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President's Message



Lisa Kerner

Greetings ISPE CaSA Members! Things are heating up for the CaSA Chapter, and we have many exciting education and networking events in the works. We started our 25th year by bringing back our Annual Planning Meeting in September. Held at Prestonwood Country Club in Cary, this meeting drew more than 50 attendees. It allowed us to introduce new Board members and provide an update of Chapter

happenings for the coming year. We also recruited many new volunteers to serve on our eight "very" active committees. This is great news for the Chapter! If you missed the event, there's still time to get involved. Visit our website to learn more about each committee and let us know if you'd like to volunteer and help support the growth of CaSA. <http://ispe-casa.org/ispe-casa-committees>

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

Oktoberfest! Back by popular demand, our Networking Committee organized another great event October 13th at Koka Booth Amphitheatre in Cary. We had another record breaking attendance with more than 150 industry professionals enjoying a fun evening while networking with fellow friends in the life sciences industry.

Save the Date!! Mark your calendar for our next Education Event scheduled for Thursday, December 1st in the Research Triangle. We're excited to be hosting a Talk & Tour at Novo Nordisk in Clayton. Details are still being developed, so keep an eye on our weekly eblast and website for more information.

Many more education events are being developed for RTP and ATL beginning early 2017. Updates will be posted on our website and weekly eblasts, so please keep an eye out for upcoming events!

Thanks to an amazing Board of Directors, we are starting the year off with a bang! I am truly honored to serve the Chapter and am thankful to be working with such an amazing group of people. Thanks to all of their hard work and our dedicated committee members, the CaSA Chapter will continue to shine!

To our members and sponsors---thank you for your continued support of the CaSA Chapter. We couldn't do this without you!

Lisa Kerner

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

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SAVE THE DATE!



ISPE | Carolina-South
Atlantic Chapter

ISPE-CaSA 24th Annual Life Sciences Technology Conference

Tuesday, March 14, 2017 • Raleigh Convention Center



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Membership Corner

Networking Committee

By Kevin Debbs, Networking Committee

Upcoming Networking Events

Therapeutic Thursdays

November 17 – sponsored by Hydro Services
The event will be held at the Carolina Ale House
(Brier Creek)
7981 Skyland Ridge Pkwy
Raleigh, NC 27617
www.carolinaalehouse.com/our-restaurants/brier-creek-raleigh-nc/

December 1 – sponsored by NNE Pharmaplan
The event will be held at Lonerider Brewery
8816 Gulf Ct #100
Raleigh, NC 27617
www.loneriderbeer.com/

Save The Date

- Saturday, Jan 28 - Winter Gala at the NC Museum of Art
- Monday, May 22 – Annual Golf Tournament at Prestonwood Country Club

Please contact Kevin Debbs at Kevin.Debbs@crbusa.com or Claudia Carroll at ccarroll@FirstPointResources.com if you are interested in sponsoring a Therapeutic Thursday in the greater RTP or greater Atlanta areas. 🏠



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Membership Corner

Annual Meeting

By Marisol Patino

ISPE-CaSA hosted a delightful dessert reception at the ISPE Annual Meeting this year. There were several dessert offerings along with coffee, hot chocolate, and an open bar. Guests were invited to come mingle with fellow meeting-goers after

a long day of formal networking. Several of the CaSA chapter members were in attendance, along with new and old friends alike from other chapters and affiliates. It was a great way to wind down before action-packed conference activities in the days ahead! Thank you to all those who came out to enjoy the festivities! 🏠



Membership Corner

2016 Annual Meeting Experience

By Tony Le

I had a great time at the Annual Meeting this year. I did not know what to expect going into the event, but the experience far exceeded any reasonable expectations. I was able to speak with people that were from all over the world and learn about the differences between the United States and other countries. The education sessions I attended were very interesting as well, because I got a chance to learn about the newest techniques and state-of-the-art technology in the pharmaceutical industry.

One of the people with whom I made a connection and spoke with a few times was Mr. Pierre Winnepenninckx. Mr. Winnepenninckx works for No Deviation in Singapore and is part of the ISPE Singapore affiliate as the Chair of the Conference Planning Committee. He was very friendly and seemed interested in my career path. Another person I made a connection with, is Darrell Erese from NNE Pharmaplan. NNE is a company that I have been targeting and Mr. Erese was more than willing to speak with me about potential opportunities at NNE.

The event that I enjoyed the most during the Annual Meeting was the party at the Georgia Aquarium. I enjoyed this event the

most, not because of the food or the aquarium exhibits (which were amazing in themselves), but because I had a chance to speak with people I had been networking with in a casual environment. It can be intimidating going up to Directors, CEOs, or anyone in upper management, but at this event, the atmosphere was more relaxed, which made it easier to talk to the professionals.

