



President's Message



Lisa Kerner

Welcome to a new year for the ISPE CaSA Chapter! Your Board of Directors has been working hard throughout the summer to develop plans for the upcoming year and we have many exciting education and networking events in the works! After our Therapeutic Thursday events in August and September, we will kick things off with Oktoberfest on Thursday, October 29 from 5 pm - 8 pm at Koka Booth Amphitheatre in Cary. Thanks to Heather Denny's vision and the support from our volunteers, this combined committee recruiting session and fall networking event was a huge success for our Chapter in 2014. Let's keep the momentum going in 2015!

We'll enjoy an evening on the Crescent Deck with live music, food and local craft brews as we connect with old and new friends in the industry. Committee Chairs and volunteers will also be on hand to provide an update of what they're working on for the upcoming year. If you would like to get engaged, Oktoberfest is the place to be!

The CaSA Chapter has eight very active committees looking for volunteers. If one of the following piques your interest, then please be sure to join us October 29th or visit our website to learn more -

<http://ispe-casa.org/ispe-casa-committees>

- Education Committee
- IT/Social Media Committee
- Membership Development Committee
- Networking Committee
- Newsletter Committee
- Student Affairs Committee
- ISPE-CaSA Life Sciences Technology Conference Committee
- Young Professionals Committee

As Heather mentioned in the June newsletter, the CaSA Chapter had many successes throughout the past year. I would like to thank Heather for her leadership and guidance throughout my tenure on the Executive Board. It is an honor to follow in your footsteps.

We have several other board members rolling off this year who are very deserving of a much needed break! LeAnna Pearson, John Marr, David Smith, Ken Ewan and Ben Hund have supported the CaSA Chapter in more ways than we'll ever know. I am thankful for your friendship and for the opportunity to serve on the board with each of you!

I would also like to introduce our new Board of Directors for 2015-2016. We held our board retreat mid-August and shared our ideas for the upcoming year. Let me just say...I'm inspired!!

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Student Affairs	Marisol Patino, Fujifilm Diosynth Biotechnologies
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It's going to be a great year! With the support of our membership, board of directors, volunteers and sponsors, it is my hope to recharge our events and continue to grow the CaSA Chapter. Please join us! Together we will do great things!

Lisa Kerner

President, ISPE CaSA Chapter
Re-Engage. Recharge. Grow.

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Membership Corner

CaSA Member Spotlight: Heather Denny

By Newsletter Committee

Q: WHAT IS YOUR FULL NAME?

A: Heather Elizabeth Denny.

Q: BIRTH PLACE?

A: I grew up in Oxford, North Carolina (Born at Maria Parham in Henderson, NC).

Q: EDUCATION?

A: Bachelors in Civil Engineering, Construction Option North Carolina State University.

Q: WHAT IS YOUR PRESENT POSITION? WHAT DO YOU DO AT YOUR JOB?

A: I'm the President and CEO, McDonald York Building Company. I am responsible for overall strategic direction, leadership and management of the company.

Q: HOW LONG HAVE YOU BEEN WITH YOUR CURRENT EMPLOYER?

A: 20 years in January.

Q: TELL ME ABOUT YOUR CAREER PATH, AND HOW YOU ENDED UP WHERE YOU ARE TODAY.

A: I started with McDonald York straight out of college as an estimator. Six months in, I went on-site at [what was then] Glaxo to support projects for the GlaxoWellcome merger. I spent 8 years on site with varying positions: estimating, cost control, project management and assistant project director. Then I spent time working on preconstruction and design for a \$60 million pharmaceutical campus. After, was in business development for 6 months before becoming Chief Operating Officer for McDonald York. Then President. Then CEO.

Q: WHAT IS YOUR FAVORITE PART OF YOUR JOB?

A: Helping clients find solutions to their needs.

Q: HOW LONG HAVE YOU BEEN A MEMBER OF ISPE/WHEN DID YOU FIRST JOIN ISPE?

