsors:

**Gold**: Novartis, Biogen Idec, Commissioning Agents, KBI Biopharma, and Fujifilm Diosynth Biotechnologies

Silver: HIPP Engineering, CRB, and Novozymes

Bronze: Novo Nordisk, Terracon, and Enpuricon



# 2013 Classroom Training

ISPE's in-depth courses cover the entire product lifecycle and are led by instructors who are active in the industry.

San Francisco Area (Burlingame), California USA

9 - 12 September

- Basic GAMP<sup>®</sup> 5, Including Revised Annex 11 and Part 11 Update (T45)
- Cleaning Validation Principles (T17)
- Clinical Trial Materials (T13)
- HVAC for Pharmaceutical Facilities (T14)
- Oral Solid Dosage Forms (T10)
- Pharmaceutical Water Generation (T04)
- Process Validation in Biotechnology Manufacturing (T32)
- Storage, Delivery and Qualification of Pharmaceutical Waters (T23)

New Brunswick, New Jersey, USA

7 - 10 October

- Auditing for GMP (G07)
- Drug Manufacturing Facility Design and Development (T09)
- Facility Project Management (T26)
- Q7A: Implementing Good Manufacturing Practices (T30)



Prague, Czech Republic

7 – 8 October

- Auditing for GMP (G07)
- Cleaning Validation Principles (T17)
- GAMP® 5 Process Control Systems (T21)
- Process Validation in Biotechnology Manufacturing (T32)
- Sterile Drug Manufacturing Facility (T12)
- Turning QbD into a Practical Reality (T43)





## Therapeutic Thursday in South Carolina

By Jeff Sieracki

On February 12, 2013, CaSA ISPE recently held its first Charleston, SC based, Therapeutic Tuesday where life science minded engineering professionals from the region took their competitive gloves off and came together for an evening of networking and enjoyed a sociable, waterfront event at California Dreaming. Ideas were shared, along with some great seafood, about the direction of the Chapter as it develops across the Southeast. The plans to expand the network from Georgia through the upstate of SC was a hot topic and had everyone's vote as a great benefit to give back to the ISPE community. This would include Atlanta GA, along with Florence and Greenville, SC.

## Therapeutic Thursday in North Carolina

By Jerry "Patch" Paciorek, CPIP

WOW! What a turnout!

We enjoyed the company of 52 attendees and the hospitality of CRB, the sponsor for our event at the My Way Tavern in Holly Springs, NC on February 28, 2013. This was our highest attendance of any Therapeutic Thursday to date and raised the bar for future events. We received a great deal of positive feedback afterward and we look forward to continuing this trend.



## Casino Night a Smashing Success!

By: Mike Kirston, Newsletter Committee Co-Chair

On February 23, 2013, the ISPE CaSA Chapter held their annual casino night event, and once again, the event was a smashing success!

Over fifty attendees made the trek to the Capital City Club in downtown Raleigh to try their hand at various casino table games including blackjack, craps, roulette, amongst others. When not tempting the fates at winning, attendees were able to network, mingle and build relationships in a casual, low-stress environment.

The event was sponsored by:

- Avid Solutions
- Bahnson
- CAI
- CRB
- RGD
- Southern Industrial Contractors

At the end of the night, the person with the most chips was **Brandy Buchanan** from NCSU, but all were winners, having created new friendships or strengthen existing ones.





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## **Upcoming Events**



## Carolina-South Atlantic Chapter

## PRESENTS...

# The 19th Annual ISPE Carolina-South Atlantic Chapter Golf Tournament

CaSA is going "All In" at this year's golf event! Join your colleagues for a great round of golf and networking opportunity. On-course games will also include hole-in-one prizes on par 3s, longest drive and closest to the pin for women and men.

Prestonwood Country Club 300 Prestonwood Parkway Cary, NC 27513 919-467-2566

Monday, May 6, 2013 | 9:30 a.m. Shotgun Start

#### **Prestonwood Country Club**

Prestonwood Country Club offers 54 holes of championship-caliber golf. The spectacular course takes full advantage of the area's gently rolling land. It boasts of uncompromising vision and impeccable execution. Designed by golf course architect Tom Jackson, the course's mirrored ponds and manicured greens offer golfers of all skill levels a challenging game.

