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President's Message



Lisa Kerner

Happy Spring! The cold days of winter have come and gone – and spring has finally sprung! Looking back, we have shared many fun times together as a Chapter and we have more fun times on the horizon.

In February, we hosted our first Gala at the North Carolina Museum of Art. The event drew more than 130 attendees who had the pleasure of touring the museum's

Modern and Contemporary Galleries located in the West Building. Thanks to Eric Mayer, Networking Committee Chair and our sponsors – McDonald York, Precision Walls, SKAN, Southern Industrial, Hydro Service & Supplies, ABEC, Bahnson and Kinetics - it was a memorable evening filled with laughter and lots of fun. It's definitely a keeper for 2017 Chapter events!

On March 31st, the Chapter held our 23rd Annual Technology Conference at the Raleigh Convention Center. What an amazing day! On behalf of the board, I would like to thank Amy Lineberry, Tech Conference Chair, LeAnna Pearson Marcum and the entire committee for working countless hours to make it happen. And to our speakers, exhibitors, sponsors and attendees – we thank you for joining us and making the event possible. We couldn't do it without you!

The month of May offers more opportunities to get involved. The 22nd Annual Golf Tournament will be held on Monday, May 16th at Prestonwood Country Club in Cary, NC. This event promises to be a fun day filled with golf and networking with friends in the industry. If you are not a "golfer", we have many opportunities to get involved throughout the day. So, please join the fun and register today! We also have many sponsorship opportunities available. Check it out - <http://ispe-casa.org>.

May also brings our annual Call for Nominations as we begin prepping for the new CaSA year and selecting new board members. This is your chapter and we hope that you will consider getting involved. Being on the board requires commitment, but it is also very rewarding. So, keep an eye on your emails – Call for Nominations will be coming soon!

With that, I would like to thank all of the current board and committee members for your time and efforts. Your passion and dedication are truly inspiring!

Thank you for being a part of our Chapter. I hope that you will continue to join us on our journey to success!

Lisa Kerner

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

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Board of Directors 2015-2016

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Terence Morrison, Membership Development
Jamie Sigmon, Young Professionals
Amy Lineberry, Technology Conference
Rich Stanfield, Newsletter



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Membership Corner

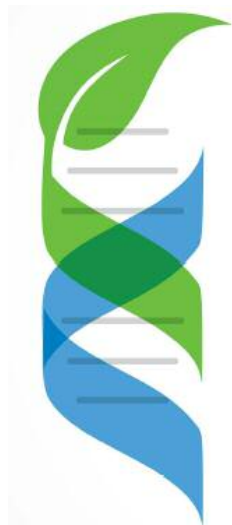
Education Committee

By Jim Hubbard, Education Committee

On behalf of the Education Committee, I would like to thank the speakers who took time out of their days to bring superb presentations to the ISPE-CaSA 23rd Annual Life Sciences Technology Conference. We appreciate their time and willingness to share important industry information with our community of professionals. We would also like to thank Jamie Sigmon and her peers for volunteering to escort the speakers.

Next Events

The Committee is planning future events in both the RTP and ATL area for the last half of 2016. More information will be coming soon.



ISPE-CaSA 23rd ANNUAL
**LIFE SCIENCES TECHNOLOGY
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Membership Corner

Networking Committee

By Eric V. Mayer, Networking Committee

The ISPE CaSA Chapter had a great first quarter for networking with five Therapeutic Thursdays, including one event in Atlanta, GA and another in Greenville, NC. The Winter Gala at the North Carolina Museum of Art was superb, so don't miss it next year! And of course, we topped it off with another fabulous Technology Conference! Hats off to the Technology Conference Committee!

Looking forward: GOLF TOURNAMENT!

The Annual Golf Tournament is always a first class event, with tons of fun, and is a great way to spend a Monday (May

16th). Please sign up your foursomes and pick your favorite sponsorship as we are expecting well over 200 people at the event. Many thanks to Gannett Fleming, Riverside Resources, and CRB for early sign-up for some of our major sponsorships.

Weiss Envirotechnics will host the Therapeutic Thursday on 28 April, and Hipp Engineering will be our host for the Therapeutic Thursday in May.