My advice to future student chapter members is to take advantage of any opportunity to attend the Annual Meeting. Hundreds of people and companies from around the world gather in one spot; go out and talk to them! These people have decades of experience from all over the world, and they are more than willing to share it with you if you ask. Also, do some research beforehand about the companies that will be attending. If you see a company you want to work for, research them, then go and find them at the meeting. Taking that initiative can lead to a potential job. You must be willing to step outside your comfort zone, and when you do, the rewards are more than worth it. 🏠

CaSA COMMITTEES 2016

Education

Rachel Leahy

Student Affairs

Marisol Patiño

Newsletter

Rich Stanfield

Membership Development

Mark Davies

IT/Social Media

Justin Rothwell, PE

Networking

Kevin Debbs, CPIP

Technology Conference

Amy Lineberry, CPIP

Young Professionals

Mariessa Perez



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Membership Corner


\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

By Mark Davies, CaSA Membership Development Chair

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Was \$ 284 Now only \$244 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!

We have a new member on the Membership Committee – Eli Jenkins of Cross 

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

Welcome New Members

New Members who joined June 27, 2016 through October 8, 2016

Aaron James Britt
Michael Zaleski
Rafael A. Garcia
Alex Tam
Katelin Austin
Swara Desai
Amreen Jonas
Braden Stanis
Akano Pinkney
Taha Rahimuddin
Richard Motruk
Michael Click
Elise Arielle Landres
Nour Bizri
Martin Singers
Gretchen Smith
Maxine Green
Bradleigh Anderson
Jeremy Johnson
Patrick Hamel

Swetha Srinivasan
James P. Brown
Sarah Elizabeth Patterson.
Samantha Duerring
Samantha Kijowski
Jose A. Cruz
Midhun Naga Kesav Anne, MS
Shreelekha Jalgama
Shrihari V. Bitragunta
Mike Miller, BSE, MBA
Brooke Johnson
Heath Mallette
Kris Nowicki
Virgil K. Dodson
Troy McLeod
Colleen Duffy, BS
John Bowen
Scott Hinshaw
Glenn F. Odle
Jeff Campaign

Marc LeBrun, BSME
Patrick Rameas
Melinda Covert
Lourdes Veronica Davila Denizard
Matthew Mudalel
Steven Galavotti
Ethan Smith
Jim Bilecky
William Hinton
Andrew G. Quebbemann
Sahil Arora
Dick Habbinga
C McKay
Dr. Eric Jayjock, PhD
Jarred Alan Christofaro, B.S.
Nicholas Lenox
Maria Shaw
Michael Carter
Tish Taylor



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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"

- Hit the "like" and "share" button under the postmade 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. 🏠

Annual Planning Session

by Rich Stanfield

ISPE CaSA Chapter's Annual Planning Session was held 09 September, 2016 at the Prestonwood Country Club.

Although the name may not impart the same meaning to all, the planning session is the Chapter's primary event to permit the new Committee Chairs to discuss their plans with interested Member's and recruit committee members to participate in the execution of these plans.

Over 50 Members were in attendance to hear each Committee Chair provide an overview of their committee, the reasons that they find ISPE participation valuable to them,

and available one-on-one discussions with each committee to hear about opportunities to contribute and lead.

The Session was followed by a networking session with beverages and hors d'oeuvres for more casual conversations and mingling.

If you are interested in volunteering your time and in meeting the membership of the ISPE CaSA Chapter, please drop a note to info@ispecasa.org with a short description of the committee or type of service in which you would like to engage. 🏠

ISPE Global Calendar/Training and Local Events

3-Nov-16	4-Nov-16	Q7A - T30	Tampa
6-Nov-16	9-Nov-16	2016 Pharma Expo	Chicago
7-Nov-16	9-Nov-16	HVAC - T14	Tampa
10-Nov-16	11-Nov-16	Facilities, Systems & Equipment - T48	Tampa
14-Nov-16	15-Nov-16	2016 Facilities of the Future Conference	Bethesda
17-Nov-16	18-Nov-16	Auditing - G07	Tampa
1-Dec-16	1-Dec-16	CASA Chapter Novo Nordisk Talk and Tour	Clayton
1-Dec-16	1-Dec-16	CASA Chapter Therapeutic Thursday	Smithfield
5-Dec-16	7-Dec-16	Basic GAMP® 5 Annex 11/ Part 11 - T45	Tampa
8-Dec-16	9-Dec-16	Oral Solid Dosage Forms - T10	Tampa
15-Dec-16	16-Dec-16	Sterile Facilities - T12	Tampa
23-Jan-17	25-Jan-17	Basic Principles of Computerized Systems Compliance - T45	Tampa
28-Jan-17	28-Jan-17	Carolina-South Atlantic Chapter Winter Gala	Raleigh
30-Jan-17	31-Jan-17	Applying Quality Risk Management (QRM) - T42	Tampa

Membership Corner

Education

by Rachel Leahy

**Join ISPE Carolina-South Atlantic Chapter Education Committee,
In partnership with Novo Nordisk**

**Launching the Largest API Project in the WORLD
December 1, 2016**

Keynote Speaker

Gary Lohr, Deputy Head and Project Director – Site Support

Mr. Lohr has been with Novo Nordisk since 2005 when he joined Novo Nordisk Site Clayton as the Validation Project Leader for the first major expansion project at the site that included Aseptic and Finished Production. Mr. Lohr assumed responsibility for operations of the newly installed FlexPen® manufacturing lines and Finished Production Process as Shift Manager in 2007. Starting in 2010, he became responsible for establishing the FlexTouch® capacity in the US as the Senior Project Manager for PDS290 Phase 3&4. In 2012, Mr. Lohr accepted the role of Director, Production Support.

