

Volume 23 • Number 3

CaSA News



June 2016

Featured Sponsors



2500 Gateway Centre Blvd., Suite 850 Morrisville, NC 27560

President's Message



Summer has arrived and I'm sure you will agree...the heat is on! While CaSA events tend to cool down during the summer, Therapeutic Thursdays will be hot!! Thanks to our sponsors, Therapeutic Thursday events offer our members the opportunity to network and build relationships in a fun, relaxed environment throughout the year. If you haven't attended in the past, please join us and

Lisa Kerner

see what it's all about. If you are a regular, then I look forward to seeing you at one of the following events:

- June 30th RTP Therapeutic Thursday at Carolina Ale House, Cary, NC – Sponsored by STI
- June 30th ATL Therapeutic Thursday at Mystic Grille, Covington, GA – Sponsored by CRB
- August 25th RTP Therapeutic Thursday (Location TBD) Sponsored by NNE Pharmaplan
- August 25th ATL Therapeutic Thursday at Ormbsy's, Atlanta, GA Sponsored by ValSource

Please visit our website www.ispe-casa.org and check our weekly eblasts for updates!

In case you missed it, the 22nd Annual Golf Tournament was held May 16th at Prestonwood Country Club in Cary. This years' tournament brought 220 players and filled two courses. And, if you haven't heard...the Chapter broke its record in charitable contributions!

This year's charity "The Holt Brothers Foundation" supports KidsCan!, which is an educational and peer empathy program for kids who have a parent with cancer, and Camp Kesem, a sleep-away camp for children ages 6-16 whose parent has cancer.

Thanks to everyone that came out to golf and network, the event raised \$11,608 through sponsorships, raffle tickets and mulligan sales. Simply amazing!! It was a beautiful day on the greens!

As things simmer throughout the summer, your board of directors continues its mission to bring meaningful events to our members. Keep an eye on your emails and our website for upcoming events beginning in August. We have big plans and hope that you will join us on our path to success.

With that I would like to thank all of the current board and committee members for your time and hard work this past year. You made it happen and I am forever grateful!

To our membership, thank you for being a part of our Chapter. I hope to see you soon!

Have a great summer!!

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

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SAVE THE DATE!



ISPE-CaSA 24th Annual Life Sciences Technology Conference

Tuesday, March 14, 2017 • Raleigh Convention Center



By registering early, you will get 10% off the price of your table and first round selection.

More information on page 7.

Board of Directors 2015-2016

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Membership Corner

Education Committee

By Jim Hubbard, Education Committee

Education Committee Chair Thank You:

I want to take the time to thank my Co-Chair, Rachel Leahy, and Atlanta Lead, Gigi Fan, for their dedication to the Education Committee and the Chapter over the past two years. They have been the key to the growth of the Committee and the success of our events in Raleigh and Atlanta. They have also become my friends and the support they gave to me is greatly appreciated. Going forward, I wish Rachel the best in her election to the Chair role – please vote for her – and to Gigi for the ongoing efforts in Atlanta. You two are amazing!! Thank you.

To the many committee members who dedicated their work and personal time to the Committee, my hats off to you. Without your efforts, what we accomplished during the past two years just wouldn't have happened. Thank you.

The thank you list grows from there to include the other Committee Chairs, the Executive Boards, FPMR, the Sponsoring Partners, many, many colleagues, speakers, and all those who made a vested interest in bringing the best education program to the Life Sciences community. The collaboration and guidance of all these people was a very important component to the programs the Education Committee brought to the industry. Thank you.

Next Events

The Committee is planning future events in both the RTP and ATL area for the latter part of 2016. More information will be coming soon.

With that said, the future of this committee is very bright. We have the right team, the right leadership, and a growing list of industry professionals who want to be a part of our events. That combination is going to lead to an even better program over the next two years. Currently, Rachel and Gigi are working on an event in both Raleigh and Atlanta before the close of 2016. Watch for those event announcements and help make them successful by participating.

Finally, I have to thank Amy Lineberry and the Executive Board for my new role as Co-Chair to the Technology Conference. We have already met several times to start the planning for the next Annual Technology Conference on March 14, 2017.

Thank you to all of you who have made the Education Committee such a success!

CaSA COMMITTEES 2015-2016

Student Affairs Marisol Patino

Education Jim Hubbard

Networking Eric Mayer

Membership Development Terence Morrison Young Professionals Jamie Sigmon

IT/Social Media Justin Rothwell

Technology Conference Amy Lineberry

Newsletter Rich Stanfield Connecting a World of

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Membership Corner

Networking Committee

By Eric V. Mayer, Networking Committee

GOLF TOURNAMENT! Wow, that was a fun day on May 16th. Perfect weather in the 70s and almost 220 golfers in two flights. Biggest tournament in our chapter history. Thanks to all golfers who supported the event.

