

Carolina-South Atlantic Chapter

CaSA News



Volume 22 • Number 5 October 2015

President's Message



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 kicked things off with a combined Education and Young Professionals event in Atlanta on October 22nd at Brio Tuscan Grille – Perimeter Circle. The education started at 3:30 pm followed by Therapeutic Thursday networking from

6-8 pm. We had some great speakers lined up and attendance was free to our members.

Keynote Speaker:

 Praveen Tyle, PhD--President & Chief Executive Officer at Osmotica Pharmaceutical "Lessons Learned from Global Recall of ReNu MoistureLoc Contact Lens Cleaning Solution"

Education Tracks:

- Janet McComas--Consultant with Azzur Consulting "Establishing a Soil Library and Determination of Worst-Case Soil for Cycle Development of Cleaning Equipment"
- Chad Patterson--Consultant, PCI
 Tony Atti, PhD--Co-Founder, President & CEO, Phononic
 "Best Practices and New Technology in Temperature-Controlled Units"

YP Tracks:

- Ted Powell--Vice President at Control Southern, Inc. "Hardcore Soft Skills"
- Melinda Parrish Brumfield--Director of Business Development at JE Dunn

"Networking – Throwback Thursday Style"

Oktoberfest! You will not want to miss this combined fall networking event and committee recruiting session--Thursday, October 29th at Koka Booth Amphitheatre in Cary from 5 pm - 8 pm. We will experience the taste of Oktoberfest through a maze of food stations paired with complimentary wine and local

(continued next page)

Social Media

By Justin Rothwell, IT/Social Media

Please follow ISPE-CaSA's new LinkedIn page at www.linkedin.com/company/ispe-casa to stay up to date with latest news and upcoming events!



Featured Sponsors



FDA Compliance Automation & Reliability Solutions Operational Excellence

PSG@controlsouthern.com www.controlsouthern.com

4242 Switchbox Position Indicator

- Class 1 Div 2 Groups C & D
- High visibility
- Mechanical Override
- 24 VDC, AS-I, DeviceNet

www.gemu.com







(continued from first page)

craft beer selections sponsored by Draft Line Brewing. Committee Chairs and volunteers will also be on hand to provide an update of what they're working on for the upcoming year. We'll also have live music by the EG Peters Band. If you would like to get engaged, Oktoberfest is the place to be!

Save the Date!! Mark your calendar for our next Education Event and Toys for Tots drive scheduled for Thursday, December 3rd in the Research Triangle. More information to follow as plans continue to develop!

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 people. Due to our dedicated committee members and the Board's hard work, the ISPE-CaSA Chapter will continue to shine!

To our members and sponsors—thank you for your continued support of the ISPE-CaSA Chapter. I look forward to seeing you at

our upcoming events!

Vice President Bruce Craven, Mangan Biopharm Treasurer Wendy Haines, Mangan Biopharm

Secretary Mike Putnam, Sequence
Past President Heather Denny, McDonald York

Director at Large Wes Robbins, Hydro Service & Supplies, Inc.

Director at Large Andy Ferrell, PCI

Director at Large Chip Chappell, Consultant

Education Jim Hubbard, AM Technical Solutions

Networking Eric Mayer, Avid Solutions Young Professionals Jamie Sigmon, Biogen

Technology Conference Amy Lineberry, Mangan Biopharm

Membership Development Terence Morrison, Acropolis Controls Engineers Newsletter Rich Stanfield, Commissioning Agents, Inc.
Student Affairs Marisol Patino, Fujifilm Diosynth Biotechnologies IT/Social Media Justin Rothwell, Red Wolf Associates

It's going to be a great year! With the support of our membership, board of directors, volunteers and sponsors, it is my hope to recharge our events and continue to grow the CaSA Chapter. Please join us! Together we will do great things!

