



President's Message



Matt Gilson

Welcome to our first newsletter of the new year! I hope you had a great start to 2014. We've been very busy at ISPE CaSA planning several events for you to participate in. I hope you will put these dates on your calendar and join us at these events.

The Toys for Tots event at Novartis was a great time! Thank you for coming and donating LOTS of toys.

(continued next page)

MARK YOUR CALENDARS!

February 7, 2014 – Annual CaSA Leadership Forum: "Taking Control of Your Career," McKimmon Center

February 27, 2014 – Therapeutic Thursday, Double Barley Brewery, Smithfield, NC

March 27, 2014 – Therapeutic Thursday, Carolina Ale House in Cary, NC

April 5, 2014 – TriSci Tech Expo at Raleigh, Museum

April 8, 2014 – 21st Annual Technology Conference, Raleigh Convention Center

May 19, 2013 – Annual ISPE Golf Tournament at Prestonwood Country Club

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President's Message

That's always a fun time to get together and give back to our community. Look for a more detailed article and pictures later in this newsletter. Thanks to TEK for sponsoring this event!

I hope everyone enjoyed the Young Professionals' bowling event at Sparians. This is becoming an annual tradition. It's a great venue and I trust that you had fun and were able to meet some new people at the event. Thanks to the sponsors of this event, PCI, Eisai, Sequence, and CRB. We greatly appreciate your support!

On February 7, we're having our annual ISPE CaSA Leadership Symposium. This is a very popular event and a great opportunity to get career tips, network, learn about possible job opportunities, and hear from some great speakers in the career development / leadership field. I'd also like to thank our event sponsors, CRB, Novartis Vaccines, Commissioning Agents, Inc., Burkert, FujiFilm Diosynth Biotechnologies, McDonald York, Sequence, Hallam ICS, Hospira, and Eisai.

ISPE CaSA recently announced that we have begun our exhibitor and presenter planning for this year's Biotechnology Day event, the Triangle SciTech Expo, at the Museum of Natural Sciences on April 5, 2014. The second annual event, BEST Fest, was held on April 6, 2013. The estimated attendance was just under 7000, and over 50 organizations exhibited along with 11 presentations by well-respected speakers. The event was a tremendous success, and the event steering committee is looking to build on last year by providing more coordinated museum activities and additional exhibitor and presenter opportunities. This is a rare opportunity to bring your family out to one of our local

museums and learn about biotechnology in our region.

Last but certainly not least, we are into the 'heavy lifting' planning phase for our 21st Annual ISPE CaSA Life Sciences Technology Conference. This is our premier event for the year so mark your calendar for April 8 at the Raleigh Convention Center and go ahead and register online at www.ispe-casa.org/2014. This event promises to be a great time of education, networking, fun, and gives you a chance to view the latest technology and services available in the pharmaceutical industry. I hope you'll make plans to join us and bring your colleagues.

As always, we continue to seek feedback for our committee chairs and the rest of our Board of Directors to understand what our membership values from ISPE CaSA. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please let me or any other Board Member know how well we are doing or what we can do to improve. Our contact information is on our website (<http://www.ispe-casa.org/>) or you can email me at president@ispecasa.org and I will respond or forward on as appropriate.

If you are interested in serving on the Board, please get involved on a committee and talk to those already on the Board for information about that process. We're always looking to replace ourselves with other passionate leaders in our industry!

Matt Gilson

President, ISPE CaSA Chapter

A couple reminders:

- Follow us and participate with our social media accounts:
- Twitter – [@ISPE_CASA](https://twitter.com/ISPE_CASA)
- LinkedIn – [ISPE-CaSA](https://www.linkedin.com/company/ispe-casa)
- Facebook – [ISPE-CaSA](https://www.facebook.com/ispe-casa)
- Google+ - [ISPE CaSA](https://plus.google.com/+ISPECaSA)

Come see us...

