

Connecting a World of Pharmaceutical Knowledge

CaSA News



Volume 24 • Number 4 August 2017

President's Message



Wendy Haines

Welcome to another exciting year in the CaSA ISPE Chapter. After our successful board orientation, plans are coming together for education and networking events you won't want to miss. We also want to hear from you, our Members, on how we can best connect people in the pharmaceutical world to meet, network and learn. The entire board would be happy to hear your thoughts and ideas at our Annual Planning Session for Members and

potential Members on August 30 at the PNC Arena. It is free to attend, but please still register on our website and hear about what's in the works for the coming year.

- In addition to networking opportunities at our popular Therapeutic Thursday's (TT) held in North Carolina and Georgia, we will also host TT in Florida this year.
- On October 11, please join us at West Pharmaceutical in Kinston, NC for a tour and education session about this 2016 Facility of the Year (FOYA) Honorable Mention Winner.
- Mark your calendars now for our 25th Annual Technology Conference at the Raleigh Convention Center on March 13, 2018.
- Golf Enthusiast will want to attend our Annual CaSA Golf Tournament at Prestonwood Country Club May, 2018.
- Back by popular demand, we will host a CaSA Durham Bulls Event for members and their families in 2018. Be on the lookout for details regarding this event.

I want to take this time to thank our outgoing Board Members: Amy Lineberry, CPIP; Marisol Hydock; Chip Chappell; Andy Ferrell; and Wes Robbins. I appreciate your time, service and commitment you have given to CaSA and hope to see at CaSA events. I would also like to welcome our new Board Members: Catherine Bays, Jason Kelly, Chris Small, David Davis, David Smith and Mark Yates. I'm looking forward to getting to know you and working with you. Last but not least...I'd like to thank our continuing Board members (see board list below) for their ongoing service to the Chapter.

With our Members, Board of Directors, Sponsors and Volunteers, we will accomplish great things as a Chapter over the coming year! Aristotle once said, "For the things we have to learn before we can do them, we learn by doing them." Thus, I encourage everyone to "Do CaSA ISPE."

Wendy Haines, PhD President, ISPE CaSA Chapter

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INSIDE THIS ISSUE

President's Message1
2017 Board of Directors2
Membership Development Committee3
Young Professionals
2018 Technology Conference5
Social Media5
Therapeutic Thursdays
ISPE Membership Benefits7
Student Affairs Committee8
CaSA Committees8
ISPE Training9
Technology Corner11
2017 Advertising and Sponsorship Opportunities12



2017 - 2018 ISPE INTERNATIONAL **BOARD OF DIRECTORS ELECTION**

Vote by 13 September 2017

You have the opportunity to choose representatives to fill open seats on ISPE's International Board of Directors.



It's an important position! The Board creates the Society's vision, establishes Society policies, and controls Society business.

Look for your electronic ballot via email* in late July.

*Email will be sent by Intelliscan, Inc., our independent outside election partner. Please add @intelliscaninc.net to your "safe sender" list to ensure you receive your official email ballot.





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Board of Directors 2017

Executive Board President Wendy Haines, PhD

Past President Lisa Kerner

Vice President

Mike Putnam

Directors **Director at Large** David A. Davis

Treasurer LeAnna Pearson Marcum **Director at Large** Mark Yates, PhD

Secretary Rich Stanfield **Director at Large David Smith**



Connecting a World of Pharmaceutical Knowledge

Kevin Walter

Membership Development Committee

By Mark Davies, Membership Development Chair

The membership committee is working on a plan to better organize ourselves and spread the responsibilities to the various members to ensure that every committee member is fully involved and has a set task. These changes within the

membership committee will be rolled out at the annual planning meeting at the end of the month.

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

Welcome New Members

New Members who joined Jun 6, 2017 through Aug 6, 2017

Hanan Ahmed Cari Kollman
Mr. Jason Ary Richard Lavallee
Mr. James V. Bailey Cliff Lee, BS

Mr. James V. Bailey

Mr. Zacharie Barrett

Dr. Wade N. Mack, II

Lourdes Bermejo

Grant Meczka

Jason Cohen, BA Mr. Akshay N. Nadkarni, MS

Crystal Coleman Mr. Josh Curt Pinwar
Bria Dawson Girly Ramirez, PhD
Richard Floyd, II Anthony Shriner
Replaced Circles Munera Mach Fina

Juan David Giraldo Munera, Mech. Eng. Robin Sun, MS Jeff Holland Rachel Tabbi

Beverly Vail Jones, MBA

Ben Hund
704.907.0323
ben.hund@crbusa.com
www.crbusa.com

Would you like to see your name in the newsletter? (See page 14 for more details.)





