



## President's Message



*Lisa Kerner*

Happy Spring! The cold days of winter have come and gone – and spring has finally sprung! Looking back, we have shared many meaningful events as a Chapter and more fun times are on the horizon.

In case you missed it, the Chapter held our 24th Annual Technology Conference at the Raleigh Convention Center on March 14th. What an amazing day! On behalf of the board, I would like to thank Amy Lineberry, Tech Conference Chair and Jim Hubbard, Tech Conference Co-Chair, as well as the entire committee for working countless hours to make the conference happen. And to our speakers, exhibitors, sponsors and attendees – thank you for joining us and making the event possible. We couldn't do it without you!

The month of May offers more opportunities to get involved. 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 of 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. Check it out – HERE!

May also brings our annual Call for Nominations as we begin preparing for the new CaSA year and selecting new board members. This is your chapter and we hope that you will consider getting involved. Being on the board requires commitment, but it is also very rewarding. So, keep an eye on your emails –

**Call for Nominations** will be coming soon!

With that, I would like to say "Thank you" to all of the current board and committee members for your time and efforts. Your passion and dedication are truly inspiring!

Thank you all for being a part of our Chapter, I hope that you will continue to join us on our journey to success!

*Lisa Kerner*

President, ISPE CaSA Chapter


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**Director at Large**  
Wes Robbins



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# Membership Corner

## Jane Brown Scholarship Winner

By Newsletter Committee

### Amanda Kaufman receives Jane Brown Scholarship

Amanda Kaufman, a student at North Carolina State University majoring in food sciences, has been awarded the ISPE-CaSA Jane Brown Scholarship. Scholarship Chair Andy Ferrell and CaSA President Lisa Kerner presented the scholarship to Kaufman at ISPE-CaSA's 24th Annual Life Sciences Technology Conference in Raleigh on March 14.

An ISPE member, Kaufman has held leadership positions in the ISPE NCSU Student Chapter as well as participating in ISPE plant tours and organizing student events. She is on track to graduate in December 2018 and is passionate about environmental sustainability as a result of "green" packaging initiatives.



From left, Andy Ferrell, Amanda Kaufman, Lisa Kerner

## ISPE-CaSA Poster Contest Winners

By Newsletter Committee

### Caudill and Chen win ISPE-CaSA Poster Contest



From left Morgan Caudill, Marisol Patino and Yen-Cheng Chen

Morgan Caudill and Yen-Cheng Chen were the two winners of ISPE-CaSA's poster contest at ISPE-CaSA's 24th Annual Life Sciences and Technology Conference on March 14. Marisol Patino chaired the competition.

Caudill, who graduated summa cum laude from N.C. State University with a Bachelor of Science degree in bioprocessing science with a focus on engineering, is in a master's program at NCSU, studying nutraceuticals utilizing continuous flow microwave processing. She also serves on the ISPE NCSU Student Chapter board of directors. She took first place in the poster contest.

In second place was Chen, a PhD candidate in chemistry and biochemistry at Georgia Tech, who is studying advancing fluorescent microscopy and applying it to studying immune system and virus entry in Robert M. Dickson's Laboratory.

## Interested in Hosting a Therapeutic Thursday?

Are you interested in hosting a Therapeutic Thursday event in the RTP or Atlanta area? Therapeutic Thursdays 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

