



President's Message



Lisa Kerner

Happy New Year! Here we are, just two months into 2017 and CaSA is already making a splash!

The Chapter hosted our 2nd Annual Gala at the NC Museum of Art and it was fabulous! With close to 200 attendees, the event offered a fun evening of networking and museum tours, as well as an amazing keynote speaker - Dr. Ted Lithgow, COO, with Humacyte -

who gave a power presentation on Regenerative Medicine. If you missed it this year, don't worry...it'll be back in 2018!

Looking ahead, the Chapter has another year of meaningful events in the works. On March 14th, the Chapter will host its 24th Annual Life Sciences Technology Conference at the Raleigh Convention Center. This is our Chapter's premier event and is definitely one you will not want to miss! With expected attendance of more than 1000 industry professionals and over 200 manufacturing and vendor exhibits, the conference will offer educational seminars and networking throughout the day. Our keynote address will be delivered by Nick Valvano with The Jimmy V Foundation. It's going to be a great day for our industry, I hope you will join us!

New this year...we've added two talk and tour education programs to be held at Catalent and Medicago in RTP on Monday, March 13th - the day before the Technology Conference. Both programs will run from 5-8 pm and space is limited. To register and learn more about the conference and the talk & tours, visit our website.

Looking forward to Spring, the 23rd Annual Golf Tournament will be held on Monday, May 22nd at Prestonwood Country Club in Cary, NC. This event promises to be a fun day filled with golf and networking with friends in the industry. If you are not a "golfer", we have many opportunities to get involved throughout the day. So, please join the fun and register today! We also have many sponsorship opportunities available. To register and learn more about the golf tournament, visit our website.

As you read your way through this edition of our newsletter, you'll find that our Chapter has been very active and is passionate about bringing meaningful (and fun) events to our members. We are very thankful for the support of our membership and sponsors, and I hope that you will continue to join us on our journey to success!

Lisa Kerner

President, ISPE CaSA Chapter

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ISPE-CaSA 24th Annual Life Sciences Technology Conference

Tuesday, March 14, 2017 • Raleigh Convention Center



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Interested in Hosting a Therapeutic Thursday?

Are you interested in hosting a Therapeutic Thursday event in the RTP or Atlanta area? Therapeutic Thursday's give your company great exposure at one of ISPE CaSA Chapter's monthly Therapeutic Thursday events! Don't miss this chance to connect with CaSA Chapter professionals in an informal, comfortable setting. This is an event featuring food and beverages at a restaurant of your choosing that provides networking among ISPE CaSA Chapter members, as well as non-members, to promote the industry and form relationships. You may also select another entertainment venue as long as ample food can be served and there's space to handle 60 people or more. 🏠

Dates Available in 2017

Date	RTP Area	Atlanta Area
27 April 2017		OPEN
25 May 2017		OPEN
29 June 2017		OPEN
27 July 2017		OPEN
31 August 2017		
28 September 2017		
26 October 2017	OPEN	OPEN
30 November 2017	OPEN	OPEN

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Membership Corner

Education

By Rachel Leahy

We have sold out on all Platinum, Gold and Silver memberships, but do have multiple Bronze Partnerships available. Our first two events of the 2017 year are quickly approaching, so now is the time to take advantage of our Partnerships!

Please use the form [here](#), if interested.

We'll see you at the Medicago and Catalent Talk & Tour on March 13th. 

The Education Committee is proud to announce our valued Education Partners for 2017



**Special thanks to our
Partners:**

Platinum



Gold



Silver



Membership Corner

CaSA Member Spotlight: Alan Jones Director of Business Recruitment at Duke Energy

By Newsletter Committee

Several invitations to long serving ISPE members, currently in the ISPE CaSA Chapter were contacted to spotlight their career and ISPE's role in their professional development and support.

We will be including these Spotlights in upcoming issues. If you haven't received a questionnaire, but would like us to include your experiences, please contact newsletter@ispecasa.org!

Q: What is your full name?

A: Alan Jones

Q: Birth Place?

A: Decatur, Alabama

Q: College?

A: East Carolina University

Q: Tell me a little about your personal life.