A: I think it was about 10 years ago. It was about the time that I was working on the campus project and ISPE was suggested as a good place for education and to meet others in the industry.

Q: WHAT BENEFITS HAVE YOU REALIZED FROM BEING A MEMBER OF ISPE?

A: Building a network within our industry.

Q: ARE YOU STILL INVOLVED WITH ISPE?

A: Yes, currently immediate past president.

Q: ANY MENTORS/ROLE MODELS THAT HAVE HELPED TO SHAPE YOUR LIFE?

A: There have been many, from clients to those that were in my life early on. I believe everyone you encounter has something to teach you.

Q: IF YOU WEREN'T INVOLVED IN PHARMA/BIOTECH, WHAT BUSINESS DO YOU THINK YOU'D BE IN?

A: Construction is in my blood and building for the pharma/biotech industry brings purpose to what we build. I have a sister that is a pharmacist and brother that is a doctor. This helps me seem a little more relevant when my grandmother asks what I do, ha!

Q: WHAT IS ONE SKILL YOU WISH YOU HAD THAT YOU DON'T?

A: The ability to keep my mouth shut. I tend to say what I think and have strong opinions. Great asset but also keeps you busy when you have such strong convictions.

Q: ANY HOBBIES? WHAT ARE THEY?

A: I love to travel, read, exercise, and do anything outside.

Q: DO YOU COLLECT ANYTHING?

A: Champagne corks.

Q: FINISH THIS SENTENCE - "I NEED MORE...."

A: Time. There is so much I want to do that I have not gotten to.

Q: FAVORITE FOOD?

A: Cheeseburger.

Q: WHAT IS SOMETHING THAT PEOPLE WOULD BE SURPRISED TO LEARN ABOUT YOU?

A: I'm a tested introvert.

Q: LAST MOVIE YOU SAW?

A: Inside Out.

Q: FOR THOSE IN THE EARLY STAGE OF THEIR CAREERS, WHAT ADVICE WOULD YOU GIVE THEM?

A: Work hard, believe in yourself and keep asking, "what's next". 🏠



Heather Denny



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Membership Corner

Networking Committee

By Eric V. Mayer, Networking Committee

I am very excited to announce we have a new Networking Committee in place at ISPE CaSA for 2015 and 2016! Many thanks to Aaron Sink of Hipp Engineering, Chris Barrow of PCI, Kevin Debbs of CRB, Joe Waters of Rovisys, and Robert Keohane of Watson-Marlow for volunteering to serve on the committee. I am sure the entire chapter will benefit from their contributions in planning our events this year.

First of all, if you made it to CRB's Therapeutic Thursday at the end of July, thanks for coming. A good time was had by all and CRB, as always, did a great job.

Although our committee has not formally met, we already have a great line up of networking events for this fall. First in line is Therapeutic Thursday (TT) on August 27 at the Carolina Ale House at Brier Creek. The infamous Roy Snipes of Ellab is sponsoring this event to kick off the year. Many thanks Roy! Also on August 27, PCI is sponsoring a TT at the Mystic Grill in Covington, GA. Just another example of PCI's continual outstanding support for ISPE CaSA. The Atlanta group is doing a great job getting people together and involved in CaSA within their community. Thanks for all the help from Gigi Fan of CRB!


September's TT will be sponsored by Rovisys and NNE Pharmaplan will be entertaining the chapter in November for Therapeutic Thursday.

What about October you say? Well we are again going to have an outrageously fun Oktoberfest at Koka Booth Amphitheatre to spur membership and committee involvement for CaSA.



The event will be held on

Thursday, October 29 and

features include a great band, exhibit tables for all of ISPE CaSA committees, outdoor games, and some great local craft beers. If you missed it last year – be sure you don't repeat that mistake. This event is a lot of fun and will be very well attended. Come out and sign up to volunteer for your favorite committee! 

UPCOMING EVENTS

September 10, 2015 - Tentative YP Education Tour of United Technologies and Education Sessions.