# Membership Corner

## 2017 ISPE

### Training Schedule (May/June)

MAY	<b>San Diego, CA</b>
	<ul style="list-style-type: none"> <li>• Bio Manufacturing Facilities, 8 – 9 May*</li> <li>• GAMP® 5 Data Integrity, 8 – 9 May</li> <li>• Water Generation, 8 – 9 May</li> <li>• HVAC, 9 – 11 May</li> <li>• Sterile Facilities, 10 – 11 May</li> <li>• Water Storage, Delivery, and Qualification, 10 – 11 May</li> </ul>
	<b>St Gallen, Switzerland</b>
	<ul style="list-style-type: none"> <li>• Operational Excellence, 8 – 9 May – <i>New!</i></li> </ul>
	<b>NIBRT, Dublin, Ireland</b>
JUNE	<ul style="list-style-type: none"> <li>• Commissioning and Qualification, 16 – 17 May – <i>New!</i></li> </ul>
	<b>Copenhagen, Denmark</b>
	<ul style="list-style-type: none"> <li>• Bio Manufacturing Overview, Dates TBD</li> <li>• Cleaning Validation, Dates TBD</li> <li>• Facility Project Management*, Dates TBD</li> <li>• GAMP Data Integrity, Dates TBD</li> <li>• HVAC, Dates TBD</li> <li>• Oral Solid Dosage, Dates TBD – <i>Updated!</i></li> <li>• Process Validation, Dates TBD</li> <li>• Technology Transfer, Dates TBD</li> </ul>
	<b>ISPE Training Institute, Tampa, FL</b>
	<ul style="list-style-type: none"> <li>• Quality by Design, 1 – 2 June</li> <li>• GAMP® 5 Process Control Systems, 8 – 9 June</li> <li>• Verification of Facilities, Systems, and Equipment Workshop, 12 – 13 June</li> </ul>
	<b>Lilly MQ Learning Center, Indianapolis, IN</b>
	<ul style="list-style-type: none"> <li>• Basic GAMP® 5, Annex II/Part II, 12 – 14 June</li> </ul>

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## Membership Corner

**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.etoouches.com/2017-ispe-casa-golf](http://www.etoouches.com/2017-ispe-casa-golf)




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Make plans to participate in the ISPE-CaSA Golf Tournament May 22. Dereck Whittenburg joins Torry and Terrence Holt on the tournament's celebrity player line-up this year. Whittenburg, a member of the North Carolina State Wolfpack men's basketball team that won the 1983 NCAA national title, is currently the Associate Athletic Director for Community Relations and Student Support at NC State and a friend of

the Holt Brothers Foundation.

Please consider taking a sponsorship to support the golf tournament and the ongoing CaSA Chapter events. If not, please support the event by registering a foursome of players to enjoy a fun day of golf and networking. Above is a link to the registration web site. 

We still have sponsorships available for the Golf Tournament

- Holt Brothers Foundation Sponsorship - \$2,500.00 – 2 Remaining
- Premier Hole in One Sponsorship - \$500.00 – 3 Remaining
- Closest to the Pin Sponsorship - \$350.00 – 1 of 3 Remaining
- Hole Sponsorships - \$250.00 – 5 of 12 Remaining

### We'd Like To Thank Our Top Tier Sponsors



# Membership Corner

## Membership Development Committee

By Mark Davies, Membership Chair

I have added a new ATL based Membership committee member. Gerald Houston is a Team Manager at PCI. I have completed paper work for the nomination of Bud Watts as Co-Chair for the membership committee.

There are still savings of 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](mailto:membership@ispecasa.org).

## Welcome New Members

New Members who joined Feb 20, 2016 through Apr 20, 2017

Ramsha Aleem  
Brandon Ames  
Monica Armstrong  
Elena Arthur  
Greco Benitez  
Nahir Berrios Laguerre  
Jesse Bishop  
Mr. Matt Brawner  
Mr. Matthew Bray, BSEE  
Danny Bukasa-Tshikuma  
Jesse Byrne  
Jesse Gilbert Campbell  
Ms. Melissa Chafin, BSPS  
Ms. Jennifer Culp, MEng  
Rosvely Diaz  
Brandy L. Doscher  
Cedric Eze  
Mr. Emeka Kingsley Ezenwenyi  
Mr. Michael William Farrell  
Ms. Rawan Mazin Fayyad  
Mr. Steven Froelich  
Joseph Fruehbrodt  
Mr. Taylor Fuller  
Katherine Gibbins  
Mr. James T. Gillis  
Ms. Charity S. Grice  
Ms. Jaquasia Shelmia Griffin