A: I grew up in Fayetteville, North Carolina as my father was a chemical engineer for Monsanto. He was transferred in 1977 to run a new polyester fiber facility. I moved to Raleigh in late 1995 and still reside here today. I have two kids, 10th and 8th grades, and enjoy watching them play sports. My son is a cross country runner and my daughter plays CASL soccer. My wife and I enjoy playing golf and I recently joined a 3.0 tennis team.

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

A: Director of Business Recruitment at Duke Energy. Our team helps manufacturing companies and consultants during the site selection phase of siting a new manufacturing facility. We identify sites or buildings in our six state service territory (NC, SC, FL, IN, OH/KY) based on site selection criteria by target markets. The team recruits companies in the Automotive, Aerospace, Batteries, Chemicals, Plastics, Data Center, Food & Beverage and Life Sciences sectors. I manage the team and recruit life sciences and food/beverage companies.

We also provide our electrical rates for projects based on electric load and incorporate electrical incentives to make our sites more competitive during the selection process. We also offer managed energy services such as back up generation, which can help reduce the client's initial capital expenditure on new projects.

Our ultimate goal is to bring jobs and capital investment to the communities we serve and help grow electrical revenue for the company!

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

A: May 2017 will be 7 years

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

A: I've been in sales my entire career after graduating East Carolina with a BS, Industrial Technology, and concentration in Sales & Service. I moved to Mobile, Alabama, in 1993 to open a new



Alan Jones

store for Fastenal to sell, nuts, bolts, threaded rods, etc. During that time I met an East Carolina Alum that worked for a construction company, Century Contractors, in Matthews, North Carolina. I interviewed for a business development position, was hired, and we opened office in Mobile, Alabama. We won a large project with Corning in Wilmington, NC and the firm had recently opened an office in Raleigh, NC and I made the move to Raleigh to help grow that office.

The company had work with several pharmaceutical clients in the area and I began to call on them to sell our process piping, mechanical, electrical and general construction building services. I learned to orbital weld pipe on the Mallinckrodt Veterinary facility which is the current home of Xellia pharmaceuticals in North Raleigh.

My career path took me to Biokinetics, Suitt Construction, and CRB, where I spent 15 years in business development aiding customers in the design and construction of FDA regulated manufacturing projects.

I met Emily Felt from Duke Energy at Interphex in New York and we began to network often as she typically dealt with real estate executives and me with manufacturing and engineering personnel. She took a new position with the company and asked if I would be interested in recruiting life sciences companies on behalf of Duke Energy.

The opportunity for career growth at Duke Energy was exciting and the ability to expand my knowledge base in the economic development realm was very enticing. I am fortunate to have worked with so many professionals in the design and construction of life sciences facilities that have helped shape my career development and leadership growth. I continue to work with many of them today in my role at Duke Energy.

Q: What is your favorite part of your job?

A: The diversity of daily tasks and the ability to help a company select a community where their business can thrive and expand. Economic development is a team game and we are only one component of that process, but seeing the announcement of new jobs to a community where you played a role is very rewarding.

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

A: 21 years, 1996, ISPE CaSA Chapter President 2003-2004

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

Membership Corner

A: Too many to count, Leadership Growth, Industry Knowledge, Teamwork, Effective Meeting Management, Organizational Skills,

Time Management....best of all...lifelong friendships.

Q: Why are you still involved with ISPE?

A: With my role at Duke, it is imperative to stay in touch with changes in manufacturing technology, monitor the clinical pipeline of new therapeutics and research companies that may need new manufacturing capacity in the years ahead. ISPE provides many venues for me to fulfill these needs.

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

A: Again too many to count, but will name a few and may leave some out by accident; Steve Jones (my brother), Douglas Armstrong, Wayne Kleven, Todd McLaren, Karl Kelly, Jane Brown, Larry Krinking, Bo Crouse Feuerhelm, Jeff Odum, Ken Ewan, Bob Muldrow, Alan Crawford, Gary Reichelt, Jason Robertson, Ronny Davis, and Stu Heishman (my current boss). Many clients have been instrumental in my development as well!

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

A: Another technical industry sector

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

A: Ability to sing - my daughter will not let me sing a song while she is in the car. I also must turn up the music loud so I don't hear myself sing!

Q: Any hobbies? What are they?

A: Golf, tennis and watching my kids compete in sports

Q: Do you collect anything?

A: No...although my wife would say golf shirts

Q: Finish this sentence – "I need more...."