Young Professionals Committee

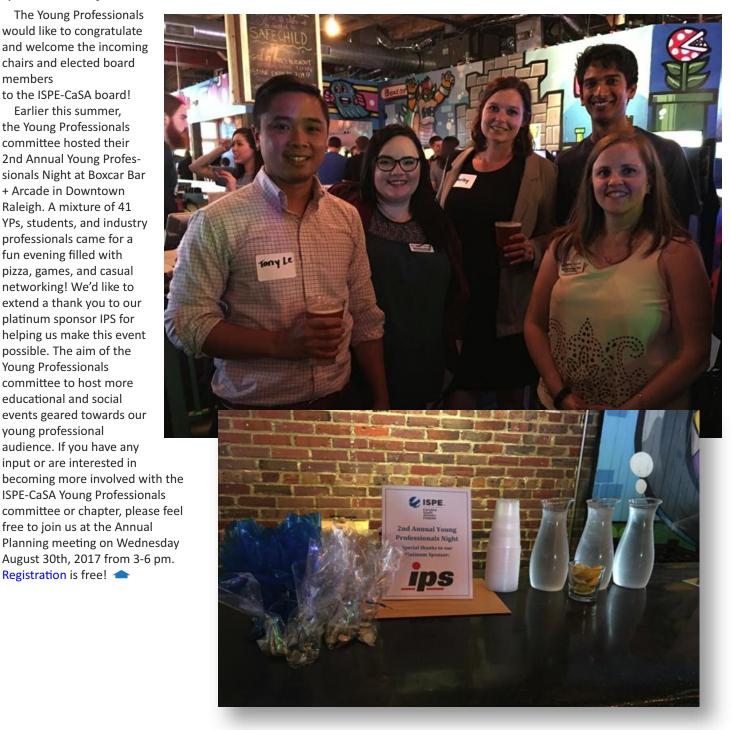
By Mariessa Perez, Young Professionals Chair

The Young Professionals would like to congratulate and welcome the incoming chairs and elected board members

to the ISPE-CaSA board! Earlier this summer, the Young Professionals committee hosted their 2nd Annual Young Professionals Night at Boxcar Bar + Arcade in Downtown Raleigh. A mixture of 41 YPs, students, and industry professionals came for a fun evening filled with pizza, games, and casual networking! We'd like to extend a thank you to our platinum sponsor IPS for helping us make this event possible. The aim of the Young Professionals committee to host more educational and social events geared towards our young professional audience. If you have any input or are interested in becoming more involved with the

free to join us at the Annual

Registration is free!



2018 Technology Conference

By Chris Small , Technology Conference Chair

Next year's ISPE-CaSA Life Sciences and Technology Conference will occur on Tuesday, March 13, 2018. It will be our 25th annual conference, and we want it to be the best one yet!

We are looking for additional Technology Conference committee members. Please contact Chris Small, csmall@clarknexsen.com if you are interested in helping make the 25th Anniversary Technology Conference a memorable one!

The website will be launching soon for those who provided early booth deposits to have first choice of booth selection. We had record response to the early deposits and booths will sell out quickly. Additionally the website will allow others to

purchase tables and sponsorships. Keep an eye out for our weekly eBlast for more updates.

Our website is nearly ready for abstract submissions. Everyone will be able to submit their abstracts and session ideas through the website, which should make things more seamless for everyone. The planning for the Keynote Address, Charity Donation, and Networking Reception are also underway. Stay tuned for additional information and announcements!

We look forward to seeing you March 13th at the Raleigh Convention Center!

Social Media Committee

By Daniel Santarsiero, IT/Social Media Chair

Our Social Media presence is growing! We've gone from 94 followers to 2,378 in the last year (July 2016 to July 2017). There are a number of avenues for our ISPE Members to get valuable information. Check out our page on LinkedIN!