Obviously everyone was in a very giving mood, as we were able to raise over \$11,608 for the Holt Brothers Foundation for kids who have parents with cancer. That is a Golf Tournament

Hydro & Commissioning Agents: \$2,500 Holt Foundation Sponsors!

Charity record by a long shot! Both Torry and Terrence spoke to the group and shared their personal experience with their mother's cancer, and they thanked our group emphatically for the support. Great job ISPE-CaSA!

The Sponsors of the event get a huge THANK YOU. We basically sold out all sponsorships. Below is the list of the entire sponsor team who made this event the success it was.

Gannett FlemingJRiverside ResourcesGRGD Project Management, Inc.JBurkert Fluid Control SystemsAPCIAAdvent BiotechBBahnson Environmental SpecialtiesIIHipp EngineeringSM.G. NewellBHolloway AmericaSCooper ElectricEFESTONMillipore SigmaSPaul Mueller CompanySSouthern Industrial ConstructorsII

JE Dunn Construction CRB Jedson Engineering Avid Solutions Aqua-Chem BHDP IPS Sieber Industrial Contractors RoviSys Sequence EHS NNE Pharmaplan SKAN Statesville Process Instruments ICQ - Integrated Commissioning & Qualification

We can't wait to have the Holt Brothers come play golf with us next year!

Dear Kevin Thank you in your support of the folt Brothers Toundation. The ISPE golf fournament yearded Toundation. The ISPE golf fournament yearded all of of fur, and enjoyed spusies the had a lot of fur, and enjoyed spusies the had a bout on work and mission. We have to be invited back! On final count put the fundbe invited back ! On final count put the fundfinal count put the fundbe invited back ! On final count put the fundbe invited back ! On final count put the fundfinal count put the fundfina On the Therapeutic Thursday front, Weiss Envirotronics hosted a great event in April, and upcoming we have STI hosting on June 30th at the Cary Carolina Ale House. We look forward to Hipp Engineering's event in July and NNE Pharmaplan's in August.

In Atlanta, CRB will host Therapeutic Thursday on June 30th, and ValSource will host in August. Thanks to all companies for sponsoring Therapeutic Thursday!

Dear Eric ~ Thank you for your support of the Holt Brothers foundation! The ISPE golf yournament was a hure success - we appreciate your leadership. We met some terrific people, had a great time and the word about on mission. Our, enjoyed spreading " Angl count put the fundraising total at 111,608. Wow. we hope to be invited back! Thank you to ISPE and All your acherosity 121 Favetteville Street, Suite 1300, Raleigh, NC 27601 • holtbrothersing

5 **Membership Corner** \$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

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

Applications can be made online at www.ispe.org/join, click on Join Now under Industry Membership, and enter CASA2016 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 Save 10% on 2 and 3 year memberships!

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

Save 10% On 2 and 3 Year Memberships!

Welcome New Members New Members who joined April 15, 2016 through June 26, 2016

Tanisha McClendon Bryan Burke Ms. Jennifer Hing Cory Ryan Pinkerman Ms. Karen Blume Brian Gilreath Mike Millner Miss Regan Margaret Sigler John R. Godshalk Fred Sieber Lauren Owens Patrick Donelan Ryan Heffner Stephen Ty Howell, Liza Lamb

Daniel Pereira De Luccas Xav Shawn A. Sullivan Eric Gray Jeff Kirby, PE Hayley Hatfield John McKinney **Michael Anderson** Justin Robertson Jesse Calibration Ken Joyner Kevin M. Wade **Rachel Shockley** Ryan Poling Matthew Elliott Erik Zengel

Tara Massie, Ph.D. Shannon M. Morris Daniel Lee **Glen Thommes** Ms. Valerie Klengson Alison Waldman William Bullock, Jr. Mrs. Collen Juliano Ms. Jennifer A. Martinez M. Jason Kelly Antonio Walker Dr. Ahmad Hashem Eric Bohne Stephen Lynn Holland

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Membership Corner

Student Affairs

by Marisol Patiño

Students are enjoying their summer break but will soon be preparing for the ISPE Annual Meeting in Atlanta this September. This year's Annual Meeting is being held at the beginning of the fall semester rather than mid- to late fall semester, as usual. For this reason, student members must submit their applications to attend by the end of July, a few weeks before the end of summer break. If you are or know a student member interested in applying for financial sponsorship on behalf of ISPE-CaSA, please email ispecasasac@gmail.com for more details.

