

Connecting a World of Pharmaceutical Knowledge

CaSA News



Volume 23 • Number 6 December 2016

President's Message



Lisa Kerner

Happy Holidays! It's hard to believe that 2016 is wrapping up and a New Year is upon us. I guess it's true when they say "time flies when you're having fun". Serving a second term as President of the CaSA Chapter has been very rewarding and a true honor. Although it comes with some challenges, I've learned that when you surround yourself with good people, you can accomplish anything. Not only

am I thankful to be working with a strong Board of Directors, I am truly blessed for the support from our members and the friendships I've grown to cherish throughout the Chapter and this amazing industry we serve. As I look back at the past year, my heart is very full..."Thank You"!

Looking ahead to 2017, the Board of Directors remains strong in its mission to bring meaningful events to our membership. As you read through this newsletter, you'll find that Education and Networking opportunities continue to thrive in the Research Triangle and Atlanta markets. We had record attendance at all of our 2016 events and it is our goal to increase attendance and keep the momentum going in 2017!

As event details continue to develop, information will be distributed via weekly e-blasts, social media and our website. To join the CaSA Chapter mailing list and follow us on Twitter, LinkedIn and Facebook, please visit our website to stay abreast of all things CaSA! http://www.ispe-casa.org/

My final thoughts are to thank each and every one of you for making CaSA what it is today. The Chapter's successes would not be possible without you! I look forward to seeing you at our upcoming events.

Warm wishes for a safe and happy holiday season!

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



See pages 10 and 11 for more details!

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Board of Directors 2016

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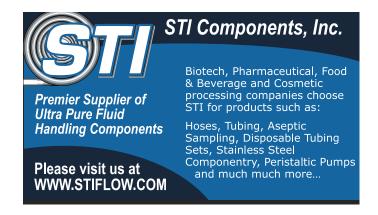
Director at Large Chip Chappell

Director at Large Andy Ferrell

Director at Large Wes Robbins







Education

By Rachel Leahy, Education Committee

On behalf of ISPE-CaSA, we would like to extend a warm "thank you" to Amy Bryson and Gary Lohr of Novo Nordisk for their warm hospitality in hosting the Talk and Tour on December 1st. The event completely sold out within the first day and was a major success!

We'd also like to take a moment to thank our 2015-2016 Education Partners. Our partners were instrumental in all of our 2015-2016 events in RTP and Atlanta, including the Talk and Tours at Fujifilm Diosynth and Three Taverns Brewery, seminar series at Brio Tuscan Grill, an Automation Forum and Atlanta

Education Roadshow, to name a few.

The 2017 programmatic year is looking to be even busier than the last. We already have some great events in the works in both the RTP and Atlanta regions. While we have SOLD OUT all Platinum and Gold Partnerships for 2017, we still have a few Silver and Bronze slots remaining. If you are interested, please complete the form, available here.

We wish you and yours a warm, wonderful holiday season and look forward to seeing you again at the next ISPE-CaSA Education event in 2017.



SPE Carolina-South Atlantic Chapter

Special thanks to our Education Event Sponsors:

Platinum





Gold









Silver







Bronze

PEG Contracting, Kymanox, CRB, Control Southern, McCann Construction Company, Castle Hill Technologies, Inc., NNE Pharmaplan, MG Newell, STI, & HIPP Engineering

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

By Mark Davies, CaSA Membership Development Chair

We have a few new members on the Membership Committee – Bud Watts of Axiom, Monica Osif of Hydro in ATL area and Jeff Weiss of Cross also in ATL area.

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Was \$284, now only \$244! Applications can be made online at www.ispe.org/join, click on Join Now under

Industry Membership, and enter CASA2016 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

http://www.ispe.org/membership-referral-program

Save 10% on 2 and 3 year memberships!

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

Welcome New Members

New Members who joined October 9, 2016 through November 15, 2016

Kyle Landvogt
Caleb Ryan Malpass
Mrs. Diana Elvington
Timothy J. Santana
Stephen Atencio

Alessandra Lee Fantuzzi Patrick M. Paczkowski

Brian Lee Carlos Miranda

Daniel Lucky Swanson, ChE

Elissa Danielle Foss Costantino Pipero Trey Martin, B.A.