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

INSIDE THIS ISSUE

President's Message	1
Education Committee	3
2015-2016 Board of Directors	3
Networking	4
Upcoming Events	4
Welcome New CaSA Members	5
CaSA Committees	5
Student Affairs	6
Technology Conference	6
Social Media	
Technology Corner	8
2015 Advertising and Sponsorship Opportunities	
Electronic Media	









Membership Corner

Education Committee

By Jim Hubbard, Education Committee

First and foremost, a big thank you to the Education Committee team. They have all worked very hard as a volunteer team to make these events come to life.

The Education Committee has been extremely busy planning this years' events, adding members, building the budget for next year, and looking at new markets to enter within our ISPE-CaSA territory in program year 2016-17. I would venture to say that this is probably the most exciting year for ISPE-CaSA's members and especially, from an educational standpoint. Here's a look at what we've been planning together over the past cou-ple months.

Remember: All Education events are Free to currently paid ISPE members (excluding the Tech Conference) October 23, 2015 2016 - Tech Conference "Call for Papers" deadline

October 29, 2015 - Oktoberfest Education Booth...come by and say hello to our team.

December 3, 2015 - Raleigh Education event, networking, and Toys for Tots

January 11, 2016 - Education Committee's "Call for Partners" – most spots were filled in 72 hours this year March 31, 2016 - Education sessions at the 2016 Tech Conference - Raleigh

April 13, 2016 - Education/Networking event in Atlanta April 14, 2016 - Education/Networking event in Raleigh June 23, 2016 - Education/Networking event in Tampa, FL

How can you participate in growing Education in our industry?

- ~ Attend an event!
- ~ Submit an abstract for the Tech Conference
- ~ Become an Education partner, there are many benefits for your company
- ~ Volunteer as a member of the committee ~ We always need SME's to speak at events ~ Offer suggestions for ideas or improvements

Please call me to discuss how you can get involved in your local ISPE-CaSA Chapter. Jim Hubbard, Education Chair, 240-344-1109.

Directors 2015-2016



Carolina-South **Atlantic Chapter**

Officers Lisa Kerner, President Bruce Craven, Vice President Wendy Haines, Treasurer Mike Putnam, Secretary Heather Denny, Past President

Committee Chairs Marisol Patino. Student Affairs

Jim Hubbard, Education Justin Rothwell, IT/Social Media Eric Mayer, Networking Terence Morrison, Membership Development Jamie Sigmon, Young Professionals Amy Lineberry, Technology Conference Rich Stanfield, Newsletter

Directors Andy Ferrell Chip Chappell Wes Robbins



- Validation
- Commissioning

- + Quality Programs
- + Remediation
- + Laboratory & IT Compliance
- + Automation Engineering + Supply Chain Quality
 - + Remote Monitoring
- + Software Management
- + Process Optimization

www.sequenceqcs.com | info@sequenceqcs.com | 855.844.7171 2500 Gateway Centre Blvd., Suite 850 Morrisville, NC 27560



Leadership. Compliance. Reliability.

Calibration and maintenance services from startup to operations to shutdown.

- Process systems
 Laboratory systems
- Building utilities
 Full asset management

Membership Corner

Networking Committee

By Eric V. Mayer, Networking Committee

Join us for Oktoberfest 2016! On Thursday, October 29th, ISPE-CaSA will be throwing our second annual Oktoberfest event at the Koko Booth Amphitheatre in Cary. The event was a huge success last year and promises to be a great one this year as well.

This event is designed to introduce everyone to all the committees that make up the ISPE-CaSA Team and give you an understanding of what each does for the chapter. Come and meet the Chair Person and Committee Members of all our teams. Hopefully you will find a committee that interests you and fits your talents to continue in the growth and vitality of ISPE-CaSA.

That aside, there will be a fantastic band, EG Peters, as well as plenty of seasonal

food and complimentary draft beer and

wine. Come join in the fun thanks to our growing list of sponsors including: CRB, Watson-Marlow, Commissioning Agents, Inc., Hipp Engineering, and Avid Solutions.