Enjoy the spring weather and the opportunity to get out and meet and mingle with your fellow ISPE colleagues! 🏠

Coming Event

22nd Annual ISPE-CaSA Golf Tournament: May 16, 2016

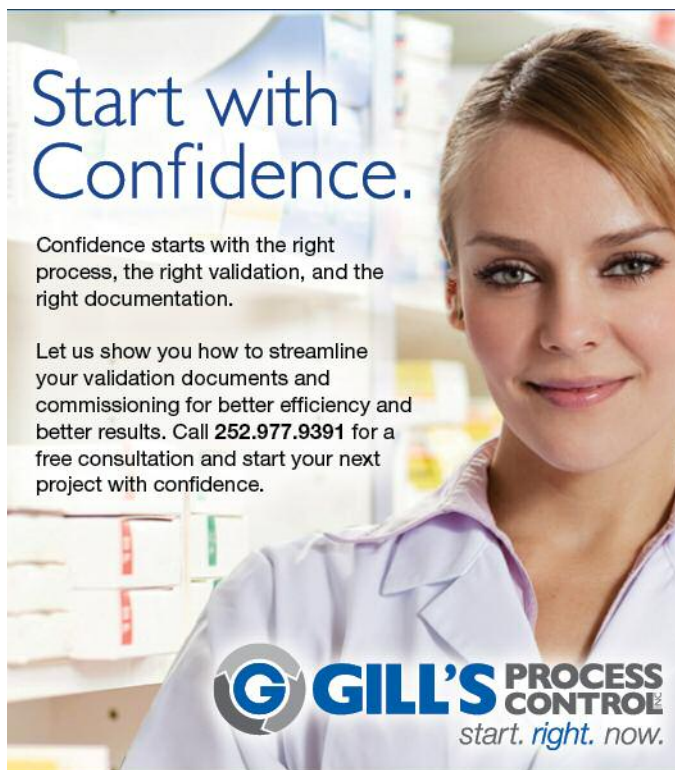
Student Affairs

By Marisol Patiño, Student Affairs Committee

We had excellent turnout at the student research poster competition preceding the ISPE Life Sciences Technology Conference on March 30th. Five undergraduate and five graduate students presented research based on their life sciences curriculum. We're happy to announce that William Kush (graduate) and Tiffany Nguyen (undergraduate) have each been awarded an all-expenses paid trip to the 2016 ISPE Annual Meeting in Atlanta. We wish them luck as they compete nationally at the Annual Meeting in September!

ISPE-CaSA will be sponsoring additional students to attend the ISPE Annual Meeting. This year, applications will be going out at the end of the spring semester; the Annual Meeting is early in the fall semester, this year. We encourage all interested students to apply for sponsorship. The ISPE Annual Meeting is an excellent opportunity to interact with international professionals.

On the International level, we are looking for Students and YPs to write articles about local events, their research, or their ISPE Experience for publication in PE magazine. For all interested, please submit your articles to Anna Maria Di Giorgio amdigiorgio@ispe.org. 🏠



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Membership Corner

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

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

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>

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

Save 10% On 2 and 3 Year Memberships!

Welcome New Members

New Members who joined February 10, 2016 through April 15, 2016

Andrew Scopel, IV
Ann Marie Jones
Anne C. Dreifke
Ashish Mohanty
Bianca Bracht
Brad Zeigler
Carl P. Rohs
Chris Musselwhite
Christan Biggers
Christopher Adkins
Christopher Helms
Christopher Joseph Dearolf
Craig Bradley
David Keith Comer, Jr.
Delaney Kolich
Divya Vijapurapu
Earlene Gibbons
Eduardo Perez
Emily Welker
Gary Pohl
George Anna Dotson
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Joshua Ross
Justin Cook
Katy Sorrells
Kenan Ezzard
Kenna Wellman
Likitha Yellaturu
Linda Proctor
Lucas Lankford
Madeline Orr
Mark Dimoff
Martin Hornbaker
Matthew Roach
Michael Cody
Michael LeCompte
Michael Scott Sherman, Jr.
Michelle Wobker
Mingchun Lin
Monica Osif
Morgan Caudill
Mukundh Chouthoy
Phil Todaro

Probir Gupta
Razeen Shepard
Richard Goulet, Jr.
Robert Richard Rankin
Russell J. Ciliento
Ryan Doxey
Shengyuan Wang
Sy-Chuong T. Le
Tanisha McClendon
Thomas Planishek, Jr.
Toddie Stewart
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Membership Corner

23rd Annual Technology Conference Wrap-up & Thank You

by Amy Lineberry, CPIP ISPE CaSA Technology Conference Committee Chair

If you attended the Technology Conference at the end of March, you had a chance to participate in the best Technology Conference yet. The ISPE CaSA Chapter Pavilion area was back and contained more manufacturers than ever. Each of those manufacturers played a huge role in the Conference and the local Chapter. I would like to thank BioTechnique, Patheon, Catalent, Novo Nordisk, Biogen, Seqirus, Merck, Hospira and FujiFilm Diosynth for their support of the 2016 Technology Conference. A special thank you to all of the Corporate sponsors as well. Without the sponsors, our Conference would not be possible.

