



President's Message



Mike Putnam

Happy Spring ISPE-CaSA Members. It's hard to believe we're already approaching summer, but hallelujah warm weather is here! On March 12, 2019, CaSA hosted the 26th Annual Life Sciences Technology Conference at the Raleigh Convention Center. This year's conference was wildly successful with attendance of nearly 1,300 and over 200 exhibitors. Perhaps the most meaningful statistic from the

conference is that 27% of attendees were employees of drug manufacturers. That level of involvement is not only exciting, but critical for the long-term success of our chapter. A special thanks goes to Andy Stober of AveXis who delivered a powerful keynote address to a standing-room-only crowd. The investment local manufacturers are making within our region is inspiring and will impact the lives of patients for generations to come. Last, I would like to thank Team Chris Combs and Project ALS for the opportunity to support their amazing organizations as part of our conference. CaSA members raised \$17,000 that will be used to fund ALS research in search of a cure.

Looking forward, it is time to dust off your clubs and join us on Monday May 20, 2019 at the 25th Annual Golf Tournament and Women In Pharma Wine Tasting at Prestonwood Country Club in Cary, NC. We anticipate over 225 players battling it out on 3 courses. Limited spots are left for players and sponsors, so please [register](#) today!

Thank you to all Members, Board of Directors, Sponsors, Volunteers, and Students who so generously support ISPE CaSA. I enjoy serving with you and look forward to many great things to come!



Mike Putnam

President, ISPE CaSA Chapter

Featured Sponsors

Discover articles from
the overlapping worlds
of pharmaceuticals and
engineering.

Visit our TechTalk Universe
nne.com/techtalk

TechTalk
powered by nne

NNE
1101 Slater Rd., Suite 120, Durham,
NC 27703, USA, T: +1 919 998 9552

nne

GEMÜ SUMONDO®
Manually Operated
Single-Use
Diaphragm Valve

Areas of application

- Pharmaceutical,
Biotechnology and
Cosmetics Industries
- Medical Systems



info@gemu.com

www.gemu.com



bürkert
FLOWave

www.burkert-usa.com

Uncompromising flow
rate measurement

RGD
Project Management, Inc.

Specializing in Construction
Management of Pharmaceutical &
High Tech Facilities

Uncompromising Values...

www.rgdinc.com

INSIDE THIS ISSUE

President's Message.....	1
Board of Directors 2018 - 2019	2
Networking Committee.....	3
25th Annual Golf Tournament.....	3
WiP Wine Tasting.....	4
CaSA Committees 2018 - 2019.....	4
Education Committee.....	5
Social Media Committee.....	6
2019 Newsletter Advertising and Sponsorship Opportunities....	8
2019 CaSA Annual Sponsorship Packages.....	10

Did You Know Some Of Our Advertisers Use Hyperlinks?

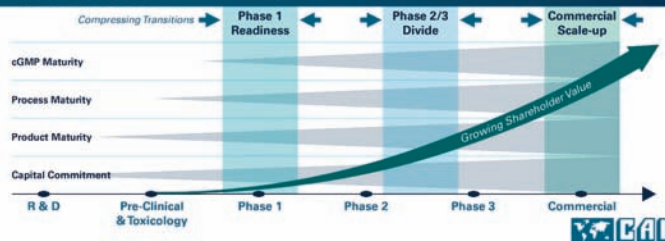
The following advertisers are using our hyperlink feature in their ads, **Gemu Valves**, **Burkert**, **AdvantaPure**, **Sequence** and **CRB**. You can "click" anywhere in their ad and you will be directed to their link. You can find them more easily by looking for the ads that are outlined in **GOLD**.

Thank you to all of our advertisers. This newsletter would not be possible without your support!



How can we help you accelerate your speed to market?

Chris Smith
Business Development Manager,
South Atlantic
chris.smith@cagents.com
+1 803-960-6405



Board of Directors 2018 - 2019

Executive Board

President

Mike Putnam
president@ispecasa.org

Vice President

LeAnna Pearson Marcum
vicepresident@ispecasa.org

Treasurer

Rich Stanfield
treasurer@ispecasa.org

Secretary

Kevin Debbs, CPIP
secretary@ispecasa.org

Past President

Wendy Haines, PhD ASQ CQA
nominations@ispecasa.org

Manufacturing Engagement Advocate

Beth Smullen

Directors

Director at Large

David A. Davis

Director at Large

Mark Yates, PhD

Director at Large

David G. Smith



Connecting a World of Pharmaceutical Knowledge

Chapter Events

Networking Committee

By Chris Smith, Chair

ISPE-CaSA Winter Gala 2019

The ISPE-CaSA Networking Committee started off 2019 with a bang at the Winter Gala in early February. Held at the Umstead Hotel in Cary, NC, over 175 people from dozens of companies played at the casino tables and danced the night away. Hundreds of dollars were raised for the Jane Brown Scholarship via the 50/50 raffle and wine pull events. The winner of the 50/50 raffle, Kyle Davidson of Evans General Contractors, even donated his share of the winnings to the scholarship! We have exciting networking events on the horizon.

