I can’t believe it is already April and we have held our 25th Annual CaSA Technology Conference. We had a record number of attendees with over 1200 registrants, which were not deterred from attending despite the winter mix we had the previous day. A big “thank you” goes out to the Technology Conference Committee Chair, Chris Small, his entire committee, our management firm, FPMR and our entire board for organizing an incredible event. Also, I wanted to thank our sponsors, exhibitors, speakers and attendees for making the conference a day to remember.

Our theme for this month’s newsletter is “Recollections from the Technology Conference.” I remember when the Technology Conference was the Technology Show, and it was held at a hotel in Durham, NC. Then, it moved to the PNC arena where there were more exhibitors, and the number of attendees continued to grow. Next, the Technology Conference was held at the relatively new Raleigh Convention Center. I believe this is where both the number of attendees and vendors started increasing rapidly. That growth has continued with both presentation quality and owner company representation increasing over the years. We have had some great keynote speakers, with one of my favorites being the former CEO of GSK, Bob Ingram. He gave an inspiring talk as to why we are all involved in the pharma/biotech industry – the patients.

We look forward to seeing everyone at our May 3 Women in Pharma event, our June 7 Education Seminar, and our Annual Golf Tournament on May 21 at Prestonwood Country Club. We would also welcome the help of our members to get involved in one of our eight committees. We do hope that everyone enjoyed our 25th Annual Technology Conference and look forward to seeing you at our upcoming events.

Wendy Haines, PhD
President, ISPE CaSA Chapter

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Networking Committee
By Kevin Debbs

Don’t Miss Our 24th Annual Golf Tournament!
The Golf Tournament is scheduled for Monday, May 21 at Prestonwood Country Club in Cary, NC. Registration is open. Please visit the registration site to select a sponsorship or to register players.


Monday, May 21, 2018

Join ISPE-CaSA and your colleagues for the 24th 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.etouches.com/2018-ispe-casa-golf

Inaugural ISPE-CaSA Golf Tournament Coming Soon to Atlanta

- Monday, October 22 at Chateau Elan
- Sponsorship and Player Registration will open in Mid-Summer.

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Thank you to all of our advertisers. This newsletter would not be possible without your support!
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Connecting a World of Pharmaceutical Knowledge
Request for Speakers for the 2018 and 2019 ISPE-CaSA Education Events

The ISPE-CaSA Education Committee is looking for industry experts to speak at our various upcoming educational events. Topics include (but are not limited to) Personalized Medicine, Gene Therapy, Regulatory Strategies, Medical Devices, New Technologies, or other state-of-the-art advances within the pharmaceutical realm. Depending on the event, we will consider various formats and talk lengths, from a 5-10 minute data blitz to a 30 minute keynote.

If interested, please email education@ispecasa.org with the following information:
- Full name, company and title
- Talk topic, or full talk title and talk length
- Abstract (optional)
- Target audience
- Locations where you would be willing to present (e.g., RTP only, RTP + Atlanta, Greenville, etc.)
- Timeframe available

Submissions are accepted on a rolling basis. Thank you for helping contribute to quality educational events for ISPE-CaSA!

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On Tuesday, 3/13/2018 at the 25th Annual Life Sciences Technology Conference, the Student Affairs Committee sponsored two events: ISPE-CaSA Annual Student Poster Competition and the SAC/Young Professionals Resume Workshop.

Competitors representing Campbell, Meredith, NCCU, and Wake Tech participated in the ISPE-CaSA Annual Student Poster Competition. It was very close (less than 10 points decided the winners in both graduate and undergraduate categories!), and the winners are

**Student Affairs Committee**

By Catherine Bays

All competitors will be eligible to present at the 2018 annual meeting being held in Philadelphia, and the winners will have expenses paid.

18 Students/Young Professionals participated in the Resume Workshop held on Tuesday afternoon as part of the Education 101 events. Each participant was assigned 15-20 minutes of one-on-one time with an industry professional to mock interview and/or provide feedback on their resumes. A special “Thank You” goes out to the 13 Industry Professionals who volunteered their time for this event. 🙌
CaSA Member Spotlight: Michael Levitt, Quality Executive Partners

Interview by Newsletter Committee

Q: What is your full name?
A: Michael I. Levitt

Q: Birth Place?
A: New York City

Q: College?
A: University of Buffalo, School of Pharmacy

Q: What is your present position? What do you do at your job?
A: I am currently the Vice President of Strategic Operations for Quality Executive Partners. We are a boutique-consulting firm that provides consulting help to the pharma and biotech industry, especially in developing strategic solutions for improving manufacturing performance and compliance. My responsibilities include managing projects and working with clients to develop solutions and ensure efficient and timely implementation.