See below upcoming networking events.



Date	Event	Sponsored By
Oct. 22	Atlanta Technical Learning and TT	Control Southern
Nov. 19	Raleigh Therapeutic Thursday	NNE Pharmaplan
Nov. 19	Atlanta & Tampa Therapeutic Thursday	CAI
Jan. 28	Therapeutic Thursday in Atlanta & Raleigh	TBD

UPCOMING EVENTS

October 29, 2015 - Oktoberfest, RDU area

December 3, 2015 - Education Event in RDU area with a charity event

March 30-31, 2016 - 23rd Annual Life Sciences Technology Conference, Raleigh Convention Center

April 14, 2016 - Education Event, RDU area

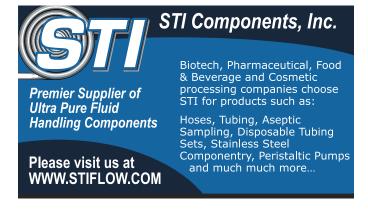
May 16, 2016 - Golf Tournament



Comprehensive Compliance Solutions

· Validation · Quality Assurance

Visit propharmagroup.com or contact us at 888.242.0559



Membership Corner \$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

By Terence Morrison, P.E., CAP, LEED AP BD+C, ISA 84 SFS

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Applications can be made online at www.ispe.org/join, click on Join Now under Industry Membership, and enter CASA2015 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 www.ispe.org/membership-referral-program Help the CaSA chapter win the 2015 Challenge!

Between June 1 and October 15 2015 the challenge is on to

recruit and retain the most Members, the most new Young Professionals and the most Annual Meeting attendees.

For each new member you recruit, you'll earn on free month of membership credits will be applied to your next membership renewal.

See website for additional chapter prizes:

http://ispe.org/challenge2015

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 August 5, 2015 through October 9, 2015

Abdullah Althaiban, Jr.

Alan Alewine

Aldon Smith Alex Miller

Ashley Kaleen Grubbs

Bill Post

Bridget Bozel

Cynthia H. Tang Damaris Martinez

Darren Canfield, A.A.S.

Dayling Chaparro

Dr. Dana Schneider

Dr. Nicole Deschamps

Dr. Robert Chad Waters, PhD,

BSChE

Ed Schall

Erika Smith

Ginny Thao

Greg Hottell

James Adam Parker

James C. Parks

James Root

Jamie Sinclair Blakeney

Jason Burkhart, BSMET, AAS, AS

Jazmyne Stokes

Jesse Gordy

Jessica Danielle Browning

Jim Fulp

Johann A. Vaz

John Karels

Jordan Yates

Joslyn Sargent

Julian C. Goins

Justin William Liles

Katlyn Mabry Nichols

Kearsten Furtick

Kent Brown

Kurt Nelson

Leah King, AIA, LEED AP BD+C

Leallyn T. Murtagh

Lisa Jones

Industry US\$269/£219

Join Now

Mari Elena Mast Mark A. Ervin Matthew M. Greer

Luke P. Dickinson

Michael Savin

Michael T. Jordan

Miss Margaret Marie Reiff, BS BME

Morgan Malick Olajumoke Akinjide

Rachel Caroline Williford

Robert Paschka

Santos Viscasillas, B.S., M.S.

Scott Cady

Scott Frazee, MS

Shaun Stroud, BSIE, MBA

Thomas Parker

Thomas Rardin

Travis Smith Tuona Lv

William Ross Groome

CaSA COMMITTEES 2015-2016

Student Affairs

Marisol Patino

Education

Jim Hubbard

Networking

Eric Mayer

Membership Development

Terence Morrison

Young Professionals

Jamie Sigmon

IT/Social Media
Justin Rothwell

Technology Conference

Amy Lineberry

Newsletter

Rich Stanfield

Membership Corner

Student Affairs

By Marisol Patiño, Student Affairs Committee

Students are back in full swing with the start of the fall semester. Meredith College is a fledgling student chapter but thanks to their highly motivated academic advisor and student chapter president, they already have several events and speakers lined up. Their first meeting of the year featured Heidi Colton, Associate Director of Toxicology at Chimerix. She delivered an informative presentation about the various roles within clinical research and toxicology. NC State hosted a joint event with their ISPE-CaSA and PDA-SE student members titled, "Meet the