Allie Ward Caitlin Kemp Hedaya Megeed Dana Raveica

Christopher Blake Wood Peter Triggiani, IV Veronica Tucker Wayne Hansley

Adrian Franzone, ChemE

Bob Sarrio

Elizabeth C. Lindsey Jenna Casady, MS Anuj Kulkarni Pedro Colon
Shane Bolding
Todd Dando
Adrian LaPorta
Andy Zhou
Ariel Lebron
Art Morse
Babu Sivaraman

Bill J. Schaidle Carlos Monge Chris Thomas

Danny Oppenheimer

Dennis Hurt Doug Makowecki Francisco Irrizary Greg Francis Irene Itturino James K. Settle

Dr. Sean D. Stowe, PhD

Ashley Coggins Dimple Desai Josh Eargle

Brennon Youngblood William Sammons CPE

Oivind Bergrav Jessica Gadbois Jim Robertson
Josh Morss
Justin Lamb
Lydia Hernandez
Maryann Moran
Christopher Salvador

Kristen Taylor
Rich Proctor
Scott Stofan
Shawn McCleskey
Stuart Mosby
Tucker Maloney

Mrs. Sheela S. Prabhu

Susan Parker

Trevor Brennan Jensen Andrew James Cooke Chelsea Hamrick

Miss Emma Beaty Moore

Matthew Wingate
Johnny Jung So
Kellie Jacobs
Alyssa Mathewson
Kimberly White
Michael Galie

Arjun Padmanabhan





Upcoming Networking Events

- 26 Jan 2017: Therapeutic Thursday sponsored by AlfaNordic Carolina Ale House Brier Creek
- 28 Jan 2017: Winter Gala at the NC Museum of Art
- 23 Feb 2017: Therapeutic Thursday sponsored by CRB Five Bar Atlanta, GA
- 23 Feb 2017: Therapeutic Thursday sponsored by CAI Location TBD
- 30 Mar 2017: Therapeutic Thursday sponsored by STI Double Barley Brewing Smithfield, NC
- 30 Mar 2017: Therapeutic Thursday sponsored by Harrington Pure Location TBD Atlanta, GA
- 22 May 2017: Golf Tournament at Prestonwood Country Club

CaSA COMMITTEES 2016

Education Student Affairs
Rachel Leahy Marisol Patiño

Newsletter Membership Development
Rich Stanfield Mark Davies

IT/Social Media Networking

Justin Rothwell, PE Kevin Debbs, CPIP

Technology Conference Young Professionals
Amy Lineberry, CPIP Mariessa Perez



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Oktoberfest

By Rich Stanfield

ISPE CaSA Chapter's Oktoberfest was held 13 October at the Koka Booth Ampitheather.

This year's event was split from the Annual Planning Session, leaving the planning session as the Chapter's primary event to permit the committee chairs to discuss their plans with interested Members and recruit committee members from the attendees.

The Oktoberfest is the premier networking event of the year,

featuring the awesome sounds of EG Peters Band, brought to us live, courtesy of CRB!

Draft Line Brewing beers were provided by DPS Consulting and Pub Glasses were provided by STI.

Sponsorships for the event were available and our sponsors for this excellent, outdoor networking event are below.

Over 100 attendees were present this year, the weather was fabulous, and fun was had by one and all!

SILVER





GOLD



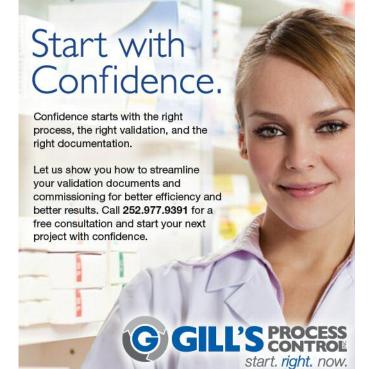
Life Sciences















Networking Committee

By Kevin Debbs, Networking Committee

The Therapeutic Thursday held immediately after the Talk and Tour at Novo Nordisk was a great success. This event, held at Double Barley Brewing Co., included donations to the Toys for Tots program. Approximately 40 gifts were donated to this incredible Marine Corps-run program!

Thanks to all for your generosity!!

Please contact Kevin Debbs at Kevin.Debbs@crbusa.com or Claudia Carroll at ccarroll@FirstPointResources.com if you are interested in sponsoring a Therapeutic Thursday in the greater RTP or greater Atlanta areas.