The morning session began with Lisa Kerner, ISPE CaSA Chapter President, welcoming attendees and introducing the ISPE CEO, John Bournas. John gave an overview of the upcoming initiatives within ISPE and spoke about the 2016 Annual Meeting in Atlanta, GA.

The conference attendees were introduced to the featured charity for 2016, The HEARTest Yard. The HEARTest Yard is an initiative under Receptions for Research: The Greg Olsen Foundation. The HEARTest Yard is a family service program administered in conjunction with Levine Children's Hospital, located in Charlotte, NC. This cutting-edge program provides families of babies affected by congenital heart disease with a multitude of services including in-home, private nursing care, physical therapy and speech therapy, among other benefits. The initiative has helped over 20 families since its inception. The charity raffle was a huge success, and with the addition of a silent auction, Technology Conference attendees donated over \$6,000 to The HEARTest Yard. We are very grateful that

(continued next page)



ISPE President, John Bournas and ISPE CaSA Chapter President, Lisa Kerner

2016 ISPE Training Schedule

Register Today at ISPE.org/Training

APRIL

Manchester, UK

- GAMP® 5 Data Integrity (T50), 4 - 5 Apr.

Los Angeles, CA

- Basic GAMP® 5, Annex 11 / Part 11 (T45), 11 - 13 Apr.
- Bio Manufacturing Processes (T24), 11 - 12 Apr.
- Facility Project Management* (T26), 13 - 14 Apr.
- OSD (T10), 13 - 14 Apr.
- Water Generation, Storage, Delivery and Qualification (T04 and T23), 11 - 14 Apr.

MAY

ISPE Training Institute, Tampa, FL

- Cross Contamination (T41), 12 - 13 May
- C&Q (T40), 16 - 17 May
- GAMP® 5 Data Integrity (T50), 9 - 10 May
- QbD (T43), 23 - 24 May

Brussels, Belgium

- Basic GAMP® 5, Annex 11 / Part 11 (T45), 23 - 25 May
- Bio Manufacturing (T31), 23 - 24 May
- Cleaning Validation (T17), 23 - 24 May
- C&Q (T40), 24 - 25 May
- Process Validation (T46), 23 - 25 May
- Project Management* (T26), 24 - 25 May

JUNE

ISPE Training Institute, Tampa, FL

- Auditing (G07), 27 - 28 Jun.
- Bio Process Validation (T32), 13 - 14 Jun.
- Sterile (T12), 6 - 7 Jun.
- Q7A (T30), 20 - 21 Jun.

JULY

ISPE Training Institute, Tampa, FL

- Basic GAMP® 5 Annex 11 / Part 11 (T45), 11 - 13 Jul.
- Cleaning Validation (T17), 25 - 26 Jul.
- HVAC (T14), 18 - 20 Jul.

AUGUST

ISPE Training Institute, Tampa, FL

- C&Q (T40), 11 - 12 Aug.
- OSD (T10), 8 - 9 Aug.
- Process Validation (T46), 22 - 24 Aug.

SEPTEMBER

Barcelona, Spain

- Facilities, Systems and Equipment Workshop (T48), 27 - 28 Sept.
- GAMP® 5 Data Integrity (T50), 26 - 27 Sept.
- GAMP® 5 Process Control (T21), 27 - 28 Sept.
- HVAC (T14), 26 - 28 Sept.
- Technology Transfer (T19), 27 - 28 Sept.
- QRM (T42), 26 - 27 Sept.

San Diego, CA

- Basic GAMP® 5, Annex 11 / Part 11 (T45), 12 - 14 Sept.

ISPE Training Institute, Tampa, FL

- Application of GAMP® 5 (T11), 12 - 13 Sept.
- Bio Manufacturing Processes (T24), 15 - 16 Sept.
- C&Q (T40), 29 - 30 Sept.

Atlanta, GA

- Cross Contamination (Risk-MaPP) T41, 22-23 Sept.
- Technology Transfer (T19), 22-23 Sept.