- ISPE CaSA Leadership Symposium – February 7, McKimmon Center, Raleigh
- Therapeutic Thursday, February 27 at Double Barley Brewing, Smithfield, sponsored by PharmaMatrix
- Triangle SciTech Expo – Museum of Natural Sciences, April 5
- 21st Annual Technology Conference, April 8, Raleigh Convention Center
- Mark your calendars for the Annual ISPE CaSA Golf Tournament – Prestonwood Country Club, May 19

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Membership Corner

21st Annual ISPE-CaSA Technology Conference

By Mike Putnam, CaSA ISPE Technology Conference Committee Chair

Don't miss early bird pricing for the best life sciences gathering in the Southeast! Attendee registration for the 21st annual ISPE CaSA Technology Conference is now open! On April 8 over 1,000 attendees and 200 exhibitors are expected to converge on the downtown Raleigh Convention Center for what's quickly becoming the Southeast's largest gathering of life sciences professionals. Educational seminars for this year's conference include everything from 'Managing the Serialization Transformation' to a special track presented by NC Biotech Center BPD (Biomanufacturing and Process Development) on 'Enabling Integrated Continuous Bioprocessing.' Early bird conference admission is \$45 for members and \$65 for non-members. Admission includes breakfast, lunch and dinner as well as full access to exhibitor area, educational seminars, and networking reception.

Quick facts about the 2014 conference:

- 21st Annual Technology Conference date is set for Tuesday, April 8
- Hosted at the Raleigh Convention Center
- New for 2014...Manufacturer Showcase area
- Attendee Registration opened Wednesday, January 29
- 5 Educational Tracks featuring industry leading professionals
- Networking Reception following conference featuring

gourmet food paired with Topo Distillery and Brewery products 5-7pm

Please look for more details about the Technology Conference in future e-blasts. In the meantime, visit www.ispe-casa.org/2014 to register to attend. The conference is expected to be a sellout, so act fast. Thanks and I'll see you there! 🏠



Triangle SciTech Expo - April 5, 2014 - Museum of Natural Sciences (11 West Jones Street, Raleigh, NC 27601)

By David Smith, Triangle SciTech Expo Committee Chair

I am excited to announce that we have begun our exhibitor and presenter planning for this year's Biotechnology Day event, the Triangle SciTech Expo, at the Museum of Natural Sciences on April 5. The second annual event, BEST Fest, was held on April 6, 2013. The estimated attendance was just under 7000, and over 50 organizations exhibited along with 11 presentations by well-respected speakers. The event was a tremendous success, and the event steering committee is looking to build

on last year by providing more coordinated museum activities and additional exhibitor and presenter opportunities. There is no fee associated with being an exhibitor or presenter, and attendance is free to the public on the day of the event thanks largely to our headline sponsor, Biogen Idec. If you are interested in joining us as an exhibitor or speaker as we celebrate our industry and provide fun education opportunities for families in the region, please contact David Smith at david.smith@ustechsolutions.com for more information. 🏠



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Atlantic Chapter**

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Jerry "Patch" Paciorek, CPIP, Membership Development
Jon Doyle, Young Professionals
Mike Putnam, Technology Conference
David Smith, Tri-Sci Tech Expo

Membership Corner

2014 CaSA Leadership Symposium: "Taking Control of Your Career"

By LeAnna Pearson, ISPE CaSA Student Affairs Committee Chair

The 2014 CaSA Leadership Symposium: "Taking Control of Your Career" will take place on Friday, February 7 at the NCSU McKimmon Center.

This event will center on leadership development for all career levels of students and young professionals working in the pharmaceutical manufacturing and services industry. The day will include a Keynote speaker, networking opportunities, and speaker panels on "how to get hired" and "what makes a great leader." This is a great venue to connect with professionals who can change your career or help guide you to your path to leadership.

Sponsorships are still available for Platinum, Gold, and Silver levels - and we would love to hear from those interested in participating as either an industry mentor or speaker.

Please contact Jennifer Lauria Clark, CPIP, at

Jennifer.Clark@CAgents.com for more information.

We are creating a resume book from this event. If you want your resume to be viewed by top companies in the area, please send your resume to casaleadershipsymposium@gmail.com. All levels of experience are welcome to participate (your information will be confidential). The deadline for resume submission is March 1, 2014. 🏠

203 New Members

By Jerry "Patch" Paciorek, CPIP

CaSA Membership Development Chair

Great news! We have 203 new members who have joined our Chapter since July 1, 2013, which is more than half way to our goal to sign up 350 new members by June 30, 2014. Thanks for all your efforts and support in spreading the word about ISPE and the CaSA Chapter!