2017 - 2018 ISPE INTERNATIONAL BOARD OF DIRECTORS ELECTION

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Upcoming Networking Events

By Kevin Debbs, Networking Chair

The tables below identify the upcoming Therapeutic Thursday events for the remainder of 2017. Registration is now open to book a Therapeutic Thursday for 2018. Companies interested in sponsoring a Therapeutic Thursday should contact our chapter manager using the information below and complete a

Sponsorship Form with payment to reserve a date for an event. Inquiries and Sponsorship Forms should be submitted to: ISPE-CaSA, 1500 Sunday Dr., Ste 102, Raleigh, NC 27607, Phone: (919) 573-5442, Fax: (919)787-4916, info@ispecasa.org



Date	RTP Area			
	Sponsor	Venue	Location	
31-Aug-17	AlfaNordic	Carolina Ale House, Briar Creek	7981 Skyland Ridge Pkwy, Raleigh, NC 27617	
28-Sep-17	PCI	TBD	Greenville, NC	
26-Oct-17	PCI	TBD	Raleigh, NC	
30-Nov-17	CAI	TBD		

Date	Atlanta Area			
	Sponsor	Venue	Location	
31-Aug-17	CAI	Barleygarden Kitchen & Craft Bar	900 Avalon Blvd., Alpharetta, GA	
28-Sep-17	NNE	TBD		
26-Oct-17	Harrington PURE	TBD		
30-Nov-17	Available			

Date	Florida			
	Sponsor	Venue	Location	
31-Aug-17	Harrington Pure	Blackfinn Ameripub	4840 Big Island Dr.	
			Jacksonville, Fl., 32246	
28-Sep-17	Available			
26-Oct-17	CAI	TBD	Tampa	
30-Nov-17	Available			



Benefits of ISPE Membership to Global Regulators

Global Regulators can join ISPE on a complimentary basis to gain access to the most effective means for engaging industry in discussion about the various ways industry interprets GMPs, regulations, best practices, and ensuring quality systems.





Additional benefits to Regulators for joining ISPE include:

- Complimentary Membership for Regulators (or pay just \$119/€99 for those Regulators who are not permitted by their agency to receive complimentary Membership).
- Valuable resources:
 - ISPE Guidance Documents, Concept Papers and Discussion Papers
 - ISPE Quality Metrics Pilot Program Reports
 - ISPE Drug Shortages Tools and Publications
 - Product Quality Lifecycle Implementation (PQLI®)
 - Cultural Excellence Report
 - Blend and Content Uniformity Tools
- Subscription to ISPE's *Pharmaceutical Engineering* magazine and the opportunity to publish articles as a means for communicating with industry in a neutral environment.
- Access to technical discussions and content within ISPE's technical network Communities of Practice. You may either just observe or actively participate. Like all ISPE members, you would be doing so as an individual and not an official.
- Connect at the local level: dozens of ISPE Affiliates and Chapters around the world offer programs in the local language and provide opportunities that will keep you abreast of the latest happenings in the industry on a regional level.
- Ability to receive training customized for the specific needs of Regulators.
- Become better known and build rapport with professionals responsible for GMPs, risk management, quality systems, and more.

For more information www.ISPE.org/Member-Benefits To join, contact ISPE at ask@ISPE.org or +1-813-960-2105

Student Affairs Committee

By Catherine Bays, Student Affairs Chair

It is a NEW START as the SAC bids farewell to the previous chair, Marisol Hydock, and welcomes its new Chair, Catherine Bays.

Catherine has been a member of ISPE since her student days in 2007, and she was one of the first members of the NCCU Chapter. She has been a member of the CaSA SAC for the past couple of years and served as a Co-chair for the NCCU-ISPE Chapter Community Outreach Committee as a student. She been working with Mangan Biopharm as a Validation Specialist since March 2015, and spent five years with Merck as an Operations Technician prior to this.

As students begin to return to classes over the next few

weeks, the SAC is looking forward to another successful year beginning with a shared networking event with the YP Committee around 11 September 2017. Details are still being planned.

The SAC is also anticipating welcoming a new Georgia Tech Student Chapter in 2017, pending completion and approval of the application process.

Finally, one or two additional events will be planned for the SAC and sponsors will be sought. These requests will be posted in the eFlashes once the SAC has a chance to meet and plan.