OCTOBER

Boston, MA

- Bio Process Validation (T32), 19 - 20 Oct.
- Cleaning Validation (T17), 17 - 18 Oct.
- GAMP® 5 Data Integrity (T50), 17 - 18 Oct.
- Project Management* (T26), 17 - 18 Oct.
- QRM (T42), 19 - 20 Oct.
- Water Generation, Storage, Delivery and Qualification (T04 and T23), 17 - 20 Oct.

Copenhagen, Denmark

- Basic GAMP® 5, Annex 11 / Part 11 (T45), 31 Oct. - 2 Nov.

NOVEMBER

ISPE Training Institute, Tampa, FL

- Auditing (G07), 17 - 18 Nov.
- HVAC (T14), 7 - 9 Nov.
- Facilities, Systems and Equipment Workshop (T48), 10 - 11 Nov.
- GAMP® 5 Process Control (T21), 14 - 15 Nov.

DECEMBER

ISPE Training Institute, Tampa, FL

- Basic GAMP® 5, Annex 11 / Part 11 (T45), 5 - 7 Dec.
- Cleaning Validation (T17), 12 - 13 Dec.
- OSD (T10), 8 - 9 Dec.
- Sterile (T12), 15 - 16 Dec.



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

Membership Corner

23rd Annual Technology Conference (continued from previous page)

Kellie McGregor was able to attend and share more details about what these families go through starting just hours after their children are born.

After the opening remarks, the morning started with seven tracks of educational sessions ranging from Facilities of the Future to a track for Young Professionals and Students. Approximately 20 different companies were represented during the educational sessions throughout the day. After lunch, attendees packed the Keynote room to hear Morten Nielsen, Novo Nordisk Senior Vice President- Diabetes API US, discuss the upcoming expansion of the Novo Nordisk site in Clayton, NC.

The networking reception began with a special member-recognition award presented to David Brande.

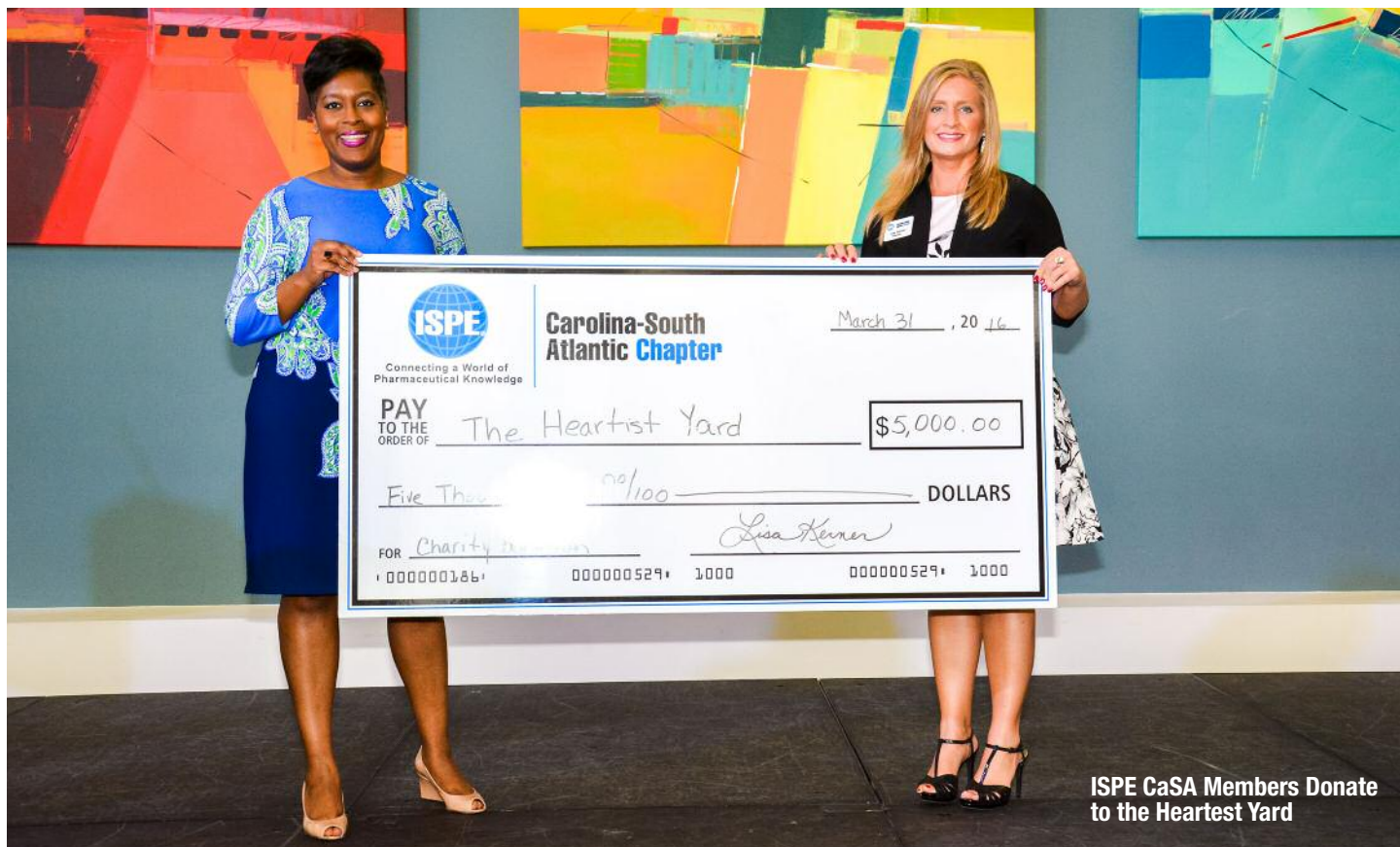
David has held many roles for the Chapter and has dedicated lots of time and energy to ensuring that the Technology Conference and the Chapter are a smashing success. Following the presentation, Cirque de Vol Studios entertained everyone with great feats, from juggling to partner acrobatics.