9:00 a.m. – 10:00 a.m. —— Registration
10:00 a.m. — Golf Tournament
3:00 p.m. — Buffet/Awards Reception

## The 19th Annual ISPE Carolina-South Atlantic Chapter Golf Tournament

Prestonwood Country Club | Monday, May 6, 2013

Register by April 15 for a 10% early bird discount. (Excludes Dinner and Breakfast Sponsors – Deadline 4/1/13)

	9	Sponsorship Registration	
	Sponsorship Item	Sponsor Benefits	Amount
	Dinner & Logo Gift (1 sponsor)  Deadline April 1 <sup>st</sup>	Signage at registration and in half-poor recognition at awards presentation, company and the state of the sta	<b>\$1,200</b> (\$1080 early bird)
	Breakfast & Logo Gift (1 sponsor)  Deadline April 1 <sup>st</sup>	Signage at registration sea, recognition at awards presentation, company logo on gift to the ded to little lers.	<b>\$1,000</b> (\$900 early bird)
	Beverage Carts (2 sponsors)	Signage on two beverage carts (one on each course). Strongly encouraged to provide own employees to drive carts and network during the tournament. Carts will be stocked by ISPE with sodas, water, beer, energy drinks, and snacks.	<b>\$800</b> ea (\$720 early bird)
	Par 3 Hole-in-One Win a Harley (2 sponsors)	Sponsor may have table and 2 chairs at tee box to network with players and monitor the hole contest. Signage at the hole. May provide additional giveaways (ISPE approval required), and may provide their own signage at table.	<b>\$800</b> ea (\$720 early bird)
	Team Putting Contest Win \$10,000 (1 sponsor)	Sponsor may have table and 2 chairs at the putting green to network with players and monitor the contest. Opportunity to provide additional giveaways (ISPE approval required), and may provide their own signage at table.	<b>\$750</b> (\$675 early bird)
	Par 3 Hole-in-One Win Callaway Clubs (1,3,5 woods & 3-PW irons) (2 sponsors)	Sponsor may have table and 2 chairs at tee box to network with players and monitor the hole contest. Signage at the hole. May provide additional giveaways (ISPE approval required), and may provide their own signage at table.	<b>\$550</b> ea (\$495 early bird)
	Par 3 Hole-in-One Win \$750 Visa Card (2 sponsors)	Sponsor may have table and 2 chairs at tee box to network with players and monitor the hole contest. Signage at the hole. May provide additional giveaways (ISPE approval required), and may provide their own signage at table.	<b>\$550</b> ea (\$495 early bird)
	Par 3 Hole-in-One Win "The Apple Package" (IPad, IPod and \$100 Apple Gift Card) (2 sponsors)	Sponsor may have table and 2 chairs at tee box to network with players and monitor the hole contest. Signage at the hole. May provide additional giveaways (ISPE approval required), and may provide their own signage at table.	<b>\$550</b> ea (\$495 early bird)
	Scoreboard and Rules Sheet Sponsor (1 sponsor)	Identification on rules Spited Dutt scoreboard and recognition at awards Sold Dutt	<b>\$350</b> (\$315 early bird)
	Hole Sponsor (28 sponsors)	Includes your choice of signage at the tee box. (No early bird discount available).	<b>\$250</b> ea
	Longest Drive & Closest to the Pin Sponsor (2 Sponsors)	Includes your choice of signage at the tee box. (No early bird discount available).	<b>\$350</b> ea
(Note	:: Any sponsor giveaways must be pre-app	roved by ISPE-CASA prior to the event)  Total =	\$
1	Company:		
	· · · · —	Card #: CC Exp. Date:	

Return completed form to: ISPE-CASA, 1500 Sunday Dr, Ste 102, Raleigh, NC 27607 Phone: (919) 573-5442 Fax: (919)787-4916 <u>info@ispecasa.org</u>

## **Upcoming Events**

## Medicago Plant Tour: May 17, 2013

The ISPE CaSA Chapter will be touring one of our newest facilities on May 17. Medicago USA is a wholly owned subsidiary of Medicago Inc. headquartered in Québec. Medicago USA recently completed construction of its cGMP facility in RTP. The 97,000 square-foot, plant-based vaccine facility includes a fully automated greenhouse and a state of the art extraction and purification unit. Medicago is targeted to produce 10 million doses of pandemic influenza vaccine per month.

The tour will be broken into two groups of 30 people (60 people maximum). Each group will hear a short presentation before heading into the facility. The first group will start at 2pm and the second group will be targeted to start at 3pm. Before and after the tour refreshments will be available. Thank you to Clark Nexsen for sponsoring the event.