CaSA COMMITTEES 2017

Education Rachel Leahy

Student Affairs Catherine Bays

Young Professionals Mariessa Perez

Newsletter

M. Jason Kelly, Ph.D.

Membership Development

Mark Davies

3

Technology Conference Chris Small, PE

IT/Social Media
Dan Santarsiero, PE

Networking Kevin Debbs, CPIP



Pharmaceutical Knowledge



2017-2018 ISPE-CaSA Board Orientation Board members present were (left to right) Front Row: David Smith, Lisa Kerner, LeAnna Pearson Marcum, Dan Santarsiero, Wendy Haines, Rachel Leahy, Claudia Carroll (Chapter Manager), and Mariessa Perez; Back Row: Catherine Bays, Chris Small, Rich Stanfield, Mike Putnam, David Davis, Mark Davies, Jason Kelly, and Mark Yates. Missing: Kevin Debbs





Learn from Subject Matter Experts and Top Pharmaceutical Industry Leaders with ISPE Training



Instructor Spotlight:

Stephanie Wilkins, PE, Lean Six Sigma Green Belt, is an ISPE trainer for Managing Cross Contamination and Risk-MaPP Principles. She has over 30 years of professional experience in project management, risk management, engineering, and validation solutions. A member of ISPE since 1993, she is the Co-Chair of the ISPE Risk-MaPP Baseline® Guide Task Team and was a member of the ISPE International Board of Directors. Currently she is the President of PharmaConsult US.

Learn firsthand from Stephanie Wilkins by registering for the updated <u>Managing Cross Contamination with Risk-MaPP</u> training course, 6 – 7 November in Tampa, Florida.

The <u>ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products</u>
(Second Edition) is now available in book or PDF format.

September 2017 Tampa, FL USA

- Commissioning and Qualification
 7 – 8 September
- GAMP®** Data Integrity 21
 CFR Part 11
 11 13 September
- Quality Risk Management
 18 20 September
- Process Validation
 25 27 September

October 2017 Tampa, FL USA

- Overview Biotechnology Mfg. Processes
 2 – 3 October
- Pharmaceutical Technology Transfer
 5 – 6 October
- GAMP®** 5 GxP Compliance 12 – 13 October

November 2017 Tampa, FL USA

- Process Validation
 Biotechnology Manufacturing
 1 2 November
- Basic GAMP®** 5, Annex 11/ Part 11 1 – 3 November
- Managing Cross
 Contamination with Risk
 MaPP
 6 7 November
- CIP System Design, Integration and CIP Chemicals
 13 – 14 November
- ICH Q7A GMPs for Active Pharmaceutical Ingredients 16 – 17 November



September 2017

Amsterdam, Netherlands

- Cleaning Validation Principles
 25 – 26 September
- Biotechnology Mfg.
 Facility Design
 25 26 September
- Basic GAMP®** 5,
 Annex 11/ Part 11
 25 27 September
- GMP Sterile Pharmaceutical Manufacturing Facility
 27 – 28 September
- GAMP®** 5 GxP Compliance 27 – 28 September
- Commissioning and Qualification
 27 – 28 September

October 2017

Boston, MA USA

- Pharma Water Generation USP WFI and PW
 23 – 24 October
- Cleaning Validation Principles
 23 – 24 October
- Biotechnology Mfg.
 Facility Design
 23 24 October
- HVAC CGMP Regulations
 23 24 October
- Storage/Qualification of Pharma Water
 25 – 26 October
- Pharmaceutical Facilities
 Management*
 25 26 October

November 2017

Manchester, United Kingdom

- GAMP®** Data Integrity 21 CFR Part 11 13 – 15 November
- Pharmaceutical Transfer Technology
 20 – 21 November

Manchester, United Kingdom

Pharmaceutical Water
 Systems
 23 – 24 October

Share with a Colleague!

Unable to attend? Share this email with a fellow colleague who may be interested in a training course. In return, they can share all that they learned with you.

Don't forget—ISPE also offers <u>online learning</u> and <u>onsite training</u> opportunities. View our global calendar for a complete list of 2017 training courses.



*ISPE has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI®)





**GAMP® is a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry and is a registered trademark of ISPE.

Technology Corner

Personalized Medicine Diagnostics Will Lead the Way!

By Christa Myers

We have been talking about Personalized Medicine for years. "Wouldn't it be better if the medicine that I was taking was designed just for me?" We all know that personalized medicine would greatly benefit individual patients.

So how will we get there?