Keynote Speaker: Morten Nielson, Senior VP of Diabetes API Novo Nordisk

As you can imagine, the Technology Conference requires months of planning. While the Technology Conference Committee has had a few weeks of much needed relaxation, we will begin planning for the 2017 Technology Conference very soon.

(continued next page)



ISPE CaSA Members Donate to the Heartist Yard

(continued from previous page)

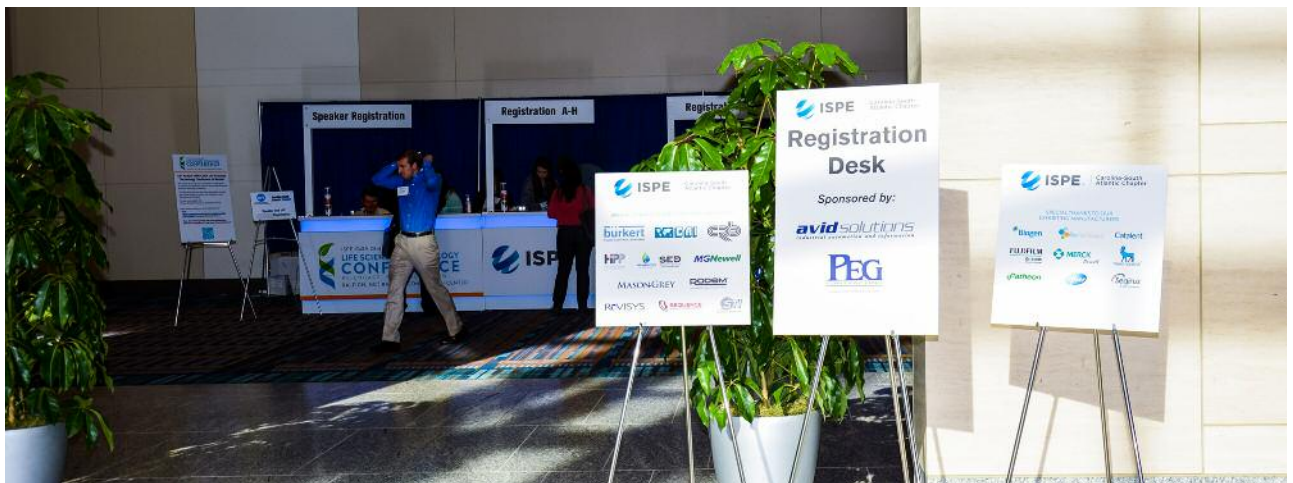
Mark your calendars for March 14, 2017! We are accepting deposits for tables and are always looking for new hands to help plan this great event. If you have any questions or would like to become more involved with the planning for next year, please email us at techconference@ispecasa.org. I look forward to seeing everyone at a CaSA Chapter event very soon!



(Above)
A Group of Young Professionals

(Left)
Post-Conference Reception Entertainment

(Below) Thank you to our Sponsors!



Technology Corner

The Future of Dosing Technologies: Multiply your Biotech Capacity and Reduce Cost



When I started my first job in college, I worked in a vaccine manufacturing facility. I was thrilled that my job was to do research and development on children's vaccines. I relished learning all that I could about the process, utilities, valves, reactors, piping, separation processes and philosophies involved, along with anything else they threw at me. I knew so little. I still marvel in wonder at the vast changes that occur in the industry on a daily basis.