Ms. Kathleen Guay  
Dr. Robert Guenard, PhD  
Ricardo A. Gutierrez  
Carlos J. Harper  
Kala Hayes  
Mr. Te-Andre Herbin  
Ms. Latisha Rene Hightower  
Mr. Junius Hipp, Jr.  
Mr. John Hogshead  
Mrs. Janice James  
Jefferey Jones  
Jamario Jarelle Joyner  
Dana Keizer  
Oconnor Joseph Kenneth, BA  
Hamzah Kharabsheh  
Jamil Kirk  
Mr. John Koukoutsis  
Danielle Kuyltjes  
Malika Malhotra  
Mr. Shilo James Matson  
Joseph Michaelchuck  
Ms. Sabina Morgan  
Claudia Nsiah  
Brian Oehler  
Mr. Larry Osborne  
Will Parks  
Nijil Persaud

Victoria Plyler  
Ms. Melissa Porazzo  
Mr. Cody Smith Powell, BS, MS, EI  
Raven Symone Powell  
Mr. Chase Warren ReBarker  
Mr. Reynaldo A. Reyes  
Mr. Robert P. Schiros  
Kathye Segala, BSCET, MBA  
Jiyoung Shin  
Sara R. Silver  
Kayla S. Sutton  
Miss Latifah Syeh  
Olivia Taylor  
Edzer Tessier  
Patrick Tessier  
Alessandra Torres Pineda  
David Tremain  
Andrey Tsybulya  
Alex Nicole Vanhoy, CHE  
Samantha Watson  
McKayla H. Webb  
Samantha Jo Wilkison  
Roland Williams, Jr.  
Melissa Wooten  
Alexzandria Worthy  
Ilse Zainos

## Networking Committee Update

By Kevin Debbs, Networking Committee

### Upcoming Networking Events

RTP Area Sponsor: Harrington PURE	Thursday, May 25	RTP Area Venue - TBD
<b>AVAILABLE</b>	Thursday, May 25	Atlanta Area



# Membership Corner

## Technology Conference News

*By Amy Lineberry, CPIP, Technology Conference Chair*

### Recap of the ISPE CaSA 24th Annual Life Sciences Technology Conference

This year's Technology Conference was another huge success and celebrated the 25-year anniversary of ISPE CaSA at the Raleigh Convention Center in downtown Raleigh, North Carolina. With over 1,000 attendees and almost 200 exhibitors for 2017, the Conference continues to grow each year. Among the exhibitors were 8 manufacturing companies including: Merck, Novo Nordisk, Fujifilm Diosynth, Seqirus, Biogen, BioTechnique, Catalent Pharma Solutions, and Pfizer. These manufacturers were highlighted in the CaSA Pavilion with the Corporate Sponsors.

For the past few years the Chapter has highlighted a local non-profit to raise monies for and bring awareness to the attendees. This year's non-profit was The V Foundation for Cancer Research. The foundation was started in 1993 by Jim Valvano and ESPN and since then has donated over \$170 million to cancer research grants nationwide. Attendees had a chance to donate funds by purchasing raffle tickets and participating in the silent auction. This year, almost \$6,000 will go to The Foundation.

The education for the Conference has evolved into the premier life sciences education event for the Southeast. This year hosted the most education to date with tracks highlighting some of the top industry speakers. Topics included serialization, information management, cleaning, engineering, and project management. The Investigational Products Community of Practice (COP) also hosted a track along with tracks from the new Women in Pharma Initiative and the NC BioProcessing Development Group. Each year the Conference also hosts a track for the students and young professionals to provide them with career development advice and help grow their knowledge of the industry. Thank you to all the speakers at the Conference and for sharing your insights and knowledge throughout the day.