RTP Golf Tournament and WiP Wine Tasting

The 26th annual RTP Golf Tournament is scheduled for Monday, May 20th at the Prestonwood Golf Club in Cary, NC. Breakfast and registration is at 8am with a tee time of 9am. We have games, prizes, raffles, and hole-in-one giveaways planned for this great event. Awards will be presented at the networking lunch following the event. Pull your team together and register today! The event sold out last year.

Following the golf tournament, a Women in Pharma (WiP) Wine Tasting Social will take place at the Prestonwood Golf Club from 4:00-6:30pm. Gentlemen are welcome, and encouraged, to join. A sommelier will walk the group through a series of tastings that will test your palate and knowledge of wine. Then, Mimosa and Aperol Spritz stations will open, and the evening will conclude with an open wine bar and

networking. Register [here](#) for both the golf tournament and WiP wine tasting (see next page for more details) events.

Networking Committee objectives and accomplishments:

The Networking Committee is dedicated to helping people connect with others in the industry. This helps individuals grow professionally, personally, and intellectually. Our group works closely with the Membership and Education Committees to provide the most value for members who are taking time and effort to attend our events. 🏠



Join ISPE-CaSA and your colleagues for the

25th Annual Golf Tournament

**Help us make our
25th anniversary the
best ISPE-CaSA
Golf Tournament ever!**

To register, please visit:

www.etches.com/2019-ispecasa-golf



Monday, May 20, 2019

Prestonwood Country Club • Cary, NC

Chapter Events

ISPE CaSA Women in Pharma Wine Tasting



Following golf, join us from
4:00 — 6:30.

- Wine Tasting and a brief Industry Presentation.
- Featuring special Wine Spritz Cocktails, Hors D'oeuvres and Networking Reception.



CaSA COMMITTEES 2018 - 2019

Education

Andy Ferrell
education@ispecasa.org

Newsletter

M. Jason Kelly, Ph.D.
newsletter@ispecasa.org

IT/Social Media

Dan Santarsiero, PE
infotechnology@ispecasa.org

Student Affairs

Catherine Bays
studentaffairs@ispecasa.org

Membership Development

Bud Watts
membership@ispecasa.org

Networking

Chris Smith
networking@ispecasa.org

Young Professionals

Mariessa Perez
youngprofessionals@ispecasa.org

Technology Conference

Chris Small, PE
techconference@ispecasa.org



Membership Corner

Education Committee

By Andy Ferrell, Chair

ISPE-CaSA Facility Tour & Spring Educational Event

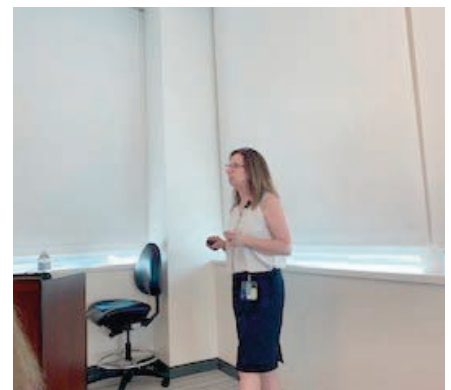
ISPE-CaSA partnered with Grifols to host a tour of their Clayton, NC facility on Thursday, May 2. The sold-out event had one hundred attendees with a waiting list to get in the doors. This was the first of four educational events scheduled for 2019.

Grifols featured three speakers, providing insight on Grifols plasma-derived medicines. Doug Burns, President of Grifols Therapeutics, welcomed the group and provided an overview of Grifols worldwide, the products manufactured, and Grifols engineering capabilities at the Clayton site. David Kistner, VP of Engineering, provided an overview of current and future projects.

Jennifer Culp, VP of Manufacturing, ended the talks with an overview of Grifols' unique sterile filling process. Following the talks, attendees were able to tour the North Fractionation Facility, one of the largest plasma fractionation plants in the world, and view the Sterile Filling operation.

Following the tour, Mason-Grey and JE Dunn Construction, sponsored a networking event onsite at Grifols where attendees were able to connect with industry leaders.