Q: Tell me a little about your personal life.
A: I live in a small town in the North Georgia Mountains with my wife, Pam. We live in a log home about 20 miles from the start of the Appalachian Trail. Our closest neighbor is a family of black bears who share a beautiful view looking south to Atlanta from the ridge where our house sits. We have no children, but numerous rescue cats and dogs populate our home. Besides our alma mater, our favorite charities support children’s health and animal rescue. After moving 14 times throughout my career, we are now permanent residents of the North Georgia Mountains.

Q: How long have you been with your current employer?
A: I just completed a year at QxP, but I have been consulting for about 15 years.

Q: Tell me about your career path, and how you ended up where you are today.
A: I began my career with Eli Lilly, and thanks to their commitment for developing people, I had the opportunity to move from sales to a role in toxicology, then human resources, and finally into manufacturing management. I had assignments in the US, Mexico, and Puerto Rico. After 18 years at Lilly, I decided to try my hand with a smaller tech company, and after 5 years in California Biotech, I assumed a role as head of manufacturing for Solvay Pharmaceuticals in the US. After Solvay and 15 geographical moves, my wife and I decided to stay rooted in Georgia, and I began my consulting career.

Q: What is your favorite part of your job?
A: Without a doubt, working with a lot of very smart and dedicated people in our industry.

Q: Finish this sentence – “I need more…”
A: I need more time to read journals and keep up with the literature on changing technologies and regulations.

Q: What is one skill you wish you had that you don’t?
A: The skill to pick up different languages. I have worked in 8 different countries during my career, and I always wished I had the capability to learn at least the rudiments of the language of the country I was visiting.

Q: Wow, 8 different countries? Where? Do you have a favorite adventure (or two) you could share?
A: I have worked in the US, Mexico, Puerto Rico, Germany, India, Switzerland, England, and Italy. Each country presented an adventure but the highlights, maybe more appropriately the low lights, were during my first week in Puerto Rico when the island was hit by Hurricane Hugo and we were without power for several weeks and during my assignment in Mexico, when Mexico City was hit by the biggest earthquake in a century. After those two experiences many of my friends asked that I not transfer to their town!

Q: For those in the early stage of their careers, what advice would you give them?
A: Whatever your degree, take the opportunity whenever it presents itself to learn new skills or become familiar with new technologies. The most valuable asset to any employer is an individual with a broad set of skills that can adapt to our constantly changing business.

Q: Any Mentors/Role Models that have helped to shape your life?
A: Too many to list. My first manager in HR told me that I would work for many people in my career, and I should learn from each one, adopt the good traits of my bosses, and avoid the bad ones. I have lived by that principle my entire career.

Q: How long have you been a member of ISPE? Why are you still involved?
A: I have been a member of ISPE since the mid 1980’s. I joined ISPE when I joined the Lilly manufacturing management team. Unfortunately my schedule and location throughout the years have prevented me from being a more active participant, but the technical resources and the knowledge gained from the journal and guides have been invaluable. It is a terrific organization that brings cohesion and insight into the constantly changing technical issues in our industry; there isn’t a better resource for anyone involved in pharmaceuticals or biotech.

Q: If you weren’t involved in pharma/biotech, what business do you think you’d be in?
A: It’s hard to say, but for sure it would be one that is motivated by helping people.
Membership Corner

Q: Any hobbies? What are they? Do you collect anything?
A: I am exploring options for the day retirement arrives but no specific hobbies right now. I suppose we collect rescue animals since we currently have 5 cats and 3 dogs.

Q: Last movie you saw?
A: Star Wars, The Last Jedi

Q: Favorite Food?
A: Growing up in New York, my favorite to this day is NY Style Pizza.

Young Professionals Committee
By Tony Le

From Student to Young Professional: A New Perspective on Attending ISPE Conferences

This was my third year attending the ISPE Tech conference, but I was excited to attend for the first time as a Young Professional and representative of CAI! This year I did not feel as overwhelmed as I did when I attended in the past. I think this was due to me being more prepared and having more realistic goals in mind.

In the past, I attended as a student and was just concerned with making a good impression and trying to meet as many people as I could. This year I researched the companies that I was not familiar with, picked 3-5, and made it a priority to meet someone from that company. I did not try to meet as many people as I could. Instead, I tried to meet fewer people but have more meaningful interactions. I found this approach much more rewarding because I was actually investing myself in the conversation and my time into one person.