A: Exercise, see answer below

Q: Favorite Food?

A: French Fries and Fried Chicken


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

A: I am an Eagle Scout

Q: Last movie you saw?

A: Tin Cup

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

A: Get involved, you must own your professional development, don't wait for someone to do it for you. Do things that put you outside your comfort zone. Network, network, network, many times opportunity arises from who you know and not what you know. Always pay it forward and never burn a bridge. 



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Membership Corner

Networking

By Kevin Debbs, Networking Committee

Upcoming Networking Events

- March 30, Therapeutic Thursday - RDU Sponsor: STI Double Barley Brewing, 3175 US-70, Smithfield, NC
- March 30, Therapeutic Thursday - ATLANTA, Sponsor: Harrington Pure, Atlanta – Venue TBD
- April 27, Therapeutic Thursday - GREENVILLE, NC, Sponsor: PCI Greenville, NC – Venue TBD
- April 27, Therapeutic Thursday - ATLANTA, Sponsor: (AVAILABLE) - (ATLANTA)
- Monday, May 22, Golf Tournament, Prestonwood CC

**Thank You To The Sponsors That Have
Already Donated \$1000
To Support This Great, Annual Event!**

Monday, May 22, 2017



Prestonwood Country Club, Cary, NC

Join ISPE-CaSA and your colleagues for the

23rd Annual Golf Tournament

Enjoy a great round of golf and networking opportunities.
We are proud to present this yearly event. Help us make
this the best ISPE-CaSA Golf Tournament ever!

To register, please visit:

www.etches.com/2017-ispe-casa-golf



Breakfast will be sponsored by **NNE Pharmaplan**

- Beverage service for our thirsty competitors will be courtesy of:
Rovisys • Harrington Pure • Total Facility Solutions
- STI Components** will be sponsoring a Party Deck!

Membership Corner

Social Media

By Daniel Santarsiero

The ISPE-CaSA Social Media Committee would like your help improving our social media presence. ISPE-CaSA is always increasing its' activity on LinkedIn, Facebook, and Twitter. With your help we can drive more awareness to the exciting things going on with ISPE-CaSA.

Here are a few simple tips to help us get to the next level:

- **Sign in** to your LinkedIn account
- Go to the search bar at the top of the screen and type "ISPE-CaSA"
- Look for and select "ISPE-CaSA Biotechnology 11-50 employees"


LinkedIn

facebook

twitter

- Hit the "like" and "share" button under the post made on the ISPE-CaSA page.

These steps will help bring traffic to our LinkedIn page, increasing the awareness of the exciting events, technology shows and other valuable information being shared by our organization.

If you have any questions, please feel free to email me at dsantarsiero@sequenceqcs.com. The ISPE-CaSA Social Media Committee will be posting frequently so please be as interactive as you can. 

CaSA COMMITTEES 2017

Education

Rachel Leahy

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Marisol Hydock

Newsletter

Rich Stanfield

Membership Development

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Membership Corner

Technology Conference

By Amy Lineberry, CPIP

The 2017 Technology Conference is just around the corner! The Keynote speaker will be Nick Valvano from the Jimmy V Foundation. The charity for the Conference will also be the Jimmy V Foundation. The V Foundation for Cancer Research was founded by ESPN and legendary basketball coach Jim Valvano with one goal in mind: to achieve victory over cancer. Since its start in 1993, the V Foundation has awarded over \$170 million in cancer research grants nationwide and has grown to become one of the premier supporters of cutting-edge cancer research funds. The raffle and silent auction will be back for 2017.

There are lots of new things happening at the Tech Conference. The ISPE CaSA Chapter is celebrating 25 successful years! There will be a Continental breakfast for the Past Presidents and special recognition during the Keynote Session. We will also be announcing the Student Poster Competition winner and the Jane Brown Scholarship winner. We have added a phone/tablet charging station to make sure everyone can stay connected. With help from the committee, all of the education topics have been selected and there will be a "Women in Pharma" Panel. This panel was a huge success at the Annual Meeting in Atlanta, and should be a great session. Also, back by popular demand is the Casino Night!

As you can tell, the Technology Conference Committee has been hard at work to bring you the best Technology Conference yet! We hope you will be able to attend the Conference and network with us for the day. As always, we will have lots of fun too!!

www.ispe-casa.org/2017 🏠

Young Professionals Update & Call for Volunteers!