Thank you to our education event sponsors: PCI, Avid, IMA, Azzur, and Gemu. 🏠



CASE STUDIES on

- Filling assemblies
- Tubing
- Container closures
- Pass through systems

AdvantaPURE
NEWAGE INDUSTRIES
www.advantapure.com



SEQUENCE
Total Quality Solutions Provider

- + Computer System Validation
- + Process Validation
- + Automation Systems Validation
- + Equipment Validation
- + Laboratory Instrument Validation
- + Quality Program Development
- + Remediation
- + Auditing
- + Quality Assurance
- + ASQ Certified

SequenceEngineering.com | SequenceQCS.com | SequenceSDMS.com
info@sequenceqcs.com | 855.844.7171

Membership Corner

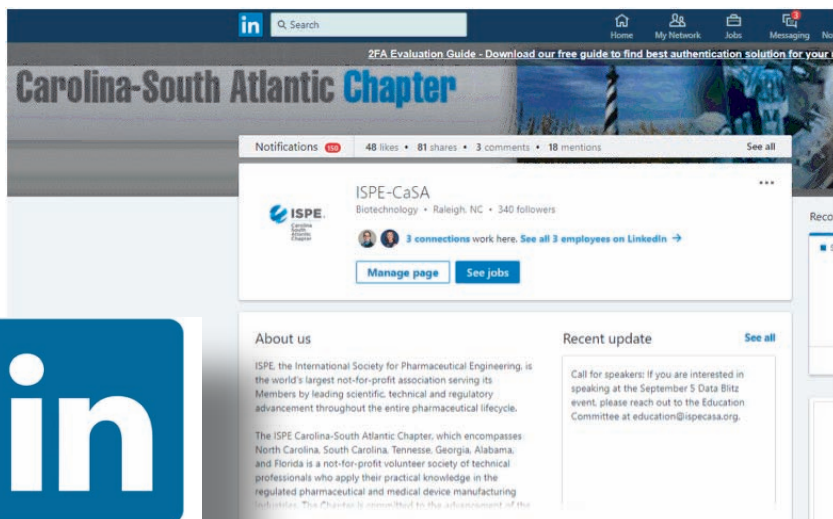
Social Media Committee

By Daniel Santarsiero, Chair

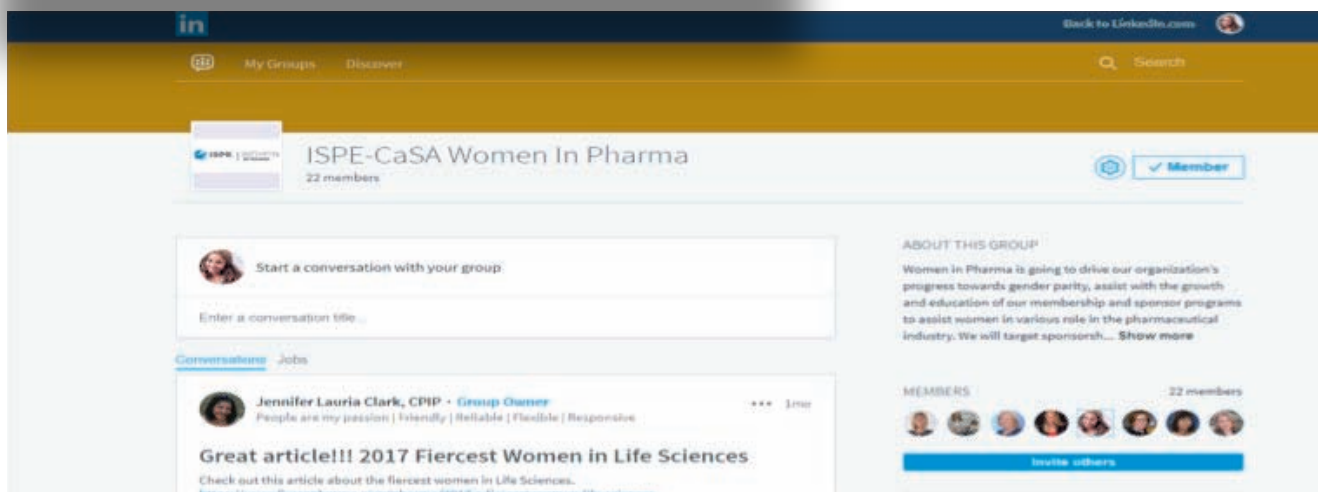
Attention! LinkedIn Update! Follow Us On LinkedIn

**Join the movement and be part of the first 1000!
Join us now! Don't delay!**

Stay in immediate communication with your favorite professional organization by connecting with us on our [ISPE-CaSA Company](#) page. Stay in touch with all exciting upcoming events, industry news, and other relevant information related to the Chapter and National Organization. Follow this [link](#) to join the ISPE-CaSA page for updates! And follow our [Women in Pharma Group](#)! www.linkedin.com/company/ispe-casa/ 🏠



LinkedIn





PCIC
Calibration, Commissioning & Consulting

Calibration
Service Continuity

Commissioning
CQV Solutions

Consulting
Solutions that Matter

887.724.2257 • www.pci-llc.com



**Specialists in
Ultrapure Water
Since 1967**



Bud Watts
Director of Business
Development Life Sciences
bwatts@hydroservice.com
(919) 274-9401



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 \$1,000 for your full color, business-card-sized ad for six insertions. That's only \$1,000 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 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 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!