Meredith College
Virginia Tech University
Need Academic Advisors
Interested In Volunteering?
Email
ispecasasac@gmail.com

Mangan, Catalent, and Biogen. NC Central University hosted Laurin Mancour, CCRA at their first meeting to provide students an overview of the clinical research business. Additionally, 12 students amongst all of our student chapters have been selected to attend the annual meeting in Philadelphia. This is a great opportunity for them and they are very excited!

It is undeniable that many students rely on guidance from industry professionals to develop themselves professionally as they progress

in their studies and seek careers. NC Central University, Meredith College, and Virginia Tech University are in need of academic advisors. Please email ispecasasac@gmail.com if you are interested in volunteering.

Technology Conference 2016 Is Right Around the Corner

By Amy Lineberry, CPIP, Technology Conference Chair

Planning has begun for the 2016 Technology Conference to be held on March 31, 2016 at the Raleigh Convention Center. The Committee is working to plan the best Conference yet. The call for papers has generated lots of topics for the education sessions and the Keynote Speaker will return. The Committee is excited about the Conference and we hope that all the attendees and exhibitors will be as well. We have hired Freeman to help with exhibitor setup, logistics and a new, improved layout is sure to impress. We will return to the CASA pavilion and lunch will be held in the exhibit hall as well to help maximize the attendees' time with the exhibitors. The product demos will take on a new feel and we are planning to showcase new and innovative technology. Over 50 exhibitors are pre-registered for the 2016 Conference. We would like to thank every company that signed up early for your continued

Professionals". Students had an opportunity to hear about

questions. Campbell University will also be hosting a panel

various roles within the pharmaceutical industry and ask

next week of young, professional women representing

support of the Conference and our Chapter. The featured charity and raffle drawings will return as well. Exhibitor registration will open in early November, so be sure to check the weekly email for more information about the Conference. Early bird registration for attendees will be opening in January 2016.

We hope you are able to attend the 2016 Conference to Re-engage with friends and colleagues, Recharge your company with innovation ideas for the future and grow your knowledge with top-tier education sessions.

The Technology Conference Committee is always looking for new members! If you would like to help with the planning for ISPE-CaSA's biggest event please stop by our table at the Oktoberfest on October 29th. If you can't be at Oktoberfest send me an email at alineberry@manganinc.com.



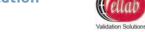
Be sure to follow us on: @ISPE_CASA



Check out our Facebook page: facebook.com/ispe.casa

TrackSense Pro Sky Solution Real Time Data





- Lyophilization
- Sterilization
- Depyrogenation
- Mapping Applications
- Interchangeable sensors

For an in-depth demo contact | P. Roy Snipes Regional Sales manager | rs@ellab.com | 919.414.9812

LIFE SCIENCES TECHNOLOGY CONFERENCE



Carolina-South Atlantic Chapter

MARCH 31, 2016 | 10:00 AM - 7:00 PM | RALEIGH CONVENTION CENTER | RALEIGH, NC

EARLY BIRD REGISTRATION RATES:

ISPE Members \$45 / Non-Members \$60

REGULAR REGISTRATION RATES:

ISPE Members \$65 / Non-Members \$75

ONSITE REGISTRATION RATE: \$85

- Source state-of-the-art technology
- · Discuss novel applications and solutions with over 200 exhibitors
- · View product demonstrations
- · Network with more than 1,000 industry professionals
- · Participate in industry-specific informational sessions
- · Enjoy food and beverages throughout the day





EARLY BIRD REGISTRATION STARTS:

January 4, 2016

REGULAR REGISTRATION STARTS:

March 1, 2016

REGISTER NOW AT:

ISPE-CaSA.org/2016

Technology Corner

GET WHAT YOU PAY FOR

Keys to Effective Factory Acceptance Testing (FAT)

It can be exhausting—safeguarding your project schedule while ensuring every piece of equipment arrives at your facility ready to be installed and functioning properly. Stop trying to force square pegs into cylindrical holes to keep your project on track.