Please remember ISPE's Refer-A-Friend Program! Earn one free month of membership for every friend you refer. All the details are available at <http://www.ispe.org/membership-referal-program>

If you have any question about ISPE or the CaSA Chapter, please contact me at paciorek@cagents.com. 🏠

Welcome New Members


New Members who joined November 18, 2013 through January 21, 2014

Sindhu Addala
Hector Alvarado
Michael Berg, PhD
Mariessa Blunt
Dorian Boone
Justin Caldwell, PE
Swapna Charla
Ting Cheng
Mohit Chintakindi
Bhasker
Tim Davis
Vidhi Desai
AJ DiDuro

Vaishnavi Dodwadkar
Megan Fruchte
Tom Goodwin
Nolan Gregory
Yousef Hanif
Cameron Hanson
Monica Haubenschild
Tom Hefferan
Larry Herbst
Scott Hughes
Chelsea Kellinger
Mitchel Kevern, MEM
Kendra King

Jess Kruh
Jason Layne
Dave Lescinski
Sarah Lipinski
David Maeng
Anne-Marie Marquez
Mauro Milchteim
James Mulling
Greg Nelson
Sonali Patel
Marisol Patino
Luis Ramirez
Tim Rodgers

Alycia Rouffa
Matt Schrader
Nolan Shen
Chris Small, PE
Bryant Sprinkle
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Stephen Turner
Burak Ucar
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Chris Wilkins
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Young Professionals Carolina-South Atlantic Chapter

9th Annual

LEADERSHIP SYMPOSIUM



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8:30 – 4:00 pm

NC State McKimmon Center

This Day of Highly Interactive Activities Includes:

- ✓ Access to Local Life-science Companies in Hiring Mode
- ✓ Talent Management/HR Panel Discussion
- ✓ Speakers covering Leadership and Generational Differences
- ✓ Roundtable discussion with career professionals
- ✓ Access to latest Leadership Trends and Knowledge Centers

REGISTRATION/INFORMATION:

2014casaleadershipsymposium.eventbrite.com/?aff=flyer1



**Carolina-South
Atlantic Chapter**

AGENDA

"Take Control of Your Career!" - 2014 CASA LEADERSHIP SYMPOSIUM

Nobody should be more interested in your career than you.

Friday February 07, 2014

NC State McKimmon Center 1101 Gorman Street Raleigh, NC 27606

ATTENTION JOB SEEKERS:

All attendees to this event may submit a soft copy of their resume to casaleadershipsymposium@gmail.com which will be shared with some of our company sponsors. Deadline for submission is **Friday, March 1st, 2014.**

8:30 a.m. Registrations - Continental Breakfast

9:00 a.m. Introduction
Welcome
Table Introductions

*Matt Gilson, GSK, CaSA President
Jennifer Lauria Clark, CPIP, CAI*

9:15 a.m. Leadership & Generational Speaker

Frank Gozzo, Noverant, CEO

10:00 a.m. Networking Break

10:15 a.m. Roundtable
Overview
Interactive Table Discussions

*Wendy Haines, PhD, ASQ CQA, Mangan
Amy Lineberry, CPIP, Mangan*

**11:00 a.m. Talent Management and Staffing
Panel Discussion & Networking**
Perspective, Insights and Guidance
Q&A with panel
Interactive Table Discussions

Facilitator, David Smith, US Tech Solutions
1. Blake Derrick, Novartis
2. George Kafes, Biogen Idec
3. Sequenom
3. Virginia (Crumby) Hall, SPHR
4. Karen A. Cutler, SPHR

12:30 p.m. Networking Lunch

1:30 p.m. What Makes a Successful Leader Panel
Specific Attributes and Characteristics of a leader
How they succeed and Measure to Roundtable Discussion

Facilitator, Jennifer Lauria Clark
1. Darren Dasburg, VP MedImmune
2. Invited
3. Sandra Birkhead, Past GSK Exec
4. Grant Godwin, Past GSK Exec

2:30 p.m. Benefits of ISPE
Overview
Ways to get involved in ISPE & Testimonials

Jerry Paciorek, CPIP, CAI

2:45 p.m. Leadership - who would want to be led by you?