I was also a bit more involved within the conference this time around. I helped facilitate an education session which I had planned on attending in the first place, and I helped judge the student poster competition. I was extremely honored to be asked to judge the student poster competition. I enjoyed learning about the types of research students from different schools are working on today and it almost made me miss being in school...almost.

Tips and Tricks / My advice for students or anyone attending the event for the first time:
• Do a little research about the conference beforehand and have a plan in place. The plan doesn’t have to be set in stone, but from my experience it’s better to have a guide in mind instead of just winging it.
• Research 3-5 companies, then go and find people from those companies and have meaningful conversations. If you go around and try to talk to 10-15 companies you won’t be able to have those conversations that leave a lasting impression.
• There are countless pharmaceutical companies in the area but the community itself is small. While the company you talk to may not have any jobs, that person may know someone else at another company that could use your help!

Q: What is something that people would be surprised to learn about you?
A: That a kid from the Bronx, New York now lives on a mountain ridge in a log home with a family of black bears as his nearest neighbor.

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Technology Conference Committee

By Chris Small

The ISPE Carolina South-Atlantic Chapter Technology Conference occurred on March 13th at the Raleigh Convention Center. The Silver Anniversary event was very successful after a chilly start to the day! Paul McKenzie, PhD kicked off the event with insights into Biogen ongoing innovations! The day was full of networking, education sessions, food, and a little bit of fun as well.

At 3:00 PM, during the conference we held the first Women in Pharma event for the chapter. The networking session was very well attended and set a foundation for future Women in Pharma events within the CaSA chapter. Stay tuned for future events to be announced soon!

We will be announcing the date and location of the 2019 Life Science Technology Conference very soon. We will also be opening Booth/Table registrations as well as Education Session Abstracts in the coming months. We look forward to seeing you again in 2019!

1 Paul McKenzie, PhD, Keynote Speaker, shares Biogen Foundation’s partnership with Student U’s Executive Director, Alexandra Zagbayou.

2 Jane Brown Scholarship Winners with Scholarship Chair Andy Ferrell (center). Natalie Thompson of Bel Air, MD and Colby Hill of Greenville, NC attend East Carolina University.

3 ISPE CaSA’s Contribution to Student U.

4 Making Connections at the Women in Pharma Networking Event.

5 Conference attendees wind down with networking and blackjack.

6 An Awesome Turnout at the Women in Pharma Networking Event.
**Therapeutic Thursdays**

Join colleagues and friends for an evening of networking and enjoyment on Therapeutic Thursday! The mix & mingles run from 5:30 to 7:30 p.m. There’s no need to register in advance. Just walk in the door and start networking. Sponsors will provide appetizers. Cash bar.

**April 26**

**North 30th Sports Pub & Grille**  
11402 N. 30th St,  
Tampa, FL

**Catch of the Day**  
1050 NW 42nd Ave,  
Miami, FL

Many Therapeutic Thursday sponsorship opportunities remain for 2018. Contact networking@ispecasa.org to sponsor an event.

**May 31**

**Winslow’s Deli, Tavern & Market**  
120 W. 5th St, Greenville, NC

**Whiskey Kitchen**  
201 Martin St, Raleigh, NC

**The Field Irish Pub and Eatery**  
3281 Griffin Rd, Dania Beach, FL

**Durham Bulls Baseball Game**

- Save-the-Date: Thursday, August 23
- Registration will open after the Golf Tournament is complete.
300 Followers! Join the movement and be part of the first 1000!

For better LinkedIn communication, ISPE CaSA will begin using the ISPE-CaSA Company page for the posting of exciting upcoming events, industry news, and other relevant information related to the Chapter and Organization. This change does two things for the Chapter:

1) It puts our page in compliance with LinkedIn security policies.
2) It provides more opportunity for our chapter to add additional ISPE-CaSA groups, such as the already added “ISPE-CaSA Women in Pharma Group” to our company page for more member involvement and recognition.

Unfortunately, this switch will cause us to lose a few followers who were solely connected to the older ISPE-CaSA group. Therefore, we are asking all members to make the switch by electing to join and follow our ISPE-CaSA Company page.