Thorough planning prior to and during Factory Acceptance Testing (FAT) will increase the likelihood that the equipment meets your approved specifications upon delivery.

This paper includes guidance on how to plan and conduct your FAT effectively. In it, we will discuss front-end loading activities, content that should be included in the verification or C&Q plan and vendor specifications, activities that maximize efficiency, and vendor documentation.

Implement proactive FAT practices. Get it right the first time—and get what you pay for!





COMMISSIONING AGENTS, INC.

Scott Hamm, Principal Project Manager Jackie Weichman, Global Marketing

DIMINISH SURPRISES WITH FRONT-END LOADING

Front-end loading (FEL) activities can contribute significantly to the success of FAT. Proper planning and up-front activities will drastically improve the probability of an optimal FAT with minimal rework once the equipment arrives on site and an expedited qualification process. Examples of FEL activities include the following:

- Perform vendor evaluations/audits to ensure vendor has an ad equate quality system
- Perform risk assessments to provide rationale for a risk-based approach – consider vendor history, equipment complexity, technology, product quality/patient safety
- Establish payment milestones to help ensure requirements are met

- Align schedule, detailing FAT dates, durations, and activities
- Clearly define FAT roles and responsibilities
- Hold kick-off meeting and periodic follow-ups to confirm vendors understand specification details
- Identify and procure long-lead materials to support FAT and subsequent testing
- Determine who should attend FAT and budget accordingly
- Conduct a pre-FAT visit to ensure vendor is ready for FAT-consider resources, test materials, approved protocol, documentation, data, etc.
- Develop a verification plan to document detailed testing strategy

Design reviews are another FEL activity that can add significant value to your project. Reviews are typically phased, and will verify

Front-End
Loading (FEL)
activities can
reduce or
eliminate costly
schedule delays
down the road.

that design specifications meet approved requirements.

Mechanical review allows for fabrication to begin; automation review typically occur once detailed design documents have been developed and approved.

Furthermore, pre-approval of FAT protocols and associated checklists should be completed. Review should occur at least 6 weeks prior to FAT execution to allow time for comment and editing. A cross-functional review of

FAT protocols, specifications, and verification plan can help preventmiscommunicationand improve stakeholderbuy-in.

WRITE A COMPREHENSIVE VERIFICATION OR C&Q PLAN

A detailed verification or C&Q plan is essential for a successful FAT. A robust plan will define the C&Q strategy, including detailed FAT activities and

how they fit in with other C&Q activities. If specifications are not met during the FAT, then it can be more costly to address once the equipment arrives on site.



Identifying issues while equipment is still at the vendor site allows for modifications prior to delivery, installation, and start-up, which is desirable. Content to consider incorporating into your verification or C&Q plan include the following:

- Vendor evaluation strategy
- · Risk assessment results
- List of required deliverables
- Scope/system boundaries
- Roles and responsibilities
- A testing matrix
 - ✓ What will be tested and where
 - ✓ What testing, if any, will be repeated
- Product or product combinations to be tested (when and where)
- C&Q activities to be performed (e.g., loop checks, document reviews, alarm testing, etc.)
- How documents will be used to meet Qualification requirements
- Software configuration and change management strategy
- Process Analytical Technology (PAT) strategy
- Discrepancy management strategy
- Impact of component/material variation on testing strategy
- Training requirements

DEVELOP AND COMMUNICATE DETAILED VENDOR SPECIFICATIONS

You've researched and evaluated multiple vendors, and have selected the fabricator you believe can deliver the equipment you need, in accordance with your schedule, cost and quality requirements.