When school is back in session in the fall, student chapters will be looking for industry professionals to speak at their

chapter meetings. Are you an industry professional that is interested in relaying the ins and outs of your current role? Would you like to mentor students and give the advice you wish you had gotten as a student? We'd love to have you as a short-term or regular volunteer on the Student Affairs Committee! Please fill out the interest form located here:www.tinyurl.com/ISPECASASAC or email ispecasasac@gmail.com should you have questions. We are committed to supporting students pursuing life science careers and are looking for passionate people to join us in this endeavor.

Young Professionals Night at Boxcar Bar and Arcade (Recap)

by Tim Brantley

Good beer, tasty pizza, old-school arcade games, and the company of over 30 professionals were the hallmarks of the latest Young Professionals Committee's event in Raleigh, NC.

On May 18th, the Young Professionals Committee hosted a social event at Boxcar Bar and Arcade. This event brought industry professionals together in a fun-filled environment to create and grow connections, as well as provide a mid-week opportunity to relieve stress. The Committee provided pizza from Mellow Mushroom and game tokens for the vast assortment of arcade games featured at Boxcar.

As a committee member, I had the pleasure of greeting attendees as they arrived and providing name tags. This was a



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great way to meet new people. Over pizza, I had a chance to catch up with former classmates. After pizza, I connected with Campbell and NC State Student Chapter Leadership while

playing foosball, skee ball, shuffleboard and my personal favorite Dig Dug.



Special thanks go to

the sponsors of this event: Sequence and CRB. Their support and attendance was an integral part of the success of this event.



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Tuesday, March 14, 2017 • Raleigh Convention Center



By registering early, you will get 10% off the price of your table and first round selection.

A deposit of \$250 is due by August 15, 2016.

Please contact the main office if you have questions: 919-573-5442 or info@ispecasa.org



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ISPE-CaSA 24th Annual Life Sciences Technology Conference

2017 ISPE-CaSA Tech Conference Advance Deposit

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Submit your Deposit early and get 10% off the price of your table as well as first round booth/table selection \$250 deposit due by August 15, 2016

First & Last Name	
Company	
Address	
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PLEASE PRINT LEGIBLY!!!

Advance Deposit Due: \$250

(Please note: This deposit is NOT a pre-registration for a table or booth. It is deposit on your total booth/table cost, giving your company a 10% discount from the total registration cost plus early notice when exhibitor registration opens – which is expected in November 2016. You will still need to register and pay once exhibitor registration opens.)

Pay by Check or Credit Card – You will be emailed a receipt once your payment has been processed

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Signature	Date

ISPE Carolina-South Atlantic Chapter Attn: 2017 Tech Conf 1500 Sunday Dr, Ste 102, Raleigh, NC 27607 Phone: 919-573-5442 / Fax: 919-787-4916 / Email: info@ispecasa.org

Technology Corner

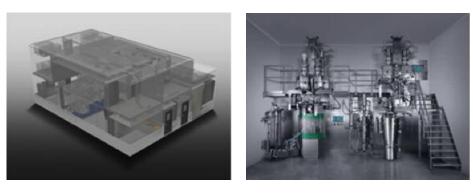
Meet The Nine 2016 Facility Of The Year Awards Winners

We've listed each category in which a winner was awarded and the winner of the category with links to the FOYA website page describing the key factors for the win.

Equipment Innovation

Winners in this category exemplify the novel application of commercially available and custom developed process manufacturing and facility management tools, which yielded For facilities served by ISPE CaSA Chapter, we've brought the entire page here to highlight their accomplishments!

superior results, advanced processing understanding and improved competitive position. Includes imaginative collaboration with vendors/suppliers/manufacturers.



Pfizer Inc. Location: Groton, Connecticut, USA **Project:** The Portable Continuous Miniature and Modular Collaboration

Equipment Innovation

Winners in this category exemplify the application of good design practices and superior conceptual planning which led to excellent integration of facility and process, yielding efficient, clean, pleasant environments promoting business advantages for staff and enterprise, encouraging excellent processing outcomes. Synergistic merging of process and building to create environment of form and functional excellence.



Takara Bio Inc. Location: Kusatsu, Shiga, Japan Project: Center for Gene and Cell Processing Construction Project

Operational Excellence

Winners in this category exemplify the application of modern management techniques aimed to improve operating





efficiencies, promote excellent quality, consistency and yield competitive cost of goods from existing and new facilities, processes and manufacturing operations.

> Baxter BioPharma Solutions Location: Halle, Germany Project: Baxter BioPharma Solutions (BPS) Oncology Manufacturing Expansion

Process Innovation

Winners in this category exemplify the application of novel process manufacturing techniques on existing and new facilities, including fundamental scientific processing approaches and related applied science-based solutions to existing and new challenges.