My First ISPE Annual Meeting Experience

By Mary Beth Pugh

Without knowing what I was really getting into, I decided to join Campbell University's ISPE student chapter last school year. As a student in the Master of Pharmaceutical Sciences program, this organization seemed like a good fit for me. I attended student chapter meetings and local ISPE-CaSA events, and I quickly realized that ISPE offered amazing networking opportunities with industry professionals that I just couldn't get at school.

After listening to other students' experiences from previous years' annual meetings, I decided I had nothing to lose by applying for the ISPE-CaSA student scholarship to attend the 2016 ISPE Annual Meeting. I was fortunate enough to be chosen, which I think was primarily because I had attended numerous ISPE-CaSA events and the people choosing students for the scholarship actually knew who I was. I happily accepted the scholarship, and prepared for my first annual meeting!

I was fortunate enough to ride from Raleigh to Atlanta with two women who work for the company I am currently interning with. Incidentally, they are also both Campbell alumna and have been active members of ISPE-CaSA for many years. I knew I needed to stick with them at the annual meeting if I wanted to meet as many people as possible and really figure out what ISPE is all about. Fortunately, they both took me under their wing and really made the annual meeting a tremendously positive experience for me, both as a student and as a young professional currently working part-time.

While in Atlanta, I attended multiple keynote sessions, student/young professional's events, and several panels/educational sessions. In one of the keynote sessions, the mother of a child who is now in remission from a very aggressive brain tumor told her family's story of how the

pharma industry gave her son a second chance at life. This particular session was extremely touching. I think it reminded everyone in attendance that, while pharma companies do need to make money to exist, the ultimate driving force behind the industry is the desire to help sometimes only a single patient. I also particularly enjoyed the "Women in Pharma" panel discussion. As a female, it was great to interact one-on-one with successful women who have thrived in an industry that has traditionally been male dominated.

Although the educational opportunities were plentiful, I think that the opportunity to meet and network with people from around the globe was invaluable as a student who will be seeking full-time employment in the near future. I was amazed at the level of attention students and young professionals received at the annual meeting and how much emphasis is currently being placed on pulling them into the professional fold. Even John Bournas, the President and CEO of ISPE, attended the young professionals event at Game-X! The Tuesday night party at the Georgia Aquarium was also a really fun event. I discovered that no matter what your age or professional status, the dance floor really levels out the social playing field!

In conclusion, I feel extremely lucky to be part of an organization that is so patient-oriented and focused on making the world a better place. I'm anxious to get more involved in the ISPE-CaSA chapter as I get closer to graduation, as I'd like to give back even a fraction of what the professionals with whom I've connected with have done for me. In the short-term, however, my mission will be to teach other Campbell University students about the endless opportunities within ISPE and get them more involved!

Social Media

By Daniel Santarsiero

The ISPE-CaSA Social Media Committee would like your help improving our social media presence. ISPE-CaSA is always increasing its' activity on LinkedIn, Facebook, and Twitter. With your help we can drive more awareness to the exciting things going on with ISPE-CaSA.

Here are a few simple tips to help us get to the next level:

- Sign in to your LinkedIn account
- Go to the search bar at the top of the screen and type "ISPE-CaSA"
- Look for and select "ISPE-CaSA Biotechnology 11-50 employees"
- Hit the "like" and "share" button under the postmade on the ISPE-CaSA page.

These steps will help bring traffic to our LinkedIn page, increasing the awareness of the exciting events, technology shows and other valuable information being shared by our organization.

If you have any questions, please feel free to email me at dsantarsiero@sequenceqcs.com. The ISPE-CaSA Social Media Committee will be posting frequently so please be as interactive as you can.





Get Involved With Your Affiliate or Chapter Today! www.ISPE.org/Affiliates-and-Chapters





SPONSORSHIPS AVAILABLE WWW.ISPE-CASA.ORG/2017

BREAKFAST SPONSOR

\$750

1 EXCLUSIVE

Be the first to welcome conference attendees by sponsoring the morning breakfast. Sponsorship signage will be displayed beside the breakfast buffet as well as on the large screens in the ballrooms. (Breakfast buffet will be located in the ballroom lobby.)