The tour will be open to ISPE Members only. Registration will open soon, so check our website, www.ispe-CaSA.org for more information.



# Save the Date!



Carolina-South Atlantic Chapter

Sponsored by CLARK NEXSEN

# Medicago FACILITY TOUR

Friday, May 17, 2013 at 2:00 PM

7 Triangle Drive Research Triangle Park, NC



## **Technical Section**

## Science Matters: What it Takes to Have Successful Vendor Relationships

By Mark Lanfear

Nurturing good relationships in business is a lot like doing the same in our personal lives. And just like in our personal lives, a one-size-fits-all approach when it comes to any type of relationship usually won't work. However, it can be wise to take at least a page or two from the book of successful relationship strategies when you're considering how to best manage a business relationship.

A vendor relationship is perhaps one of your most important in business. It should be a true partnership. It should build its foundation on a series of small, but critical, first impressions. Oh, if it were only that simple.

#### See both sides of the partnership

Yet often, it really is that simple. First, recognize that both sides in a true partnership are equal and that everyone involved brings something unique to the table. Vendors have their business models, financial goals, existing workloads, and other clients, yet many companies still treat vendor partnerships as commodities. This often happens in the pre-engagement phase when a vendor is being selected, and it suggests that there may not yet be a complete partnering mindset. However, in the economic crunch of the current global marketplace, the potential benefits of treating a vendor like a true partner and selecting the right one can be a make-or break scenario, as all companies are realizing that the world of work has changed and strategic partnership planning is a must.

#### **Timing**

Timing is also very important. The right partner may not be available to us when we are ready. Sounds familiar, right? To remedy this, both sides need to work under some basic assumptions, starting with the bid process. Proposals, deliverables, and pricing are based on what resources vendors can have available at that time.

The reason for this mutual flexibility is that both vendor and sponsor need to operate as efficiently as possible. This means that we like to keep our work capacity high, but not overloaded. Think again about your personal relationships—if you had four season sports tickets that you share with friends or family, you would want to plan so that all four tickets are used each week. But even if a friend cancels one week, that friend will still expect to go to the game the next week. Like in friendship, one side isn't more important than the other, and if you're a good friend, your parties are always full and you'll never go to the game alone. Vendors will have tuned their operations so there are very few idle resources at any point in time. When managing your vendor relationships, it will serve you well to remember these things.

#### Be ready

What's another critical relationship strategy? Don't ever stand someone up who is truly important and valuable. Having been on the contract workforce and research side of things, I can tell you firsthand that vendors try to stay ready for their best clients. So when an "A level" client gives advanced notice or "the wink" that a certain vendor is the first choice for a project, that vendor will begin to free up resources and be ready to take on the task. The vendor may even change some allocations or invest in equipment or bring additional resources on board, all based on a verbal agreement alone.



But when the client has project launch delays, or the final decision to launch at all is delayed, all those readied resources can go to waste or, at the very least, cost your vendor partner money and increased frustrations—like being stood up on a Saturday night. A way to avoid this is to simply keep in constant, open communication and to manage expectations from the beginning. We all know that being open and honest is hard in the beginning for any relationship, but remember we are talking about "A" clients. These are the kind of relationships in which that special person always gets that one extra open seat or that extra ticket to the game.

#### Small things count

As we embrace New Year's resolutions, at the very least we must all try to be more conscious of the small things we can do to execute our business relationships. From the client perspective, this means no more pretending there is a shorter

## **Technical Section**

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timeline than there is, so you have enough time to make changes—and no more holding back on part of the budget just to garner lower bids. In exchange, the vendors will not overpromise to win the contract. They won't present with the "A" team and assign with other resources, and they will ensure that their supplement supply chain to execute the work is synchronized for correct implementation. Anything less is just not partnering behavior, and our projects may be compromised. Contingency plans can compromise projects that are already on a critical path or bring in more costly resources to keep the project on track. The result may be needed cutbacks on quality or leaving out value-added extras that were planned.

Ultimately, if you plan to partner with a vendor, set a partnering tone by starting with the right behaviors during the foundation-setting phase. Invest time in knowing your partner's corporate culture, business goals, and client base. The chemistry between client and vendor, and the intangibles beyond service scores and KPIs, is something that only comes from time and relationship building. Sometimes to know if it's all going to work out, all you have to do is take small steps forward—and show up.