By Mariessa Perez

The ISPE-CaSA Young Professionals teamed up with Toys for Tots this holiday season to collect toys for less fortunate children in the local area. We had an outstanding turnout during December's Therapeutic Thursday at Double Barley Brewing. Thank you for everyone's donations, contributions, time and effort. Your support was greatly appreciated 🏠



Newsletter Committee Thanks

By Rich Stanfield, Newsletter Chair

I would like to thank the dedicated team of professionals that provide input to, edit and publish this newsletter each issue!

Input to the newsletter comes from:

1. Each Committee Chair in the CaSA Chapter provides up dates to the membership via the CaSA Newsletter, every other month.
2. Our membership submits technical articles to share with their peers.
3. We solicit feedback from members in our Member Spot light program.

The Newsletter Committee, primarily Addie Anderson,

Bruce Bartlett, Diane Darlington and Kimberley Parker do the lion's share of editing to help me assemble a quality newsletter each and every issue and we get it off to our Graphic Artist, Renée Snell of Snell Design.

Thank you!

Call for volunteers!!

We are a small committee, always looking for volunteers to gather, edit and produce content for the CaSA Chapter Newsletter. I also need a good Co-Chair!

If you are interested in participating in our committee, please send a line to newsletter@ispecasa.org! 🏠

Membership Corner

ISPE CaSA Gala post-event impressions from our Students

By LeAnna Pearson-Marcum – CaSA Chapter Secretary/Chair, National Committee for Young Professionals

"The ISPE Gala was an amazing opportunity for students to talk to professionals and see what type of opportunities exist for us. The speech was entertaining and served as a reminder that the industry is constantly expanding. As always, the food was delicious, the conversation flowed and the networking opportunities were endless. If you did not attend, then you missed out on a great event."

Razeen Shepard

"I truly enjoyed the ISPE Gala. It was a great networking opportunity where many professionals were eager to speak about their role in industry and give advice to students on how to begin a successful career. The excellent food, music, and keynote speaker all came together to create a wonderful evening."

Jasmine Spears

"The ISPE Gala was a wonderful experience. I had the chance to mingle with industry professionals while enjoying an evening of elegance. It was a great networking opportunity to meet people across the industry. The best part was the keynote speaker, who spoke on the power of regenerative medicine."

Caroline Bigelow



Membership Corner



The 24th Annual ISPE Life Sciences Technology Conference Is Officially Upon Us!

We are looking for volunteers to help with all the behind the scene efforts to make this a successful conference. Not only are you going to be a part of something that is bigger than yourself but also the benefits from your participation can impact your professional future.

BENEFITS OF VOLUNTEERING AT THE 2017 TECH SHOW

- Networking with Industry Professionals Nationwide
- Professional Development
- Community Outreach
- Exposure to Potential Job Opportunities
- Demonstrates Initiative for Potential Career Opportunities

We need Volunteers for Monday and Tuesday with various time slot options.

March 13th, Monday Night (5:30pm-8:00pm):

We need four escorts to lead talk and tours at Catalant and Medicago. (This is free, please email me your contact information and any questions you may have)

March 14th, Tuesday:

WE NEED AS MANY VOLUNTEERS AS POSSIBLE. Some of the volunteer options include:

- Registration/Check-In
- Set-up w/ Exhibitors and Breakdown
- Speaker Escorts
- Education Session Moderators

To sign up to be a volunteer click the link below and follow the steps! Once you have completed your volunteer time slot, **YOU WILL BE 100% REIMBURSED YOUR REGISTRATION FEE!**

To Register for this Event: <https://www.eiseverywhere.com/ereg/newreg.php?eventid=192345&>

I look forward to all your participation to make this year's Tech Show an absolute success!

Flexible Design And Nimble Systems Help Prepare For A Biomedical Emergency

By: CRB

A global specialty biopharmaceutical company entered into a public-private contract worth \$220 million with the Biomedical Advance Research and Development Authority (BARDA) in 2012. Its primary goal was to establish a Center for Innovation in Advanced Development and Manufacturing (CIADM) to address challenges encountered in developing biodefense medical countermeasures.