October 22, 2015 - Education Event in Atlanta area with a Therapeutic Thursday.

October 29, 2015 - Oktoberfest, RDU area

December 3, 2015 - Education Event in RDU area with a charity event

March 30-31, 2016 - 23rd Annual Life Sciences Technology Conference, Raleigh Convention Center

April 14, 2016 - Education Event, RDU area

May 16, 2016 - Golf Tournament

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www.ispe.org/membership-referral-program

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**Carolina-South
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Eric Mayer, Networking
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Jamie Sigmon, Young Professionals
Amy Lineberry, Technology Conference
Rich Stanfield, Newsletter

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Membership Corner

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

By Terence Morrison, P.E., CAP, LEED AP BD+C, ISA 84 SFS

Applications can be made online at www.ispe.org/join, click on Join Now under Industry Membership, and enter CASA2015 in the promotion code box. 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-referral-program>.


Help the CaSA chapter win the 2015 Challenge! Between June 1 and October 15, 2015, the challenge is on to recruit and retain the most Members, the most new Young Professionals,

and the most Annual Meeting attendees.

For each new member you recruit, you'll earn one free month of membership credits that will be applied to your next membership renewal.

See website for additional chapter prizes:

<http://ispe.org/challenge2015>.

If you have any question about ISPE or the CaSA Chapter, please contact me at membership@ispecasa.org. 

Welcome New Members

New Members who joined June 2, 2015 through August 4, 2015

Bobby White
David G. Hunt
Grafton Jay Corbett
Kathryn Gartland
Kit Crafton
Mark Knight
Alexander Bailey
Christopher Maglione
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Membership Corner

Education Committee

By Jim Hubbard, Education Committee

The Education Committee is having a kickoff meeting on July 22nd for the 2015-16 programmatic year.

Tentative event dates have been set for the following education events:

- Thursday, September 17, 2015 in Atlanta, GA
 - Thursday, December 3, 2015 in RTP
 - Thursday, April 14, 2016 in RTP
- Our team is also working on:
- Partnering with the IAC team to bring owner/operators high level round table discussions.
 - Working with the Young Professionals to bring seasoned veterans to their mentoring program.
 - Planning to assist the Tech Conference Committee with their event on Thursday, March 31, 2016. 🏠



**Be Heard!
Vote by
9 September**

Time to Cast Your Vote

As an ISPE Member, you have the opportunity to choose representatives to fill open seats on ISPE's International Board of Directors. The Board creates the Society's vision, establishes Society policies and controls Society business. It's an important job!

Look for your electronic ballot via email* in early August and cast your vote by 9 September 2015.

Questions? Email Susan Obarski at sobarski@ISPE.org or call +1-813-960-2105 ext. 222.

*Email will be sent by Intelliscan, Inc., our independent outside election partner.



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Marisol Patino

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Young Professionals
Jamie Sigmon

IT/Social Media
Justin Rothwell

Technology Conference
Amy Lineberry

Newsletter
Rich Stanfield

Membership Corner

Welcome Back Students

By Marisol Patino, Student Affairs Committee



Be on the lookout for applications to attend the 2015 ISPE Annual Meeting in Philadelphia, PA. Each year ISPE CaSA partially funds several students to the ISPE Annual Meeting. This year's focus will be New Paradigms for Manufacturing Excellence."

Here is what some students have said about attending the annual meeting.

"The highlight of my experience was meeting many young and seasoned professionals from the industry. As a result, I made contacts from all over the world including Mexico, Japan, China, Switzerland, Denmark, UK, US and more."

"The ISPE Annual Meeting was an eye-opening experience. Afterward, I knew I had a great foundation and felt ready to become a true young professional. This is an experience that everyone who is a member or who wants to become a member should have. ISPE Rocks!"

"This conference has given me opportunities that I could not have attained on my own, and connections that I feel will benefit me for the rest of my career."