Mark Lanfear is a global practice leader for the Life Science vertical at Kelly Services, a leader in providing workforce solutions. He has operated clinical trials around the world for almost two decades. In addition, Mark is a featured speaker at many of the Life Science industry conferences and a writer for its periodicals. He can be reached at MARL773@kellyservices.com or 248-244-4361



# 2013 Classroom Training

ISPE's in-depth courses cover the entire product lifecycle and are led by instructors who are active in the industry.



5 – 6 November

- Practical Application of CSC GAMP® 5 (T11)
- Risk-MaPP (T41)







### Tampa, Florida USA

9 - 12 December

- Cleaning Validation Principles (T17)
- Clinical Trial Materials (T13)
- HVAC for Pharmaceutical Facilities (T14)
- Pharmaceutical Water Generation (T04)
- Quality Risk Management (T42)
- Storage, Delivery and Qualification of Pharmaceutical Waters (T23)
- Science and Risk-Based Commissioning & Qualifications (T40)



## Member News & Event Calendar

### **Welcome New Members**

#### These new Members joined January 25, 2013 through March 22, 2013

Firas Abulaban Lisa Aponte-Wolff Allan Bailey **Dorothy Lou Bailey** Ben Balajonda Steven Barbe Mohannad Samy Behairy Tania Bembridge Nicholas Bernath Sandra Boyd **Dennis Brandl** Michael Brown Charles Bruns Ricardo Cairo Michael Canup, Jr. Kristi Castro **Troy Chavis** Jason Colon

Vicki Cornish

Richard Day Erin Denoo Victor Desmarais lin Di Steven Doligalski Cicelle Domingo Brian Farrell Paul Gammariello Tara Gankiewicz Stephen Gibson David Graham Allison Graves Jase Hickcox Guy Blaise Idourah Keith Johnson **Garrett Keener** Marguerite LaRonde Cris Lemay

Millard Davis

Sara Lewis Corteney Mack Tim Marcinkowski Jared Matthews Joel McCurry **Terence Morrison** Chris Navolio Jim Novitsky **Kevin Porch** Jack Powell Charles Quirico Lynne Radziwill Rick Ransom Erica Reid Beth Rhodes Sandra Meryl Rodrigues **Diane Seamans** 

Carlos Serrano, Sr. **Daniel Siegle** 

Sirat Sikka Jessika Smith Marc Sodl **David Song** Sarthak Subudhi **Denise Suter** 

Gana Venkata Pavitra Talapureddy Darrell Tanner

James Tiller Marcus Tuttle John Urbanowicz **Dwight Andrew Whitlock** 

Lenardo Youmans

Ka Zhang Katie Zhu

DATE	DETAILS
April 25, 2013	Therapeutic Thursday, location TBD
May 6, 2013	Annual CaSA Golf Outing at Prestonwood Country Club, Cary, NC
May 17, 2013	MEDICAGO Facility Tour, 7 Triangle Drive, Research Triangle Park, NC

## Do you have an idea for an article?

Send it to:

whaines@manganinc.com

Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

## **Carolina-South Atlantic Chapter**





# Electronic Media ISPE-CASA.org

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120 x 240 Vertical Banner animated	\$400	\$250
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	□ 240 x 400 Vertical Rectangle ad 6 Months, \$300 □ 240 x 400 Vertical Rectangle ad 12 Months, \$500 □ 120 x 240 Vertical Banner animated ad 6 Months, \$250 □ 120 x 240 Vertical Banner animated ad 12 Months, \$400 □ 120 x 240 Vertical Banner - non animated 6 Months, \$200 □ 120 x 240 Vertical Banner - non animated 12 Months, \$300						
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## ISPE CaSA Chapter E-Newsletter Ads

## Newsletter Ads Work for your Business!

Our Chapter produces six e-newsletters per year, and we depend on the support of our advertisers. We send out the newsletters via e-mail and via web link to all of our Chapter Members throughout the Southeastern U.S.

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ISPE-CaSA 1500 Sunday Drive Suite 102 Raleigh, NC 27607 919-573-5442 info@ispeCaSA.org

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE CaSA Communications Committee and asked to submit your advertisement digitally.

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## ISPE Carolina-South Atlantic Chapter Newsletter

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#### **EDITORIAL POLICY**

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Manuscripts should be forwarded to a Member of the Communications Committee at whaines@manganinc.com for review 30 days prior to publication. A brief three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment must accompany the article.

### **Got News?**

#### Send it to:

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Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

#### A word to the ISPE CaSA Newsletter advertisers:

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