New for 2017 were a breakfast for the Past Presidents as well as recognition for all Past Presidents in attendance during the Keynote Session. Also during the Keynote, the student

Poster Competition winners were announced along with the Jane Brown Scholarship Award winner. The student poster winners for 2017 were Morgan Caudill from NC State University and Yen-Cheng Chen from Georgia Tech. The Jane Brown Scholarship Award winner was Amanda Kaufman from NC State University. The students and Young Professionals also helped by volunteering at the Conference.

The Conference wrapped up with a wonderful Networking Reception in the Ballroom Lobby. The Convention Center provided great food for the reception and it was a great time to catch up with colleagues and co-workers. This year's reception brought back the ever popular Casino Night. Along with the Casino tables was a photo booth and relaxing seating space.

I would like to extend a special thank you to the dedicated volunteers on the Technology Conference committee. Without them this Conference would not be growing and successful each year. Also, thank you to the ISPE CaSA Executive Board and to FirstPoint Management Resources for their guidance and help with the Conference. A final special thank you to all the sponsors - without you this Conference would not happen. Thank you for the support you give to ISPE and our Chapter each year.

The 25th Annual Life Sciences Technology Conference is set for March 13, 2018. You can pre-register for your exhibit space until August 15, 2017. Visit [www.ispe-casa.org](http://www.ispe-casa.org) for more information. You will not want to miss the 2018 Conference. 🏠

## Young Professionals Committee

*By Mariessa Perez*

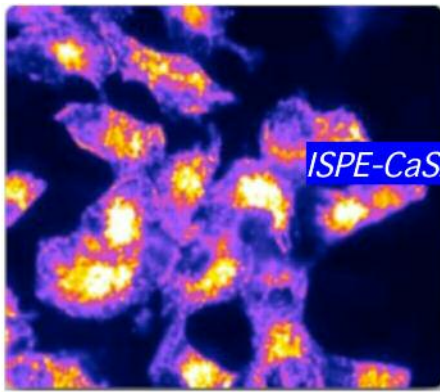
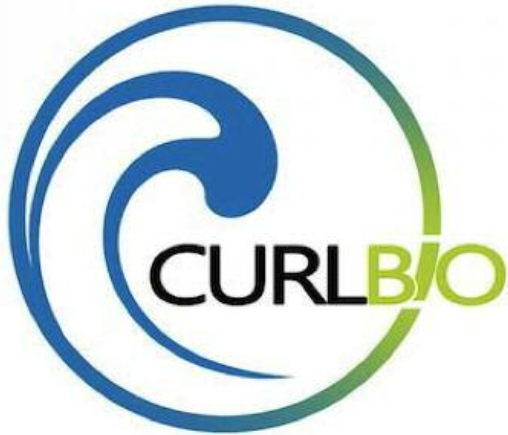
Thank you to all the ISPE-CaSA members who volunteered at this year's Life Sciences and Technology Conference! This event could not have been as successful as it was without your commitment and dedication to our community. Hope to see everyone next year!

ISPE-CaSA invites the Young Professionals and Students to join us at CurlBio for a tour and presentation of life science startup and entrepreneurial activities in Durham, NC on Monday May 8th at 5:30 pm. The event is followed by a networking hour at Alivia's Durham Bistro at 7:30 pm. Light appetizers provided.

Event Link: [Register Here](#)

Interested in volunteering? The YP committee is looking for 8-12 volunteers to help at the Annual ISPE-CaSA Golf Tournament on May 22nd at the Prestonwood Country Club. Various time slots are available from 8:00 through 2:30. Please contact the YP Chair at [perezmariessa@gmail.com](mailto:perezmariessa@gmail.com), if you would like to volunteer or have any questions. 🏠

## Membership Corner



*ISPE-CaSA Young Professionals Committee presents*

# ISPE-CaSA

Join us for an exclusive tour of CURLBIO's Laboratory Facility.