- 1. Medical doctors will have to go back to treat patients as individuals. General practitioners have become commodities and have become institutionalized. It takes YEARS to find a practitioner that treats each patient as an individual and not like a case study in some dusty book on a shelf somewhere.
- 2. Diagnostics will lead the way. The diagnostics side of the industry will be on the leading edge of making personalized medicine happen. There will have to be advanced diagnostics tests that can be used to finely hone in on sensitivities, allergies, reactions to drugs and the like. We can do part of this now, but it will become more specific as we approach a true individualized approach to medicine.
- 3. Dosage forms will change. In order to personalize medicine, the patient will be the focus. The dosage forms will have to be easy to use and stable at room temperature. Earlier this year at the Interphex show, my colleague and I did a presentation on "disruptive technologies" and discussed many of the new dosage forms being developed; i.e. micro needle intradermal patches, medicines that dose according to your wearable devices, orally dissolving films and forms, etc. They are all aimed at making the patient's lives better and easier and hopefully for less money. This will be key for getting a personalized medicine approach to the patient. Who wants to think so hard about taking a dosage at a certain time a day? Our seniors have to deal with this now and can tell you very specifically how difficult and annoying it is to have to set alarms to remember to take different medicines. Call your grandmom. Ask her. Go ahead - you probably need to call her anyway.
- 4. The pharmacists' jobs will change. If this goes the way the industry is hoping, the pharmacies that we go to may go through a drastic change. What if an automated compounding and tableting machine can be made for the most common medicines and one tablet per day per patient can be made specifically for that patient? That is the hope. What if we can set differing dosage release times? There is technology coming out with that in mind.
- 5. The wearable market is changing. All of that data that your fitness tracker can document is useful. The next generation of

wearables are getting more sophisticated – some can detect blood sugar levels, others can detect electrical signature changes in the body. One of the ones that we have looked at lately can actually dose up to seven compounds at different times during the day. It looks like a large bandage. All of this technology can be put to use to provide the patient (or medical staff) with by-the-minute feedback.

6. The equipment in the manufacturing facility will change. Personalized medicine will change the formulations of many medicines to be bio-available specifically for a given person.

So instead of machines that will make large batches of a few formulations per year, the machines will need to be able to make small batches of many formulations per year. The cleaning steps between the batches will become more important.

The industry is on its way. Research and development within pharmaceutical companies and within educational institutions are rich with ideas and programs to get closer to the best medications for each of us. It will not happen immediately, the way the politicians want. Neither will it be costless. It is a delicate process, but it is good to see progress.



Christa Myers is a Process Chemical Engineer with 20+ years of experience providing clients with insight as to how codes, past and current regulations and innovative technologies apply to their process and facility designs. With an extensive background in the design of fill finish facilities, chemical kilo labs, pilot plants, API research and manufacturing facilities, bulk pharmaceutical chemical facilities, highly hazardous compound containment, and biotech process facilities, Christa's broad range of expertise benefits her clients in the design of their facilities. Her operating experience with a

leading biotechnology and pharmaceutical company as a Process Engineer in the fermentation and purification suites, as well as pilot scale fill-finish suites, provides her with insight to the reality of daily operations. Christa knows the difference between designing for the large pharmaceutical firms, the contract manufacturing organizations, and the generic companies. The business drivers that lead to decisions on capital budgets are different for each type of company. She is recognized in the relief device design community for her papers and presentations regarding the complexities of applying general relief device design to the highly specialized pharmaceutical industry. Myers has been a frequent presenter at many industry events such as the DIERS Users Group, ISPE Containment Conference and Interphex. She is an Owner Associate / Sr. Pharmaceutical Engineering Specialist at CRB. For more information, please visit http://www.crbusa.com/christa-myers.



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):

□ \$500 Adding a hot link for directing customers to your website by a simple click

SOLD OUT! \$2,000 Full-color ad for six issues on the front page of each newsletter (\$33	3/issue)
□ \$2,000 Full-color double-sized ad for six issues (\$333/issue)	
□ \$1,000 Full-color ad for six issues (\$167/issue)	

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!



2017 Newsletter Advertisement Order Form

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ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for Your Business!



Our Chapter produces six e-newsletters per year, and we depend on the support of our advertisers. We send out the newsletters via e-mail and via web link to all of our 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 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

1500 Sunday Drive, Suite 102, Raleigh, NC 27607 Tel: 1-919/573-5442 • Fax: 1-919/787-4916 jason.kelly@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 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.

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.