Ken Ewan, KME Leadership

3:45 p.m. Closing Comments and Networking
Announcements of upcoming events
Networking

*Leanna Pearson, SAC Chair, Specline
Jon Doyle, YP Chair, PCI
Jennifer Lauria Clark, CPIP, CAI*

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Membership Corner

CaSA Member Spotlight: Jennifer Lauria Clark

By Newsletter Committee

Q: What is your full name?

A: Jennifer Lauria Clark

Q: Birth Place?

A: Rocky Mount, NC

Q: College?

A: North Carolina State University

Q: Tell me a little about your personal life.

A: I have been happily married to my husband John for over 7 years and have two beautiful children, Reese and Riley who keep me occupied when I am not working. Our whole family loves visiting family and friends, hanging out at Lake Gaston, NC State Football games, and Friday Pizza Nights.



Jennifer Lauria Clark

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

A: Southeast Technical Services Manager for Commissioning Agents. I do Business Development, Marketing and perform Technical Services for Commissioning Agents, Inc.

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

A: 2+ years

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

A: I began my first job 3 months after I graduated from NC State. I went to Europe for a month the day after I graduated from college without a job. I had some prospective opportunities but nothing final. The day before I graduated a man that I had met at the ISPE Annual Meeting two years earlier called me about a position. I told him I was about to leave for a month and he said let's talk when you get back. We talked when I returned and I went to work for his company. About 18 months later I got married and ran into the CEO of

another company, who I knew personally and from ISPE, on the return trip from my honeymoon. He said they were looking for some help and I met with his C&Q Manager and started working for them a month later. After working there for five years, I was approached by CAI at an ISPE Annual Meeting about joining their team. Within a few months, I joined CAI and began a new journey in a leadership position within our company. Needless to say...ISPE has been a large part of my career path.

Q: What is your favorite part of your job?

A: Working with a group of intelligent individuals with the same common goal of success for not only ourselves but for our employees and our clients.

Q: How long have you been a member of ISPE/when did you first join ISPE?

A: I celebrated my 10 year anniversary this past November. I joined ISPE in 2003 when I attended my first annual meeting as a student with my parents in New Orleans, LA.

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

A: There are many benefits that I have realized from being an ISPE Member the past ten years. I have made incredible friends who also encompass a large part of my professional network. I have had opportunities to serve as ISPE CaSA's Chapter President and presently I am fortunate enough to sit amongst great leaders of our industry on the ISPE International Board. My career has flourished from volunteering with ISPE and participating in training courses. Today, I am a much stronger professional in my leadership skills, management style, and have more knowledge about the industry than I would ever be able to obtain on my own.

Q: Why are you still involved with ISPE?

A: ISPE has in many ways helped shape who I am today. I am still involved because my parents (my dad is a long standing Member) encouraged me to join when I was a student at NC State. I was given opportunities to succeed as a student and a young professional by others who came before me within ISPE.

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Membership Corner

I stay because I want to give back to the students and young professionals coming after me. I want to mentor, support, review resumes, volunteer alongside and hire excellent young talent. I am fortunate enough to work for a company who supports my time and realizes the benefits of ISPE in helping our company and our employees move forward not only professionally but personally.

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

A: Wow, there are many people who have helped shape my career. The people who have taken an interest in my career and me the past 8 years have blessed me. My biggest champion is my husband, John Clark. Others who have helped mold my successful career are my parents, Tom and Debbie Lauria, my sister, Kari Lauria Delahunty, Jane, Bruce, Keith, Lisa, David, David, Scott, Mark, Bo, Heather, Matt, Tim, Bob, Dan, Tracey, Rosemary, Jon, Wendy, Amy, Sherry, Nancy, Charlotte, Emily, Nicki, Jeff, Karleen, and Bill. The expansive network that I have been afforded during my professional career humbles me. Thank you all for touching my life somehow.

Q: If you weren't involved in pharma/biotech, what business do you think you'd be in?

A: Wedding Planning.

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

A: Artistic ability – to sing or draw.