Observe entrepreneurial BioTech startup with our fellow

Young Professionals in the industry!

Join us afterwards at Alivia's Durham Bistro at 7:30pm for a networking hour.

**ISPE-CaSA CURLBIO Tour**

**@ CURLBIO**

**300 North Duke St, Durham, NC 27701 @ 5:30**

**Monday, 08May2017**

**Alivia's Durham Bistro, 900 West Main St., Durham, NC @ 7:30**

**Register Here**

**\$20 ISPE CaSA Students, YP's Ticket includes tour only.**

**Don't miss out!**

Interested in sponsoring?

Don't miss out, you can register for a sponsorship opportunity  
on the registration page!



# Membership Corner

## CaSA Member Spotlight: Larry W. Kranking Owner, Pharmaceutical Integrators, LLC

By Newsletter Committee

Q: What is your full name?

A: Larry W. Kranking

Q: Birth Place?

A: Westfield, New York

Q: College?

A: Fairleigh Dickinson University (FDU)  
- BA/MBA

Q: Tell me a little about your personal life.

A: I lived in rural New York and went into the US Air Force so I could get the GI Bill and attend college. It was the only way I could afford to go to college. While in the USAF, I met my soon to be wife and married after discharge from the military. My daughter came along while I was working full time at Hoffmann LaRoche (tablet press operator and granulator) and attending FDU. I received my BA degree from FDU in five years, and after working for HLA for 11 years, I took a supervisor role at Boehringer Ingelheim. Over 16 years, I rose from supervisor to manager of both packaging and manufacturing, site engineering director, and director of production. During this time, I attended FDU (Saturday classes) and received my MBA in Pharmaceutical Management/Marketing.

I assumed the VP role as the first employee at Eisai Pharmaceutical in Research Triangle Park, North Carolina. I was responsible for the construction of a new facility, hiring the staff, commissioning and qualification, validation of the products and obtaining FDA approval. Filed the CBE30 with the FDA, and the new facility was approved in 28 days - first to file a CBE30 for a new facility with a new product.

I left Eisai in 2004 and attempted to purchase Cytosol in Lenoir, North Carolina. I raised the funds required, but unfortunately the product I needed to pay the overhead went into a global recall before I was able to consummate the deal. I went back into operations as VP of Operations at Monosol RX, an oral thin film technology company, and from there went to Lexington, KY serving on the Board of Directors for Coldstream Laboratories (CLI), a subsidiary of University of Kentucky. CLI was in financial distress, and the BOD requested I take over as CEO and President of CLI. I was in that role for two years and had 50% year-on-year improvements to the bottom line and got CLI to break-even. I then retired and was in that role until Bob Chew, CEO and President of Commissioning Agents (CAI), requested I assist him with starting a consulting arm within CAI.

I did not accomplish the consulting request as CAI had needs in Asia, and I took over as VP of Asia until such time as CAI could find a new VP. After that position was put in place, I took on the role of VP of Operations at Prime Biologic, a new start-up company with new technology in blood fractionation.

In March of 2016, I retired once again and then was asked to



Larry W. Kranking

join Commissioning Agents, Inc. as a member of the Board of Directors.

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

A: I have a small consulting job where I am assisting a new Head of Operations with operational readiness plans and advising on overall strategic plan for obtaining DEA licensure and FDA approval. For the most part, I'm trying to be retired, but if something comes along that I believe will be fun, I will consult. There is a project in Vietnam that I will work on from time-to-time over the next few months to bring a mothballed facility back to life and hopefully get EU certification.

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

A: I have been in the industry since 1969!

Q: What is your favorite part of your job?