NETWORKING RECEPTION SPONSOR

\$1500

2 AVAILABLE

Host conference attendees to an exciting evening at the networking reception. This year's reception is sure to be the highlight of the day including gourmet food, drinks, and live entertainment. Sponsorship signage will be displayed beside the networking reception buffet as well as on the screens in the ballroom.

REGISTRATION BOOTH SPONSOR

\$750

3 AVAILABLE

Welcome conference attendees with signage from your company as they check in at the registration booths.

FRONT ENTRANCE BANNER SPONSOR

\$750

2 AVAILABLE

Place a free-standing sign (up to 4' long x 8' tall) inside the RCC front entrance. All attendees must pass this area to enter the event.

STUDENT POSTER COMPETITION SPONSOR \$500

1 LEFT!

With this sponsorship you get signage during the exhibitor reception and throughout the day of the Conference. Also, recognition after the Keynote during the announcement of the Graduate and Undergraduate winners. If you would like to be a judge for the posters please let us know.

 STANDARD TABLE
 \$925 UNTIL 1/20
 \$1075

 PARTNER TABLE
 \$1275 UNTIL 1/20
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 LEAD RETREVIAL
 \$150 UNTIL 2/9
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at the North Carolina Museum of Art



Join us Saturday, January 28, 2017 from 6:30-9:30 pm at the North Carolina Museum of Art

2110 Blue Ridge Road, Raleigh, NC 27607 • (West Building – Silver Building)

Featuring Keynote Speaker: Theodore D. Lithgow, PhD Chief Operating Officer – Humacyte, Inc.

"The Power of Regenerative Medicine"

Humacyte, Inc., is a small, but rapidly expanding biotech in the Research Triangle specializing in the exciting and emerging field of Regenerative Medicine. Dr. Lithgow's presentation will focus on the challenges and innovative solutions for bringing a revolutionary, first-in-class, and life-sustaining biologic (granted Fast Track designation status by the FDA) to the market. He will also touch on Humacyte's new manufacturing facility project in the RTP that will produce bioengineered tissue that creates a unique vascular access and benefits patients with severe kidney disease (ESRD).

Enjoy a relaxed evening of live music, museum tours, heavy hors d'oeuvres, complimentary cocktails, and dessert.

Bring your significant other to an elegant night of entertainment and networking at Raleigh's premier destination for compelling encounters with art.

Dress Code: Cocktail Attire

Registration

ISPE Members	\$70
ISPE Young Professionals	\$50
ISPE Students	\$30
Non-Members	\$80
Couples	\$120

Attendee and Sponsorship Registration

https://2017ispecasagala.eventbrite.com

(See reverse side for registration form.)

Sponsorships Available

Reception Sponsor - \$1000

Only **TWO** spots available to sponsor. Signage at Food Stations, logo on all promotions, and company "thank you" from the speaker platform. Two complimentary registrations included.

Beverage Sponsor - \$1000

Only **TWO** spots available to sponsor. Signage at Beverage Stations, logo on all promotions, and company "thank you" from the speaker platform. Two complimentary registrations included.

Museum Sponsor - \$500

Only **FOUR** spots available to sponsor. Signage at Event and company "thank you" from the speaker platform. One complimentary registration included.







Registration Form

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Technology Corner

Maintenance: A Warship Mentality

By:
Glenn Wallace,
CDCDP, CMRP
Asset Management
Discipline Lead
Commissioning Agents,
Inc.



Take a few moments and envision yourself and all of the people who work at your facility as a crew assigned to the Navy's newest and most technologically advanced warship. This vessel is being commissioned and sent to sea on an important mission in enemy waters.

If your team had commissioned this ship as you commission your facility's systems, would you be comfortable going to sea? Most people in the pharmaceutical industry would say yes since there are very stringent commissioning processes and requirements.

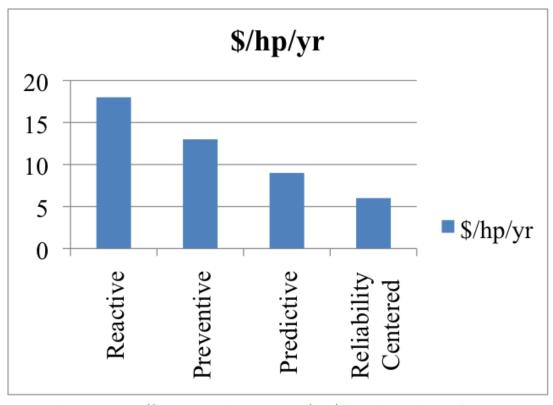
Now, if you had prepared the maintenance and inventory program for this warship like you have for your facility, would you still be comfortable taking this vessel into harm's way? Not

near as many would answer yes.