Communication of requirements and expectations is essential and will increase the likelihood of success.

Meeting with the vendor to ensure they

understand



your requirements (typically documented in specifications and purchase orders) is key. Additionally, you should discuss incentives for early completion of activities and consequences for late delivery and/or not meeting the requirements defined in the specifications or purchase order terms and conditions.

Vendor specification content should include the following, at a minimum:

- Technical equipment specifications
- FAT protocol content requirements
- System and component documentation requirements (e.g., functional specifications, software specifications, wiring diagrams, PM recommendations, operating procedures, MOC certificates, vendor manuals, spare parts list, calibration certificates, and P&ID's.)
- Component data requirements (e.g., manufacturer, model number, serial number)
- Expectations with regards to GDPs
- Process, EHS and business requirements
- Language requirements
- Timing/schedule requirements for activities and deliverables
- Shipping requirements/plans
- Spare parts requirements for startup/commissioning

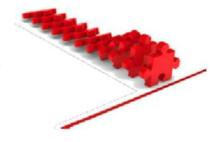
MAXIMIZE EFFICIENCY

You've prepared; you've taken part in meetings, phone calls, and emails to hash out all of the details. You and your team have your plan, make your travel arrangements, and arrive on site to execute the long anticipated Factory Acceptance Testing (FAT). This is the point of the process that can make or break your project schedule or perhaps your production schedule. Don't just go through the motions. Leave confident that your equipment will function, as anticipated,

upondelivery and installation.

The following should occur during the FAT to maximize efficiency:

 Involvement of critical stakeholders from your company



- Testing of all critical functionality
- Testing of all products or product combinations, if possible
- Review of required data and documentation
- Verification of as many installation aspects as possible to reduce on-site activities (e.g., P&ID walk downs)
- Recording of vendor utility parameters to serve as a baseline for future reference
- Operator/maintenance training, if possible
- Agreement on punch list resolution plans document what must be resolved prior to shipment and what can be resolved via SAT
- Push to have all open issues addressed prior to shipment, unless schedule demands dictate otherwise
- Rely on vendor documentation or spot checks for low risk items (e.g., alarm testing, interlocks, loop checks, calibrations, etc.)
 vs. repeating or performing during FAT

STREAMLINE YOUR PROCESS WITH VENDOR DOCUMENTATION

In some cases, vendor documentation can be incorporated into

your own documentation package rather than developing it separately. Many times this information can be easily assimilated. However, be careful with this approach, as different vendors don't necessarily

LEVERAGE VENDOR DOCUMENTATION

- Installation verifications
- Loop check documentation
- Functional verifications
- Alarm/interlock testing
- Drawing verification
- Data verification
- Functional requirement specification
- P&ID and general arrangement drawings
- Detailed design specifications
- Calibration certificates
- MOC certificates
- Passivation certificates
- Welding documentation
- √ 0&M manuals
- → GEP tests
- FAT summary report

internal quality standards. Confirm

vendor

implement

consistent

documentation meets your

requirements before using it. Performing evaluations up front can minimize the risks here.

Only use vendor documentation if it can be used without significant effort to bring it up to your standards. If documentation is poorly written, or does not meet your requirements, time may be better spent developing it yourself (e.g., FAT protocol).