New to ISPE? Here is how to reach out to your local ISPE student chapter,

<https://www.ispe-casa.org/student-chapters> ▲

2015 ISPE Annual Meeting

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Membership Corner

ISPEAK Quality Metrics

By ISPE

ISPE has been leading the charge to bring industry and regulators together to discuss quality metrics ever since it was brought to the forefront of industry thinking in the Food and Drug Administration Safety and Innovation Act (FDASIA).

ISPE has been at the forefront of gathering clear and objective data through its Quality Metrics Pilot Program. The new ISPE Quality Metrics Initiative Pilot Program–Wave 1 Report contains critical learnings on quality metrics using real data provided by 44 sites from 18 companies – a first for the pharmaceutical industry. Wave 1 included questions on process capability similar to those being considered by FDA as well as a comprehensive survey of quality culture and its impact on quality performance.

ISPE presented viewpoints and recommendations on the U.S. FDA's draft *Request for Quality Metrics Guidance for Industry* at a public meeting held at the FDA's White Oak Campus in Silver Spring, MD.

"The FDA Public Meeting marked an important milestone as FDA and industry continue on the Quality Metrics journey," noted Diane Hagerty, Vice President, Genentech, Inc., and one of the ISPE Quality Metrics Team leaders. Public comments and support for continuing the advancement of the Quality Metrics initiative were shared by all of the major industry trade associations (ISPE, CHPA, PDA, PhRMA, GPhA, IPEC and BPTF). At the same time, common themes emerged regarding recommendations to be incorporated and additional concerns that still need to be addressed. Ms. Hagerty added, "On behalf of the many people and companies that have been contributing to the Quality Metrics efforts, it was gratifying to see ISPE's work positively acknowledged throughout the discussions in the FDA Public Meeting. This underscores the value of continuing our efforts to provide objective data and experience to inform ongoing dialogue."

Among suggestions, we proposed a phased introduction to the guidance – for instance, starting with higher-risk facilities or

products, or starting with voluntary reporting during the initial learning period. We also requested more transparency from the FDA on how quality metrics data will be used, along with refined FDA definitions. Additionally, we recommended that the FDA consider revising the structure of the proposed metrics reporting templates in order to better reflect how industry is currently gathering data and to thereby potentially decrease the reporting burden on companies. In the public meeting we also commented, based on experience gathered from the Quality Metrics Pilot Program – Wave 1, that the reporting burden projections included in the Federal Register Notice accompanying the Draft Guidance appear to be significantly underestimated.

We support the FDA's effort to implement a Quality Metrics program in collaboration with the industry and back the need for the program to start with a small, targeted approach that will enable the industry and FDA to learn and advance the approach over time. Our comments represented input from our members and the knowledge gained from Wave 1 of the ISPE Quality Metrics Pilot Program; which mirrored many of the proposed metrics presented in the new FDA draft guidance.

ISPE Quality Metrics Wave 2 Study Underway – A Wave 2 of the pilot has commenced, which will enhance understanding of relationships revealed in Wave 1. Recruiting for Wave 2 is currently underway and provides participants experience in preparing for the logistics and efforts associated with gathering of product-based data, including the FDA proposed metrics set. Feedback from Wave 1 highlighted benchmarking with peers of a site's performance as an important output.

For more information on the Pilot Wave 2, contact qualitymetrics@ispe.org.

ISPE will present early insights from Wave 2 of the Pilot and its response to the FDA Guidance during the 2015 ISPE Annual Meeting to be held 8 – 11 November in Philadelphia, Pennsylvania.

(continued on next page)

Some Questions and Answers from the ISPE Quality Metrics Pilot Program, Wave I

Q: What information from the metrics program will FDA be likely to consider using and how will the pilot influence the FDA going forward with their metrics program?

A: (Russ Wesdyk, FDA) Keep in mind that the information that FDA collects is limited to information that an investigator would already be asking for, something you have to have anyway. We want to minimize the burden, keep the definitions as simple as possible, and keep the footprint as minimal as possible. We're interested in getting the most "bang for the buck" without increasing the burden. With regard to question of which metrics the FDA might use, based on where we are that's something I can't speak to specifically. Will the ISPE metrics program influence the FDA? Yes. Will it directly impact the FDA? No. ISPE is not the only stakeholder.