Q: Any hobbies? What are they?

A: When I have time, I like to read and do crafts.

Q: Do you collect anything?

A: I love office supplies.

Q: Finish this sentence – “I need more....”

A: I need more... Chocolate Chip Cookies.

Q: Favorite Food?

A: Anything Italian.

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

A: When I was in High School, I was chosen to represent North Carolina at the Asian Pacific Economic Conference (APEC) in Auckland, New Zealand. At this event, I got to be the lead interviewer at 17 while interviewing the Prime Minister of Singapore, Goh Chok Tong.

Q: Last movie you saw?

A: With kids: Frozen Without: American Hustle

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

A: Trust your instincts. Understand the decision to be made, take the time needed to deliberate the decision, and trust your decision. ▲

CaSA COMMITTEES

IT Committee

David Knorr
psudave85@gmail.com

Membership Development Committee

Jerry “Patch” Paciorek, CPIP
paciorek@agents.com

Networking Committee

John Marr
John.marr@crbusa.com

Newsletter Committee

Wendy Haines
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Student Affairs Committee

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Technology Conference Committee

Mike Putnam
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Tri-Sci Tech Committee

David Smith
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Young Professionals Committee

Jon Doyle
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Early Bird Rates: ISPE Members \$35 / Non-Members \$55

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Student Corner

Campbell University ISPE Student Chapter

By Dr. Daniel Shin

Campbell University ISPE Student Chapter was created when it had its first meeting in the spring of 1996 with seven students. Dr. Mark Yates who served as a faculty advisor launched the meeting with the help of Jane Brown, the first Chair of the Student Affairs Committee in the ISPE CaSA Chapter. The two had met several times from December 1995 to discuss various necessary things for creating a new student chapter. Their dedication and long hours of service made the student chapter creation possible at Campbell University. Thanks to the continuous support of Jane Brown and dedicated work of Dr. Yates, it started to grow and the initial small seed became a tree with a firm root system that are from the financial support of ISPE to friendly and helpful Members in the CaSA Chapter.

Campbell University has tried to support several students to attend the Annual ISPE Meetings. Many students have participated in the ISPE CaSA Student Poster Competition and won the local competition and free trips to compete in the International ISPE Student Poster Competition. One Campbell University student, Eric Blaesing who now works for Novartis in Holly Springs, won the ISPE International Student Poster Competition in 2003.

After Dr. Yates left Campbell University for Wyeth (currently Pfizer) in 2000, Dr. Daniel Shin joined Campbell University in 2001 and has served as a Faculty Advisor for the Chapter since then. Under his leadership, the chapter has grown more and

has had consistent monthly meetings, and produced active Student Members who later served faithfully for the CaSA Chapter. The Chapter won the International Student Chapter of the Year Award in 2007. This was all possible thanks to the tremendous support of the CaSA Chapter Members and leaders. In every meeting, Members were very friendly and enthusiastic about helping in Campbell University Student Chapter's meetings and other activities. Their dedication and countless hours of service have been the fertile soil for the Campbell University Student Chapter's growth. All the meetings in ISPE CaSA such as conferences, seminars, career fairs, technology shows, and leadership forums were a tremendous learning experience. The students expressed how helpful and excellent those meetings were and appreciated the opportunities for networking, socializing, learning, and presenting. Resume critiques, interviewing skills, internship opportunities, plant tours, seminars, etc. have helped the students prepare for the real world. The students have participated in many volunteer opportunities for various meetings and other philanthropy activities such as Habitat for Humanity, Toys for Tots, Race for Cure, and Relay for Life, etc. Campbell University ISPE Student Chapter is committed to help the students to become involved in all aspects of activities related to healthcare.