A few years ago, I read an article about microneedles and started tracking the technology. Instead of using one long needle to penetrate the skin and deliver a dose into the muscular or subcutaneous tissue, microneedles inject medicine directly into the skin. The skin is the largest organ in the body and is key to transmitting much of the information from the world around us through the nervous system into the brain. Microneedle technology is growing in its application and will prove to be one of those disruptive technologies that we will tell our grandchildren about.

Microneedles are being researched by [university groups](#) and

[pharmaceutical companies](#) alike for their applications in delivering vaccines and other medicines. Unlike other transdermal dosage forms, the use of microneedles is not restricted by the texture or the health of the skin. The data that is being reported with vaccine research associated with microneedles is amazing; much smaller doses of vaccines trigger the same immune response associated with current dosages.

Imagine doubling your current production capacity without building additional footprint onto your current bulk manufacturing facility. Simply changing the [dosing mechanism](#) and location of your dosage device allows very small doses of medicine to have profound effects on the body. This is beyond exciting!

Microneedles will dramatically affect the pricing of vaccines—making more vaccinations attainable worldwide. Another benefit: Vaccines may be able to be temperature stabilized so that the cold-chain storage and shipping costs are reduced by as much as 90 percent. According to current research, these factors account

for over 80 percent of the costs associated with vaccines. If we can dramatically reduce these costs, manufacturing and deploying vaccines will become more affordable for the patient population and more profitable for the companies that spend so much time and research perfecting them.

Initially, microneedles were studied primarily for delivery of vaccines, but very quickly the research has expanded to determine if they can be used for delivery of insulin and cancer fighting medicines. [University of North Carolina](#) and [North Carolina State University](#) have been researching a thin patch of microneedles that looks like a tiny bandage to provide glucose sensing and insulin dosing for patients with insulin-dependent diabetes. The biomedical engineering researchers at [North Carolina State University](#) have also expanded the usage of microneedles for delivery of cancer immunotherapies to targeted melanomas in animal studies. The immunotherapy work itself is very interesting, but using microneedles to change and enhance treatment to a localized and sustained dosage is likely to change the way we treat melanomas. The research

group is also looking for partners to develop this research for basal cell carcinomas, another type of skin cancer.

At INTERPHEX this past year, my colleague and I discussed this and other dosage form changes that will radicalize our industry and our methods for administering many different kinds of medicines in the future. Do you have a fitness tracking device on your wrist? Imagine it being electronically connected to a medicine-dosing, wearable patch on your arm that automatically doses you with needed medicines as your body chemistry changes. Now, imagine that same scenario for patients with Alzheimer's or other diseases associated with old age who have trouble remembering to take their medicines.

The industry is on the brink of a cutting-edge breakthrough in dosing technology. Microneedles, through transdermal dosing, have the ability to reduce overall cost and increase effectiveness with an easy-to-use device. This truly is the trifecta of how the pharmaceutical industry improves the lives of its patients. 🏠



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. Myers is also recognized as a Pressure Safety Relief Systems Specialist who designs relief devices and quench/catch tanks. As a member of the DIERS (Design Institute of Emergency Relief Systems) Users Group, Christa is kept current with the most recent changes in relief systems design philosophy. 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. Her process background and understanding of process operational issues and safety hazards, enables her to assess design issues based on a risk ranking matrix that is weighted by the severity and likelihood of events to occur. Myers has been a frequent presenter at many industry events such as the DIERS Users Group, ISPE Containment Conference and Interphex.



Carolina-South
Atlantic Chapter



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 (pro-rated for partial-year advertising):

- ⌚ \$1,500 Full-color ad for six issues on the front page of each newsletter (\$250/issue)
- ⌚ \$1,500 Full-color double-sized ad for six issues (\$250/issue)
- ⌚ \$ 750 Full-color ad for six issues (\$125/issue)
- ⌚ \$ 200 Full-color ad in 1 newsletter of your choice
- ⌚ \$ 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 2016 ISPE CaSA e-newsletter.

To reserve a placement of your ad for the remainder of 2016 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. Deadline for 2016 advertisements, starting in the June 2016 issue is June 10th.

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!



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If you are interested in advertising with the ISPE CaSA e-newsletter, please contact our Chapter headquarters at:

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ISPE Carolina-South Atlantic Chapter Newsletter

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