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Genentech, a Member of the Roche Group Location: Vacaville, California, USA Project: CCP2 Manufacturing Facility and Return to Service (RTS)

Project Execution

Winners in this category exemplify the application of novel tools and approaches to delivering projects that improved efficiencies, overcame unusual challenges, promoted effectiveness, and organized stakeholders and project team participants in ways that led to successful outcomes.



Janssen Vaccines AG Location: Bern, Switzerland Project: ZEBOV in 81J

Sustainability

Winners in this category exemplify the application of modern management techniques aimed to improve operating efficiencies, promote excellent quality, consistency and yield competitive cost of goods from existing and new facilities, processes and manufacturing operations.





Ethicon, LLC Location: San Lorenzo, Puerto Rico, USA Project: San Lorenzo Conservation Strategy

Honorable Mention to Local Manufacturer

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Honorable Mention (only winners within ISPE CaSA Chapter listed)

Recognizes projects that do not win a specific category but were clearly successful projects that overcame significant challenges in planning, execution, and delivery. Special recognition is typically given to projects in new technology or in challenging regions of the world.



West Pharmaceutical Services, Inc. Location: Kinston, North Carolina, USA Project: Kinston, NC Ready-to-Sterilize (RS) Expansion

Biopharma companies continue to bring new molecular entities into the market, addressing unmet medical needs for the benefit of patients all over the world. As industry evolves there is the realization that components enabling the delivery of new as well as old molecular entities play a significant role preserving the integrity and efficacy of drugs. Increasingly regulators are paying more attention not only to the properties of the drugs but also to the components that may come into direct contact with them. Components such as vials, stoppers and syringes if not properly manufactured, processed, packaged and shipped have the potential to render pharmaceutical products adulterated or contaminated. There are examples of drug shortages created by components quality issues, impacting patients all over the world. Regulators are requiring Drug manufactures to collaborate with raw material and primary components suppliers in raising the standards by which these important components are manufactured.

West Kinston is a primary component supplier which is raising the bar on how these components are manufactured. While expanding to introduce new RS product capabilities they took upon themselves to upgrade its facilities to align with industry trends as well as to meet drug manufactures and regulators requirements. The facility expansion was designed with transparency and compliance in mind. A new glass wall system makes the process visible to customers eliminating the need for visitors to gown and enter controlled areas minimizing production interruptions and contamination concerns. Visitors can walk across the aisle and observe different unit operations, from rubber extrusion, molding to the Westar process. Phones are strategically located so customer can ask questions in real time

to production staff while manufacturing processes are taking place. Enhanced HVAC and environmental monitoring systems allows West Kinston to tightly control its production environment ensuring quality products for customers. Special care was taken to introduce a clean room design that has become the standard within the west manufacturing network. Lean techniques and principles were used during design to optimize flow, eliminate waste and facilitate quality and compliance.

FOYA is recognizing West Kinston with an honorable mention for their industry leading efforts to align primary components manufacturing process with current industry trends and standards.

Key Participants

- Designer/Architect: Eric Walker, AIA, CCS
- Engineer: DME Alliance Inc.
- Construction Manager/Main/General Contractor: Horst Construction
- Piping Subcontractor/HVAC Subcontractor: Gamewell Mechanical
- Automation and Control Supplier: Siemens Major Equipment Supplier(s)/ Contractor(s): Temtrol, Inc.;

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Advertising Opportunities in ISPE-CaSA 2016 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 to only four, and is offered 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.

You may choose one of the special offers below (pro-rated for partial-year advertising):

- \$1,500 Full-color ad for six issues on the front page of each newsletter (\$250/issue)
- \$1,500 Full-color double-sized ad for six issues (\$250/issue)
- \$ 750 Full-color ad for six issues (\$125/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 2016 ISPE CaSA e-newsletter.

To reserve a placement of your ad for the remainder of 2016 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. **Deadline for 2016 advertisements, starting in the August 2016 issue is August 5th.**

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

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

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A hot-link can be added to your ad, connecting readers directly to your company website for an additional \$500.00 for a whole year.

If you are interested in advertising with the ISPE CaSA e-newsletter, please contact our Chapter headquarters at:

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Would you, or someone you know, like to publish your technical content in these pages?

Please submit any and all technical content to info@ispecasa.org or send directly to our Newsletter Chair at rich.stanfield@cagents.com.

EDITORIAL POLICY

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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 submitted with 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.

A word to the ISPE CaSA Newsletter advertisers:

Thank you all for your continued support. Without it we could not have the wonderful support staff to get our ISPE CaSA Members the news in such a timely and professional fashion. If you have updates to your advertisements or find any other error, please contact us so that we can serve you better.