Our goal is a 1000 members connected by the end of 2018. Follow this link to join the ISPE-CaSA page for updates! And follow Women in Pharma Group!
21 CFR 11
The Code of Federal Regulations (CFR) Title 21 Part 11, commonly referred to as 21 CFR 11 or Part 11 establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). The regulations require the use of authority checks to ensure that only authorized individuals can access the operation or computer system input or output device, use the system, sign a record electronically, alter a record or perform the operation at hand. The criteria established in the regulation defines the requirements that electronic records and signatures must meet to be considered trustworthy, reliable and equivalent to paper records.

FDA predicate rules based on Part 11 require that pharmaceutical manufacturers have audit, system validation, audit trail, electronic signature and documentation controls in place for all software and systems that process electronic data that the predicate rules require them to maintain.

Electronic Signatures for HVAC Control Systems
In order to meet 21 CFR 11 requirements of an electronic signature feature incorporated into an HVAC control system users gain access to the system via unique sign-on credentials. Using electronic signatures, the system creates an audit trail to track and verify modifications performed on the facility management and monitoring system that may have a direct impact on product quality and/or safety. Additionally, all database audit logs must be secure and incapable of being deleted from the system.

Electronic signatures are made up of a unique username and password for each individual who has access to the system. An electronic signature is required to complete a task that changes systems operational data. Users must record notes about why a change was made in accordance with a change control process. Each user is assigned to security groups that authorizes the level of modifications allowed within the system. Utilizing security groups reduces validation efforts and strictly defines the user access levels from read-only to full administrative privileges within each area of the facility.

Depending on the level of their system authorization level, users can apply their electronic signatures when completing these tasks:
- Acknowledging alarms
- Setpoint and other value modifications
- Modifications made to any object pages
- Modifications made on dashboards and widgets
- Modifications made to the following administrative tasks (which are done as a result of a change control to meet quality compliance requirements): deleting all alarms\(^\star\), restoring configuration backup, loading device databases
  \(^\star\) Deleting alarms does not remove the alarm occurrence record from the audit trail.

When a user does not enter the correct password in the electronic signature window, an incorrect password message should be displayed and the user is not allowed to complete

(continued next page)
the action. User accounts should lock out after a number of consecutive unsuccessful logins. This prevents attackers from infinitely retrying user password combinations and thereby possibly gaining access. These failed attempts should be recorded in the event log.

A site can choose to set up an LDAP (Lightweight Directory Access Protocol) server to authenticate usernames and passwords and enforce organizational password aging policies. When the systems detects a period of user inactivity after the start of a session, the session should time out and the user should be logged out of that session. The user would then need to sign back into the system. This restricts the unauthorized use of a vacated workstation. The system administrator should have the authority to set the time period of inactivity.

Each electronic signature is recorded in the audit trail. Each log entry includes the following items:

- Name of the user who made the change
- The date and time the change occurred
- Value before the change
- Value as a result of the change
- Electronic signature comment recorded by the user

This log and its contents should not be modifiable.

A site that uses an electronic signature feature should make daily manual backups of the database (with MySQL Workbench or similar database management system) a part of the site’s data protection strategy.

In conclusion, a 21 CFR 11 compliant electronic signature feature incorporated into an HVAC control system can eliminate the need to maintain paper documentation, however, adherence to FDA predicate rules regarding electronic signatures must be maintained. Qualification and vetting of HVAC system integrators is critical to the successful implementation of a 21 CFR 11 compliant electronic signature installation. A comprehensive supplier audit of potential vendors to insure that the electronic signature feature is truly 21 CFR 11 compliant is highly recommended.
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 for a whole year.

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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 jason.kelly@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.

Would you like to see your name in the newsletter? Contribute content! We’re looking for the following:

Reviews of ISPE-CaSA Events
Did you meet someone inspiring, find a job, or just have a great time at one of our events? Let us know!

Lessons Learned
Have you learned an interesting lesson at work recently? Write it up and share it! Our members are always interested in improving their skills.

Pharmaceutical Funnies / Biotech Bloopers
Did something entertaining happen at work? Tell us about it! If we laugh, we’ll publish it and give you the credit.

Your contributions help us keep the newsletter fresh. You’ll get full credit, and bragging rights, when we publish them. We love to hear from you, and our members do, too!

Please send your submissions to newsletter@ispecasa.org or directly to our Newsletter Chair, Jason Kelly at jason.kelly@cagents.com.

You will be notified via e-mail or telephone by the 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!

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.
Advertising Opportunities in ISPE CaSA 2018 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.

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☐ $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 2018 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2018 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. Deadline for 2018 advertisements, to start in the February 2018 issue is January 19th, 2018.

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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