Current organization and officers in Campbell University ISPE Student Chapter below. ▲

Student Chapter: ISPE Campbell University Student Chapter

Institution: Campbell University

Industry Advisor: Dr. Mark Yates

Faculty Advisor: Dr. Daniel Shin

Faculty Co-Advisor: Mr. Mike Gallagher

President:

Name: Pratibha Chowdary Koneru

Email: pckoneru0919@email.campbell.edu

Vice President:

Name: Jenny Hughes

Email: jlhughes0623@email.campbell.edu

Secretary:

Name: Courtney Huffman

Email: cnhuffman0308@email.campbell.edu

Director of Public Relations:

Name: Swanalika Avula

Email: s_avula1002@campbell.edu

Director of Campus Recruitment:

Name: Pravallika Vinnakota

Email: p_vinnakota0225@email.campbell.edu

Director of Student Activities:

Name: Leslie Phillips

Email: ldphillips1030@email.campbell.edu

Social Chair:

Name: Ramya Patibandla

Email:

r_patibandla1217@email.campbell.edu

Website Manager:

Name: Sonali Patel

Email: sppatel0324@email.campbell.edu

Networking

ISPE Toys for Tots Wrap-Up

ISPE-CaSA held its annual Toys for Tots Holiday Toy Drive and Breakfast Wednesday, December 18, 2013 at the Novartis campus in Holly Springs, NC. The event kicked off with an early breakfast of muffins, pastries, fresh fruit and hot coffee. Members dropped by to deliver toys, enjoy a bite to eat and network with other ISPE Members.

The donations this year were remarkable! By the end of the event, Nerf guns, Barbie dolls, footballs and teddy bears filled the donation table. Members helped load the toys into a large truck for delivery—it was filled to the brim!

ISPE would like to thank TEK for co-hosting the breakfast and Novartis for providing the location to host the event. And a big “thank you” to everyone who donated and helped make this event a huge success! 🏠



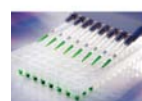
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Young Professionals Corner

What Defines Success - A President's Perspective

So what really is success and how do we get there? It seems that we all are trying to figure it out, whether in professional or personal life. The Young Professionals Committee has recognized a great opportunity in hosting four very successful business leaders to share their invaluable insights and lessons learned from their personal road to success: Mike Putnam of Sequence Inc, Andy Ferrell of PCI, Heather Denny of McDonald York, and Bruce Craven of Mangan Biopharm.

The path to success was different for each of our guests and motivations were not all the same, although there were a few key elements that seemed to be common. First, the "Drive" that propels us forward each day. Find that motivation that will drive you to seek opportunities, and go after them, because you never know where they might lead you. Second, find a good mentor and do not underestimate the people around you. Be it a book, a friend, or a variety of people who advise you in your development and help you understand how you are seen by others, you need to learn how to trust.

Third, give yourself a break. Learn from failures, because the road to success involves failures. Failures are really opportunities "in disguise" for learning and improvement.

So where are you going in your development? What are your personal and professional goals? And when you finally get there, is it going to be what you were expecting? Our guests, who have gotten a long way in their success, told us about their busy lifestyles and their commitment to what they are doing. It became apparent that the end goal did not seem to be as important anymore, as much as the passion that got them there. They pointed out: figure out who you are and where you want to fit. If you are true to yourself and you constantly search and adjust you might just create a success story of your own!

The event culminated at Natty Green's where we could interact with our guests and enjoy the rest of the evening in good company. Stay tuned for our next Young Professionals event! 🏠



Left to Right, Mike Putnam of Sequence Inc, Andy Ferrell of PCI, Heather Denny of McDonald York, and Bruce Craven of Mangan Biopharm

Technology Corner

How Does Facility Layout Affect Segregation Strategies in NextGen Pharmaceutical Manufacturing Facilities?

By Mark Witcher, PhD

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Complete separation of process and products from each other within a biopharmaceutical manufacturing facility is an operational and regulatory imperative. But does that necessarily mean physical separation? Or can separation be achieved in common space?

I developed a discussion article for the latest electronic supplement to Pharmaceutical Engineering which I hope will stimulate dialogue on concepts and approaches related to facility designs and their impact on segregation strategies required to assure process separation during multiproduct, multiphase manufacturing. Significant pandemic threats, rapid production of Medical Counter Measures (MCMs), and advanced biopharmaceutical business models require rapid development to commercial manufacturing timelines that are only achievable by facilities capable of supporting

high-utilization, multiproduct, multiphase manufacturing employing methods and approaches outside previous manufacturing practices. While ISPE's Baseline Guides present important and useful current best practices, the industry faces many challenges from rapidly evolving technologies, threats, and opportunities.