Additional potential pitfalls that you may encounter when leveraging vendor documentation include the following:

- Poor GDPs
- Vendor documents subject to regulatory agency review
- Lack of client availability to witness vendor testing
- Varying test results due to utilities not being comparable to client site

- Quality unwilling to accept since not involved in review/ approval
- · Generic forms that lack sufficient detail
- Document issues due to language translation (e.g., units of measure are not converted)
- · Equipment disassembled invalidating wiring continuity checks
- Equipment damaged during shipment potentially impacting calibrations, etc.
- Inconsistent documentation practices and formatting issues
- · Poor change management practices and revision history
- Lack of knowledge of client's processes
- · Lack of qualified reviewers/approvers
- Unwillingness of vendor to give up code
- References to vendor documents not available to client

THE BOTTOM LINE

Whittling away at your FAT strategy as you go will not result in efficient equipment delivery, but rather, increase your chances of

wasting significant time and money. Upfront planning is a worthwhile investment to ensure you get what you pay for and that your new piece of equipment performs as intended.

FEL activities can save time, headaches, and money later in the

process. Invest early and communicate

frequently with the vendor to ensure you get what you pay for, on schedule and within budget.

Commissioning Agents, Inc. (CAI) provides technical and consulting services to improve the delivery, reliability and efficiency of your equipment, facilities, and production operations. For manufacturing start-up, smart operations, asset



Scott Hamm is an electrical engineer with more than 25 years of engineering and project management experience. He is a global presenter of topics relating to a risk-based approach to commissioning and qualification, and authored a chapter of the International Society for Pharmaceutical Engineering (ISPE) Good Practice Guide — Applied Risk Management for Commissioning and Qualification, published in 2011. Previously, Scott served as Engineering Manager of C&Q for Eli Lilly and Company. www.commissioningagents.com





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:

- \$\times\$1,500 Full-color ad for six issues on the front page of each newsletter (\$250/issue)
- ② \$1,500 Full-color double-sized ad for two issues (\$250/issue)
- ② \$750 Full-color ad for two issues (\$125/issue)
- ② \$200 Full-color ad in 1 newsletter of your choice (\$200)
- ② \$500 Add a hot link for directing customers to your website by a simple click (\$500)

We hope you will take advantage of these opportunities and advertise in the 2015 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2015 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. **Deadline for 2016 advertisers to be in the February 2016 issue is January 22.**

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!

Carolina-South Atlantic Chapter





Electronic Media ISPE-CaSA.org

Now you can reach www.ispe-casa.org audience by advertising on our website. A limited number of advertising spots are now available so don't delay. Contact the ISPE Carolina-South Atlantic Chapter to reserve your space. (Please note: ISPE-International-forbids website ads on our chapter's home page, so they are on subsequent web pages.)

To learn more about this opportunity, contact Penney De Pas, Chapter Manager, at 919-573-5442 or pdepas@ispecasa.org. If you are interested in signing up for the program, please complete the form and return to pdepas@ispecasa.org or fax 919-787-4916. Advertisements are sold on a first-come first-served basis.

SPECS OF ADVERTISEMENT:

Top Placement Ad 120 pixels wide by 240 pixels high; File formats accepted: .GIF, .JPG, .SWF Bottom Placement Ad 240 pixels wide by 400 pixels high; File formats accepted: .GIF, .JPG

	12 months	6 months
240 x 400 Vertical Rectangle	\$500	\$300
120 x 240 Vertical Banner animated	\$400	\$250
120 x 240 Vertical Banner - non animated	\$300	\$200

		240 x 400 Vertical Rectangle ad 240 x 400 Vertical Rectangle ad 120 x 240 Vertical Banner anima 120 x 240 Vertical Banner anima 120 x 240 Vertical Banner - non 120 x 240 Vertical Banner - non	12 Months, ited ad 6 Mo ited ad 12 M animated 6	\$500 onths, \$250 lonths, \$400 Months, \$200		
Name:		Member #:				
Title:						
Address:						
City:			_State:	Zip:		
Tel:		Fax:		- 0.000000 o 0.00000		
Email:						
PAYMENT T	YPE:	□□Visa □□MasterCard □□AMEX				
		able to: ISPE-CASA)				
Card #:			Expi	ration Date:		
Cardholder N	lame	(as it appears on card):				
		ure:				
	_				$\overline{}$	

ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for Your Business!



Our Chapter produces six enewsletters 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 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

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