One component of the CIADM's vision was an expansion of the client's facility to provide flexible vaccine manufacturing capabilities. The investment came as part of a private-public partnership with BARDA to establish the client's facility as one of three new CIADMs to develop and manufacture vaccines and medical countermeasures according to its own mission and business objectives on a day-to-day basis.

If a public health crisis arose, each CIADM needed to transition from normal operations to emergency production mode and provide surge manufacturing to address the crisis. The client had to produce at least 50 million doses of pandemic influenza vaccine within four months.

The existing facility was a 32,000-square-foot, three-story structure. Expansion to the facility added 64,000 square feet of manufacturing, administrative, quality and warehouse space.

While the production processes were being developed, the client proceeded with the design and construction of a multi-process manufacturing space. CRB met the demanding criteria of a multi-platform, multi-product and multi-scale manufacturing facility—along with the client's desire to maximize the utilization of capital investments such as equipment, space and utilities— by designing a flexible facility that is easily reconfigurable between campaigns.

To address the various scales and types of processes, equipment pieces were carefully selected and sized to create a broad process envelope. The expression systems were as follows:

- 500-liter microbial
- 2,000-liter monoclonal antibody
- 2,000-liter insect cell/baculovirus
- 2,000-liter mammalian cells/virus propagation

There were numerous production technologies and regulatory considerations:

- NIH BSL-2 containment
- Intra- and extra-cellular product recovery and purification
- Open and closed processing unit operations
- Hybrid process equipment approach of portable process

(continued next page)

stations with fixed stainless-steel equipment and single-use systems

- Process suites configurable for multiple products and scales

The open processing unit operations and BSL-2 containment requirements created an interesting twist to the notion of flexible facility design. Industry trends and CRB's FutureFacility™ concept approach move toward flexible facility design with open ballrooms and minimal segregation based on closed processing. Being flexible with the client's project parameters and ranges meant physical segregation of various operations, air classification, gowning and airlock transitions that allowed the option to run open processes and provide BSL-2 containment. The layout provided five adjacent process suites that provided cell+/cell-, virus+/virus-, and open- or closed-processing segregation.

In addition to the architectural considerations, CRB paid close attention to the design of utility generation and distribution systems. Generation systems were sized to account for large swings in utility usage with turndown capability provided to improve efficiency. The distribution of critical process utilities maximized flexibility by allocating utility drops at areas that could accommodate the various process scenarios. These interchangeable utility stations allowed for plug-and-play operation, allowing the client to move equipment in and out of the space in rapid response to production demands.

The client's desire for flexibility required a layered design approach that accounted for these goals:

- Conceptual design focused on layout development, factoring in equipment move-in paths, multiple equipment arrangements and physical segregation of spaces
- Basic design focused on right-sizing the process and process utility systems to meet varying demands while maximizing operating efficiencies
- Detailed design focused on leveraging distribution of systems throughout the space and ensuring final design accounted for multiple operating scenarios

This careful examination and prepared approach resulted in an adaptable facility built to accommodate the client's developing business needs while also meeting rigorous demands established by BARDA in the event of pandemic declaration, all within established industry costing benchmarks. •

About the Authors



Allan Bream

Allan Bream is a Process Engineer at CRB in our Raleigh, North Carolina office.



Matthew Khair, EIT

Matthew Khair, EIT, is a Process Engineer at CRB in our Philadelphia, Pennsylvania office.



Grace Linton, AIA, LEED AP

Grace Linton, AIA, LEED AP, is an Architect at CRB in our Rockville, Maryland office.



Jack Striebel

Jack Striebel is an Associate/Process Specialist at CRB in our St. Louis, Missouri office.



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**Carolina-South
Atlantic Chapter**

Advertising Opportunities in ISPE CaSA 2017 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 \$1000 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional \$1000 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 for the entire year.

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

SOLD OUT! \$2,000 Full-color ad for six issues **on the front page of each newsletter** (\$333/issue)

- ☐ \$2,000 Full-color double-sized ad for six issues (\$333/issue)
- ☐ \$1,000 Full-color ad for six issues (\$167/issue)
- ☐ \$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 2017 ISPE CaSA e-newsletter.

To reserve a placement of your ad 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 Newsletter Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5" x 2") or double-sized ads (3.5: x 4") 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, JPG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!


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

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 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 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!

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 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.