This article proposes ideas and concepts which I hope will stimulate discussion and debate required to evolve methods and approaches for future Baseline Guides required to meet those challenges. The industry and the patients of the future need your participation in helping the industry quickly and efficiently produce high quality products in the next generation of manufacturing facilities. Please read the article, and then contribute your feedback on ISPEAK.

Regulatory Update: EMA Presentation, EU Regulator Training By ISPE

Reprinted with permission from ISPEAK, the official Blog of ISPE

This post is another a series of reports on the many regulatory-related activities your fellow ISPE Members are undertaking, and how you can add your voice to these impactful initiatives.

Members Represent ISPE at Prestigious EMA Events Presentation to EMA on Drug Shortages

ISPE was among a limited number of organizations invited to an invitation-only EMA workshop in October intended to increase awareness and investigate the possible causes of shortages in the supply chain. The workshop involved discussion with patient and patient supply groups as well as technical representatives from industry. ISPE's Drug Shortages Team members provided input from the ISPE Drug Shortage survey conducted earlier this year. ISPE plans a series of Drug Shortage session in 2014.

Presentation to EMA on Dedicated Facilities

In September, ISPE was represented at an invitation-only workshop with members of the Quality Working Party (QWP), Safety Working Party (SWP) and Inspectors' Working Party to discuss responses to the SWP draft guideline on setting health-based limits for shared facilities and the updates to Chapters 3 and 5 of the EU GMPs. Stephanie Wilkins, PE, (PharmaConsult US), former member of the ISPE International Board and co-Chair of the ISPE Risk-MaPP Baseline Guide Task Team, and ISPE Regulatory Advisor John Berridge, PhD, provided a presentation based on earlier ISPE comments. ISPE provided input to a proposed submission drafted by EFPIA. The EMA expects to issue a further draft during the first half of 2014.

Presentation to EMA on Process Validation

Earlier in 2013, Steve Tyler (AbbVie), former member of the International Board and current Chairman of the PQLI Steering Committee, represented ISPE at an invitation-only EMA break out session with members of the QWP on the revision of the process validation guideline. The break out session was held to discuss written stakeholder proposals on questions put forth by the QWP on continuous process verification, continued (ongoing) process verification, design space verification and non-standard manufacturing processes. ISPE joined other interested parties representative of a cross section of the European pharmaceutical sector. The ISPE responses to the QWP questions reflected industry experiential learning captured through the PQLI Technical Committee members.

ISPE Members Deliver Training to EU Regulators on QbD, QRM

The second ISPE-organized training event took place in October for more than 30 European GMP inspectors. The first training event, also on QRM, took place in June with approximately 15 GDP inspectors participating. Attendees included MHRA inspectors as well as inspectors from other regulatory agencies, including the Irish Medicines Board. The ISPE group organizing and presenting the training is being led by Chris Potter, a member of ISPE's PQLI team.

Each of the single-day programs included a review of the different QRM tools used by industry and a discussion about how QRM might be used by in relation to proposed changes in Annex 16 of the EU GMP Guide. The GDP QRM event also looked at the impact of the introduction of QRM into the EU GDP Guidelines. Following on the positive feedback from the regulators in attendance, a two-day training for an additional 30-plus inspectors and assessors is scheduled for February 2014. This event will look in depth at the application of QbD as well as touching on QRM and ICH Q10. ▲



**Young Professionals
Carolina-South
Atlantic Chapter**

9th Annual

LEADERSHIP SYMPOSIUM

Friday, February 7, 2014

8:30 – 4:00 pm

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2014 Food and Pharmaceutical Industries Division (FPID) Symposium—NEW EVENT!

5–6 March 2014

ISA Headquarters, Research Triangle Park, North Carolina, USA

It's easy to lose your bearings given the many changes and challenges affecting the quality and safety of food and pharmaceutical supply chains. Recent legislation and incidents of contamination and tampering have raised the importance of automation to reduce errors and implement enhanced serialization controls to improve tracking and tracing throughout distribution channels.

Attending the 2014 ISA Food and Pharmaceutical Industries Division (FPID) Symposium will help you stay on course—protecting consumers, reducing your risk exposure, and improving operational efficiency.