Q: How will the metrics pilot program benefit companies that were not involved in Wave I?

A: (Diane Hagerty, Genentech) First, you are here! That's great! The report is going to be available to everyone, including regulators. Many things were learned in the case studies and what we learned will be considered in Wave II.

Q: Given the estimate that it took an average of 90 hours for participants to collect data, will there be a report addressing the ranges of how long it took for companies to collect the data?

A: (Vanya Telpis, McKinsey) We will work to provide information on the ranges.

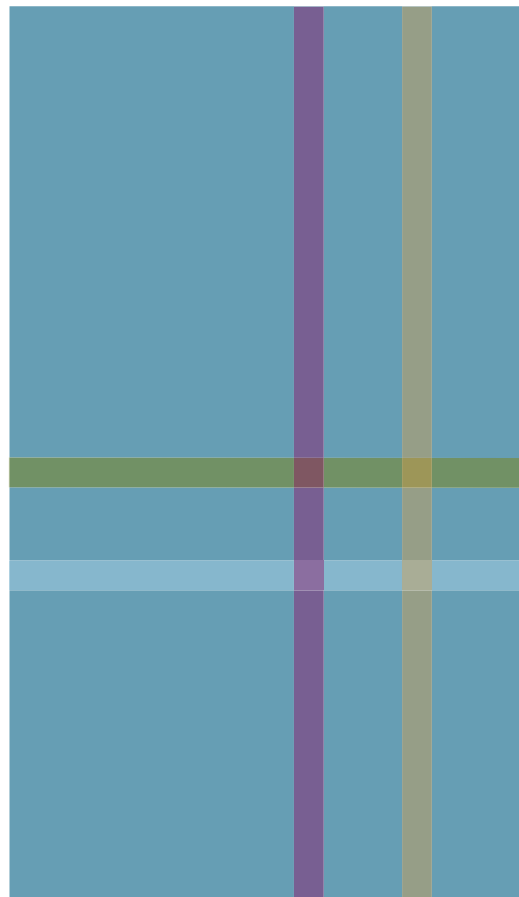
Q: Please comment on the report data that says "Total Complaints" were difficult to provide.

A: (Russ Wesdyk, FDA) We would be interested in hearing from companies on why they were difficult to provide. I'd welcome any feedback on it. *Feedback from the floor suggested that while Total Complaints are routinely collected, they may not be collected for "all sites" for the company, but may have been in the past collected for specific sites, a simpler task. Asking for the metrics with a new, specific definition may have required a different process for collection for some companies.*

Q: (Rick Friedman, FDA) – Across the supply chain there is no standard platform for the exchange of data, and that is a challenge to a robust quality system. This issue of IT structure might be the "elephant" in the room.

A: (Diane Hagerty, Genentech) A point well taken. The issue of different platforms is getting the attention of senior management. It's not going to be easy moving forward, considering multinational companies, for example.

A: (Russ Wesdyk, FDA) I'd like to comment on data systems and where data resides. An annual product review is a requirement. (Russ Wesdyk conducted an informal, on-the-spot survey and asked the audience to self-identify if their company did not do an annual review across all sites and found that only 30 percent (estimated) of the audience did do an APR across all sites.) Everyone in your family takes drugs that you make, yet 60 percent do not aggregate an annual product review to understand at the corporate level what is happening with your product across the supply chain. Think about that. ▲





**Carolina-South
Atlantic Chapter**



Advertising Opportunities in ISPE-CaSA 2015 Electronic Newsletter

The ISPE CaSA Chapter will produce two more e-newsletters this 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.

Also, if you would 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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To reserve a placement of your ad for 2015 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org.

Deadline for 2015 advertisers to be in the October 2015 issue is **September 25, 2015**.

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Carolina-South Atlantic Chapter



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