Why is this? Because it is not a specific requirement? Because it is "just maintenance" and therefore not important to the "bottom line"? It doesn't provide "value"? In order for maintenance and proper inventory control to be important, it has to be made a priority. To allow the processes that make life-saving drugs reliably and in a repeatable manner, proactive maintenance programs must be developed from the start.

Based upon multiple study results, the below table represents the costs of each of the types of maintenance programs. The left axis in the graph represents the cost of operating equipment per year, based upon horsepower. This includes maintenance costs.

(continued next page)



Source: Chapter 5 - Http://www.motordiagnostics.com/rcm/omguide_complete.pdf

Take a few moments and envision yourself and all of the people who work at your facility as a crew assigned to the Navy's newest and most technologically advanced warship. This vessel is being commissioned and sent to sea on an important mission in enemy waters.

If your team had commissioned this ship as you commission your facility's systems, would you be comfortable going to sea? Most people in the pharmaceutical industry would say yes since there are very stringent commissioning processes and requirements.

Now, if you had prepared the maintenance and inventory program for this warship like you have for your facility, would you still be comfortable taking this vessel into harm's way? Not near as many would answer yes.

Why is this? Because it is not a specific requirement? Because it is "just maintenance" and therefore not important to the "bottom line"? It doesn't provide "value"? In order for maintenance and proper inventory control to be important, it has to be made a priority. To allow the processes that make life-saving drugs reliably and in a repeatable manner, proactive

maintenance programs must be developed from the start.

Based upon multiple study results, the below table represents the costs of each of the types of maintenance programs. The left axis in the graph represents the cost of operating equipment per year, based upon horsepower. This includes maintenance costs.

Why is inventory management important? Why not just keep two of everything? A warship does not have the ability to go to the store whenever it needs a part nor does it have the space to keep two or even one of everything. While a pharmaceutical facility has a lot more flexibility, it still does not have unlimited funds. Inventory costs much more than just the cost





of each part. It is not unusual for companies to have inventory carrying costs exceeding 25%. As such, a little inventory management can mean a lot to the bottom line and keep your ship from sinking under the excess weight of unnecessary parts.

This is where I believe the "Warship Mentality" is necessary. Manufacturing facilities are always in a fight for a company's future and survival. We must start making and communicating the importance of proper maintenance program development. How is this done?

- 1. When developing a new facility or product line, get maintenance and warehousing involved from the start of the project —and keep them involved through the entire length of the project.
- 2. Update ineffective existing maintenance programs. Start fixing them and make it important to do so.
- 3. Get your smartest and most capable technicians involved in program development.

- 4. Put in place processes requiring suppliers to provide the necessary information that allows for the development of the right maintenance tasks and inventory levels for spare parts.
- 5. Do not be afraid to make changes and improve the process; but do not make changes just to change. Be smart and manage change.
- 6. Most of all, write out your plan for improvement and follow the plan.

These steps will allow for the maintenance program to be in place with the right spare parts on site the day the equipment goes operational. Focusing on operating procedures and product materials will get you up and running, but your maintenance program will keep you there.

Treat maintenance for your facility as it is for every vessel that is out there protecting our country and make it a priority. Get your facility ready for battle. •

Glenn Wallace, CMRP, CDCDP Asset Management Discipline Lead Commissioning Agents, Inc.



Glenn Wallace is a Certified Data Center Design Professional (CDCDP) through CNet Training and a Certified Maintenance and Reliability Professional (CMRP) through the Society for Maintenance and Reliability Professionals (SMRP) with extensive experience developing, supervising and providing predictive, preventive and corrective maintenance. Glenn served 24 years in the United States Navy, leading personnel in the operation and maintenance of submarine nuclear propulsion plants.



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):

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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 2017 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2017 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. Deadline for 2017 advertisements, to start in the February 2017 issue is January 20th, 2017.

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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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.

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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.

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ISPE Carolina-South Atlantic Chapter Newsletter

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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 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.