A: I love creating a culture where the operation has fun (I measure how I am doing by how many times I hear laughter throughout the day, as lack of laughter is a sign of stress in organization). This culture is based on the fact that it is the team that will generate high quality, if properly trained, and with good procedures (not complicated SOPs), and a management staff that works to remove roadblocks (not be a roadblock) based on the strategy and business plans, plus overall goals of the organization. Having a content workforce is the very first step to an organization being successful. To show results of this culture, my operations' last FD 483 was in 1993. Eisai, during my tenure (1996-2004), did not have any observations. That means the team was the very best at what they did, wonderful accomplishment.

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

A: I joined ISPE in 1983 while I was with Boehringer Ingelheim (BI), who sponsored my membership. During next couple of years I, along with Tim Tyson, founded the New England Chapter of ISPE from which the Boston Chapter spun off. This was at a time when members paid for the activities of chapters in order for ISPE to expand and grow its mission.

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

A: I have built a network of professionals in the industry and, best of all, friendships along the way. I can call and get answers to just about any issue or challenge I or my team encounter in the biopharma world.

Q: Why are you still involved with ISPE?

A: As one of the founding members of the International Leadership Forum (ILF) now Global Pharmaceutical Manufacturing Leadership Forum (GPMLF), I remain interested in

(continued next page)

## Membership Corner

assisting the industry in global initiatives and remaining current. I enjoy mentoring new leaders in the biopharma world and doing all I can to assure patients receive the finest products we can provide. Allowing as many as possible to have a better quality of life is a lifelong quest. This is why I was Chairman of the Alzheimer's Association in North Carolina for many years. We need to give back to society and communities in which we live. ISPE has allowed me to fulfill that quest.

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

A: I have had wonderful mentors along the way; we all need good-to-great mentors. My first mentor was Frank Eaton at HLA who told me after I got my degree from FDU that I needed to leave HLA as I would always be "Larry the Operator" even with a degree. This was great advice. Then I had the pleasure of having Dr. Wulran Polonius, SR VP at BI, who felt I had good leadership abilities and moved me to different positions in the organization: Manufacturing, Packaging, Engineering (I was not an engineer) and then as head of all production.

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

A: I would probably have gone into my father's construction business in western NY.

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

A: I worked in a technical focused industry and had to work hard to learn science and engineering skills and knowledge to assist my team in making the right decisions along the path of the company and teams to ensure all succeeded. I surrounded myself with people I considered to be significantly more technical than myself and encouraged all to "take my job". I look in the industry and am proud of how many of my team members are leaders in our industry.

Q: Any hobbies? What are they?

A: Now that I am "almost" retired, I am enjoying getting back to playing more golf. In the evenings I do a lot of reading. My wife, Lily-Ann, and I enjoy traveling - our neighbors asked us why we have a house since we seldom there.

Q: Do you collect anything?

A: I collect antique pipes. No I do not smoke pipes but was given one a long time ago from my step-father and have continued to grow my collection over the years.

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

A: time... I really do not know how I had any time to work. Life can be fun or frustrating, it all depends on how one wants life to

be. I chose to have fun and laugh as often as I can. At this stage in my life, if it is not fun, I do not need to do it. That in itself is very rewarding.

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

A: I have had many jobs over my life span, from farming, working as garbage man, hanging TV antennas (yes I know I am a senior citizen), carpenter, plumber, factory worker, tree surgeon, pizza baker, etc.

Q: Last movie you saw?

A: Star Wars Rogue One

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

A: Network, network, network. Meet as many people as you can, write little notes on their business cards and properly file the names, keep in touch as much as possible. Also, never stop learning and try to stay one step ahead of what those around you are learning. But most of all - WORK TO MAKE OTHERS SUCCESSFUL, for if you make others successful, you cannot help but be successful yourself. 🏠