Mr. Lohr now focuses again on strategic expansions in his role as Project Director-Site Support and Deputy site head for Diabetes API, US project – a position he has held since the expansion was announced in August 2015.

Location

3612 Powhatan Road, Clayton, NC

Guest Parking is in front of flag pole

PLEASE CARPOOL IF POSSIBLE AS PARKING IS LIMITED

Doors open at 3:00pm

Event Start Time: 3:30pm

Event Tours: 4:00, 4:30, 5:00 & 5:30

Networking Reception: 4:00pm to 6:00pm

Tour Highlights

This will be a full tour of the existing manufacturing facility, including aseptic production, assembly and finished product areas. Each tour will be approximately 60 - 75 minutes.

Please wear closed toe shoes and no skirts or shorts

This event is limited to 40 people only, so don't delay! ➡

Watch your inbox for an E-Blast with registration information!

REMINDER: ISPE-CaSA Jane Brown Scholarship Program



The ISPE-CaSA Chapter established a scholarship to encourage students who seek a career in the life sciences industry. The ISPE-CaSA Jane Brown Scholarship will be awarded to an eligible CaSA Student Chapter member. Application information will be announced in the October Newsletter. This award will be announced at CaSA's 2017 Technology Conference event at the Raleigh Convention Center in March. ➡

Membership Corner

YPs at the 2016 ISPE Annual Meeting Recap

by Mariessa Perez

ISPE- CaSA hosted this year's ISPE Annual Meeting in Atlanta, Georgia. On Monday night, the young professionals and student attendees gathered together for a fun-filled night at Game-X in downtown Atlanta. Young professionals and students had the opportunity to network with industry professionals while enjoying a variety of foods, drinks, and arcade games. Young Professionals and students also had a blast at the Tuesday night party at the Georgia Aquarium. Attendees were able to explore the exhibits and enjoy live music, networking, and unique photo opportunities, including a photo opportunity with CEO of ISPE John Bournas! Lots of learning, networking, and fun was accomplished at this year's ISPE annual meeting. We hope to see everyone, new or returning, at next year's meeting in San Diego, California. 🏠



Membership Corner

Education



CALL FOR PARTNERSHIPS
from
ISPE-CaSA Education Committee
2017



In the past, support from our industry partners has been crucial for the success of ISPE-CaSA Chapter's Education Committee events. To assure the future success of our Education activities, having the ongoing support from our industry partners is extremely important. The past education events have provided our local community with a bandwidth of knowledge shared among our peers. To continue the outstanding training provided by this program, the Education Committee is offering an opportunity for you to become a valued partner of the Education Committee for the 2017 programmatic year. Think of this opportunity as not just a one-time "sponsorship," but as an on-going partnership that recognizes your organization as a key component to the education forum for our ISPE-CaSA members, non-members, young professionals, and students.

There are many benefits for becoming a partner. Here are a few to mention:

- **Networking** opportunities
- **Marketing** your company through advertising visibility at Chapter Education Events
- **Influencing** young professionals, peers, and students
- **Community Outreach** to generously support the people and companies of our biotechnology community

Our committee is comprised of volunteers who work tirelessly to orchestrate affordable educational events on topics of direct relevance to the pharmaceutical industry. We have a variety of partnership opportunities and hope that you might consider one of the options below. ➡

Partnership Opportunities

Your commitment includes a total of eight events split between RTP and Atlanta in 2017:

ISPE-CaSA Education Committee Partnerships	Bronze \$500 (10 available)	Silver \$1000 (5 available)	Gold \$1500 (4 available)	Platinum \$2500 (2 available)
Marketing Tier at <u>8</u> Events	Fourth Tier	Third Tier	Second Tier	Top Tier
Marketing Format in Print	Company Name Only	Company Logo	Company Logo	Company Logo + Name
# of Free Registrations per Event	1	2	3	3
# of Exhibitor Opportunities (<i>as space allows</i>) <i>Opportunity may be an exhibitor table or display</i>	0	2	3	3
# of Times to Introduce Guest Speaker	0	1	2	4



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Advertising Opportunities in ISPE-CaSA 2016 Electronic Newsletter

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 December 2016 issue is December 10th.**

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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☐ Full-color, 1 issue (\$200)
☐ Add Hot Link (\$500)

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Chapter Members throughout the Southeastern U.S.

That means you get targeted access to top-notch pharma, biotech, and bio-science professionals and managers. These newsletters are also posted on our website so your ad can be accessed by interested visitors to our site.

Best of all, the cost is only \$750 for your full color, business-card-sized ad for six insertions. That's only \$750 for targeted advertising in full color for an entire year!

Ask About HOT LINKS!!

Would you like to have targeted customers simply click on your ad and get right to your website?

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:

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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rich.stanfield@cagents.com

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

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.