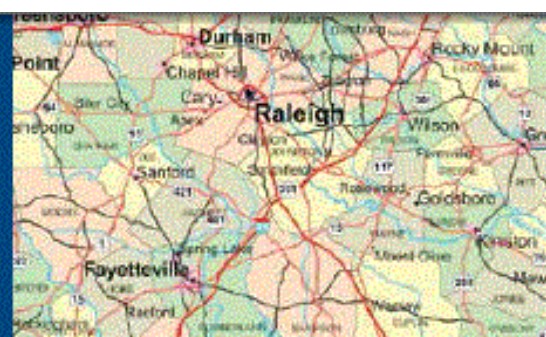
You'll learn—directly from industry leaders and experts—how emerging serialization requirements are driving major changes in food and pharmaceutical distribution, and how to implement a highly coordinated serialization strategy that skillfully leverages automation, supply chain management, and information security.

In addition to serialization, other key topics to be covered include:

- Track & Trace
- Validation
- Cybersecurity
- Radio-Frequency Identification (RFID)
- Process Analytical Technology (PAT)
- Quality by Design (QBD)
- Virtualization
- Batch Controls
- Manufacturing Execution System (MES)
- Project Management



Visit www.isa.org/FPID2014 to receive more details on the 2014 ISA Food and Pharmaceutical Industries Symposium as they become available.



Research Triangle Park, North Carolina, USA

—Coordinates:

35°54'29"N 78°51'46"W

—Weather:

During March, the average high is 63.4°F and the average low is 39.9°F. North Carolina's climate varies from the Atlantic coast in the east to the Appalachian Mountain range in the west. The mountains often act as a shield, blocking low temperatures and storms from the Midwest from entering the central part of the state.

—Quick facts:

The Research Triangle Park (RTP) is home to more than 170 global companies that foster a culture of scientific advancement and competitive excellence.

RTP in central North Carolina between three major universities: Duke University in Durham, North Carolina State University in Raleigh, and the University of North Carolina at Chapel Hill.



Carolina-South Atlantic Chapter



Advertising Opportunities in ISPE CASA Electronic Newsletter

The ISPE CaSA Chapter produces **six** e-newsletters per year. ISPE CaSA sends out the newsletters via e-mail and via Web link to all of our Chapter Members throughout the Southeastern U.S., which reach top-notch pharmaceutical, biotechnology, and bio-science professionals and managers. These newsletters are also posted on our **Web site** so your ad can be accessed by interested visitors to our site.

The cost for a full color business-card-sized ad is \$750 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional \$750 per year for six issues. Space limits the number of front page ads to only **four**, and is to the first four paid advertisers on a first-come, first served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad; a hot-link can be added to your submitted ad file for an additional \$500.00 for the entire year.

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- \$ 750 Full-color ad for six issues (\$125/issue)
- \$1,500 Double business card size ad for six issues (\$250/issue)
- \$200 Full-color ad in 1 newsletter of your choice
- \$500 Adding a hot link for directing customers to your website by a simple click

We hope you will take advantage of these opportunities and advertise in the 2014 ISPE CASA e-newsletter.

To reserve a placement of your ad for 2014 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at 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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We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!

Carolina-South Atlantic Chapter



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Electronic Media ISPE-CaSA.org

Now you can reach www.ispe-casa.org audience by advertising on our website. A limited number of advertising spots are now available so don't delay. Contact the ISPE Carolina-South Atlantic Chapter to reserve your space. (Please note: ISPE-International-forbids website ads on our chapter's home page, so they are on subsequent web pages.)

To learn more about this opportunity, contact Penney De Pas, Chapter Manager, at 919-573-5442 or pdepas@ispecasa.org. If you are interested in signing up for the program, please complete the form and return to pdepas@ispecasa.org or fax 919-787-4916. Advertisements are sold on a first-come first-served basis.

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240 x 400 Vertical Rectangle	\$500	\$300

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Full-color business card-sized ads (3.5" x 2") may contain your logo or other artwork. Artwork should be sent directly to info@ispeCaSA.org

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG or TIF formats are easiest for us to work with. Space is limited, sign up today!

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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.

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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.

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