# Membership Corner

## Student Affairs Committee

By Oneal Campbell from BRITE

On February 28, 2017, the ISPE CaSA student chapter of North Carolina Central University hosted a panel of Industry representatives for a discussion on "When Success Meets Reality at ISPE." The goal of this meeting was to have the panelists emphasize the importance of being an ISPE member and detail how it contributed to their success in gaining leadership roles and employment in Industry. The panel consisted of three NCCU-BRITE Alum: Marisol Hydock, Natasha Wiley, LeAnna Marcum and the ISPE CaSA YP chair, Marissa Perez. Upon

hearing very useful information from each panelist, the students asked various questions regarding the pharmaceutical industry, networking, employment, and career development. The overall message, that active involvement in ISPE as an undergrad can help lead to a successful transition to the workforce, was well received by the students. In the future, we hope that this interaction will lead to a renewed interest in ISPE and increased participation amongst our students. . 🏠



## CaSA COMMITTEES 2017

### Education

Rachel Leahy

### Newsletter

Rich Stanfield

### IT/Social Media

Dan Santarsiero, PE

### Technology Conference

Amy Lineberry, CPIP

### Student Affairs

Marisol Hydock

### Membership Development

Mark Davies

### Networking

Kevin Debbs, CPIP

### Young Professionals

Mariessa Perez



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# Membership Corner

## ISPE Bio-STEM Career Fair

*By Newsletter Committee*

On Monday, February 27th, the Virginia Tech ISPE Student Chapter hosted their first Bio-Stem Career Fair. With 10 companies and over 150 students in attendance, this proved to be a phenomenal event at the university. This was no small undertaking for the Student Executive Board for the VT Chapter. They reached out to local companies that post on virtual job boards and invited companies from all over the region. 🏠

### Participating Companies

- |                 |                |
|-----------------|----------------|
| 1. Design Group | 6. TechLabs    |
| 2. Novo Nordisk | 7. K2M         |
| 3. GSK          | 8. AstraZeneca |
| 4. CRB          | 9. Genentech   |
| 5. CAI          | 10.iScholars   |





# Industry Leaders Discuss Data Integrity

On March 29, 2017, PCI hosted the Annual Calibration Discussion Group at the RTP Foundation on Davis Dr. This one-day forum brings together professionals in an interactive environment to share common approaches, issues, and solutions related to managing and executing calibration programs in the Life Sciences Industry. This year's event leveraged experiences and vantage points from over 20 operating companies, including those attendees from as far away as Maryland, Illinois, and Colorado.

The theme of the event was Data Integrity, which was facilitated by Subject Matter Experts leading discussions on topics such as:

- Identification of equipment criticality, impact assessments and associated levels of reporting
- Key elements of calibration & maintenance programs such as establishing critical parameters (tolerances, ranges and services frequencies), guard-banding techniques and RISK assessments
- CCMS/CMMS process flows and leveraging pre-existing data, enterprise solutions and paperless applications to drive efficiency and effectiveness

The keynote speakers from Biogen, Tanisha McClendon and Brian Urban, discussed the importance of Data Integrity throughout the manufacturing process, while specifically addressing RISKS and associated containment techniques deployed across their facilities.

The open forum, networking, and presentations resulted in a better understanding of industry trends and common program approaches. PCI would like to thank all those in attendance for their participation, in-turn making this year's event a great success!

### Background

The Calibration Discussion Group (CDG) was established in the early 1990's in response to the lack of training courses offered for instrumentation professionals working in the Pharmaceutical Industry. In 1990, local leaders from companies such as Abbott Labs in Rocky Mt, Glaxo in Zebulon, Miles Laboratories in Clayton, and Burroughs Wellcome in Greenville, collaborated to form a one-day meeting where industry professionals could discuss common problems and learn of innovative solutions. The leadership of the Calibration Discussion Group consists of regional biopharmaceutical calibration professionals who are addressing the same issues and asking the same questions as their constituency. As a direct result, the learning technique applied at a Calibration Discussion Group allows attendees to return to their company with information and tools that can be directly applied at their facilities. In recent years, the attendees have expanded to include professionals from QA, Maintenance, Engineering, and Manufacturing. •



# ISPE®

## Carolina-South Atlantic Chapter

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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.

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