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.



ISPE®

Carolina-South Atlantic Chapter

Advertising Opportunities in ISPE CaSA 2019 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):

- ☐ \$2,000 Full-color ad for six issues **on the front page of each newsletter** (\$333/issue)
- ☐ \$2,000 Full-color double-sized ad for six issues (\$333/issue)
- ☐ \$1,000 Full-color ad for six issues (\$167/issue)
- ☐ \$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 2019 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2019 please complete the form and send via e-mail to info@ispecasa.org. **Deadline for 2019 advertisements, to start in the February 2019 issue is January 25, 2019.**

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!


ISPE®
**Carolina-South
Atlantic Chapter**

2019 Newsletter Advertisement Order Form

Company Name:	
Contact Name:	
Billing Address:	
Contact Email:	
Contact Phone:	

Check all that apply:

**Note: Ads are business card size- 3 5/8" (w) X 2" (h)
Double-Sized Ads are 3 5/8" (w) X 4" (h)**

☐ \$2,000 Full-color ad for six issues on the front page of each newsletter (\$333/issue)
☐ \$2,000 Full-color double-sized ad for six issues (\$333/issue)
☐ \$1,000 Full-color ad for six issues (\$167/issue)
☐ \$500 Adding a hot link for directing customers to your website by a simple click

Payment:

Make checks payable to: ISPE-CASA

Mail to: ISPE-CASA / Newsletter, 1500 Sunday Drive, Suite 102, Raleigh, NC 27607-5151

Or pay by Credit Card: ☐ VISA ☐ MasterCard ☐ AMEX

CC#: _____ Exp Date _____

Signature: _____ Date: _____

• info@ispecasa.org • Ph: (919) 573-5442 • Fax: (919) 787-4916 •

For office use only: GL000-2240/100-3300 Pd by Ck # _____ CC processed: Date: _____ Initials

ISPE CaSA 2019 Annual Sponsorship Program



MANUFACTURER

VENDOR

UNIVERSITY

Includes:

Major Education Events - 10 Attendees

Tech Conference - Career Fair Table, 25 Attendees, 2 Leaders in IAC Lunch Meeting

Golf Tournament - foursome in one golf tournament

Newsletter - Business Card Ad in 2019 newsletters

Membership - One (1) Annual ISPE Membership for Site Lead

Total Retail Value: \$2,769

**Annual Sponsorship: \$1,750
(37% Discount)**

Includes:

Major Education Events - 10 Attendees

Tech Conference - Premium Table, 10 Attendees

Golf Tournament - foursome in one golf tournament

Newsletter - Business Card Ad in 2019 newsletters

Membership - Five (5) Annual ISPE Memberships

Total Retail Value: \$5,895

**Annual Sponsorship: \$5,000
(15% Discount)**

Includes:

Major Education Events - 10 Attendees

Tech Conference - University Table, 15 Attendees

Golf Tournament - twosome in one golf tournament

Newsletter - Business Card Ad in 2019 newsletters

Membership - One (1) Academic and fifteen (15) Annual ISPE Student Memberships

Total Retail Value: \$2,729

**Annual Sponsorship: \$750
(72% Discount)**

* Manufacturer - business entity with primary concentration on drug or medical device manufacturing. Not intended for equipment manufacturers supporting drug or medical device manufacturing industry

** Education event attendance may exclude plant tours due to capacity limitations

*** 2019 Sponsorships (e.g. Gala attendance, Tech Conference sponsor, etc.) purchased prior to joining Annual Sponsorship Program will be credited toward program cost at the time of joining

Organization Type: ☐ Manufacturer ☐ Vendor ☐ University

Organization Name: _____ Contact Person: _____

Phone: _____ Email: _____

Payment:

Checks: make payable to ISPE-CASA | Mail to: ISPE-CASA 1500 Sunday Drive, Suite 102, Raleigh, NC 27607

Credit Card: ☐ VISA ☐ MasterCard ☐ AMEX | Email info@ispecasa.org | Ph: (919) 573-5442 | Fax: (919) 787-4916

CC#: _____ Exp Date: _____ Signature: _____ Date: _____

**To join Annual Sponsorship Program, complete
above section and email form to info@ispecasa.org**

Office use only: GL100-_____ Pd by Ck # _____ CC processed: ☐ Date: _____ Initials: _____