ISPE® | Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

CaSA News

Volume 25 • Number 6

December 2018

President's Message

Mike Putnam

Happy New Year ISPE CaSA Members! I'll give you one guess on the luckiest band to listen to on New Years Day. I've got a feeling it's the Black Eyed Peas! What an exciting year 2018 was for our chapter as we hosted more than 60 events across multiple states. 2018 highlights included:

- 800+ attendees in 22 education sessions
- First Women in Pharma event held at CaSA Technology Conference
- Record turnout of 250+ for CaSA Triangle golf tournament
- First Annual CaSA Greater Atlanta golf tournament
- $15,000+ raised for Jane Brown Scholarship
- 14 CaSA student attendees sent to ISPE Annual Meeting in Philadelphia

CaSA board members are hard at work to ensure 2019 is another great year for our chapter. Our goal is to maximize value to membership through high-quality events and increased industry engagement. Please join us in starting the new year with a bang at our upcoming Automation Forum and Networking Session January 24, 2019 and Winter Gala Casino Night February 2, 2019. These events are open for registration and are filling up quick!

To facilitate increased industry engagement in 2019, CaSA is offering discounted annual sponsorship packages (see page 13) to manufacturers, vendors, and universities. These packages not only score marketing visibility for your organization, but also include admission to most CaSA events as well as annual ISPE memberships. Please encourage your organization to take advantage of this offering and sign up today to maximize your value.

(continued next page)

CaSA Toys for Tots Networking Event held 12/6/2018

Featured Sponsors

Save the Date! Mark your calendar for our upcoming events:

- Automation Education Event (RTP, NC): 1/24/2018 - Register
- Winter Gala (Umstead Hotel Cary, NC): 2/2/2019 - Register
- Technology Conference (RCC Raleigh, NC): 3/12/2019 - Register
- RTP Golf Tournament (Prestonwood CC Cary, NC): 5/20/2019 - Registration coming soon

Thank you to all Members, Board of Directors, Sponsors, Volunteers, and Students that so generously support ISPE CaSA. I look forward to serving with you in 2019 to accomplish great things!

President, ISPE CaSA Chapter

INSIDE THIS ISSUE

Did You Know Some Of Our Advertisers Use Hyperlinks?

The following advertisers are using our hyperlink feature in their ads, **NNE**, **Gemu Valves**, **Burkert, PCI**, and **03 Sterilization**, **BTEC, AdvantaPure and Sequence.** 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!

ISPE Carolina South Atlantic Chapter

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ISPE Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

Chapter Events

Networking Committee

By Chris Smith, Chair

Therapeutic Thursday

Therapeutic Thursday: January 24 Rookies Sports Bar, 4911 Central Park Dr., Durham, NC

The January Therapeutic Thursday will be offered in conjunction with the ISPE Educational Event focused on Automation on January 24th. The networking event will follow the education session and will be held at Rookies Sports Bar at the usual time of 5:30-7:30pm. There's no need to register. Sponsors provide appetizers and soft drinks. Cash bar.

Please come out for a great opportunity to connect with colleagues as we continue to expand the value and impact of ISPE-CaSA.

2019 ISPE-CaSA Winter Gala: February 2, 2019 Umstead Hotel & Spa, Ballroom & Terrace, 100 Woodland Pond Drive, Cary, NC

Enjoy an extraordinary evening featuring casino tables, a DJ, heavy hors d'oeuvres, open bar, and delectable desserts. Valet parking is provided. Due to popular demand, the wine pull raffle will return.

Bring your significant other to a grand evening of entertainment and networking at North Carolina's premier hotel and spa. Dust off those dancing shoes and start practicing your James Bond moves. It will be a night to remember. Dress code is Cocktail Attire.

Last year our event sold out. Don't miss out! Register early!

Company sponsorships are available.

CaSA COMMITTEES 2018 - 2019

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ISPE® | Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

Chapter Events

Greater Atlanta Golf Tournament

Thanks to our sponsors for the Atlanta Golf Tournament at Chateau Elan Winery and Golf Club.

PCI Calibration, Commissioning & Consulting

PSC Biotech

SEQUENCE

Harrington Pure

PROUD MEMBER HOLLOWAY AMERICA

CAI COMMISSIONING AGENTS, INC.

MUELLER

Chapter Events

Greater Atlanta Golf Tournament

And thanks to all our members who came out for a perfect day!

Golf Tournament

Awards Reception

Women in Pharma Spa and Wine Tasting Event

Membership Corner

Education Committee

By Andy Ferrell, Chair

Gene Therapy Seminar

On November 14th the Education Committee held a Gene Therapy Seminar at The Frontier at RPT. The event which attracted over 90 attendees featured two talks presented by leading experts!

Gretchen Smith, Director of Manufacturing at bluebird bio, Inc., presented *Internalizing Vector Manufacturing as a Supply Strategy for Gene Therapies*. She leveraged her broad background as a biomedical engineer with over 20 years of pharmaceutical experience in engineering, consulting, and manufacturing to share interesting insights on the gene therapy market in general. She reported that the global gene therapy market is growing at a rapid rate. Hundreds of therapies are currently in clinical trials, and a recent MIT study estimates that 39 commercial treatments will be approved by 2022. This growth presents supply challenges across the industry. She went on to describe the steps bluebird bio is taking to internalize lentiviral vector manufacturing as part of an overall commercial supply strategy.

CRB Process Engineers, Allan Bream and Emily Thompson, presented *Cellular and Gene Therapy Facilities – Designing for Flexibility, Scalability, and Cost Effectiveness*. Together, Bream and Thompson have more than four decades of manufacturing- and process-oriented pharmaceutical engineering experience. They presented a fascinating overview of the different types of cellular and gene therapy technology including CAR-T, CRISPR, and viral vector manufacturing. They also discussed facility requirements for cellular and gene therapy products, cGMP flows, HVAC zoning and room pressurization strategies, and FDA and NIH requirements for cellular and gene therapy.

The event sponsor was GEMU Valves, represented by Mr. Trey Stalnaker.

Membership Corner

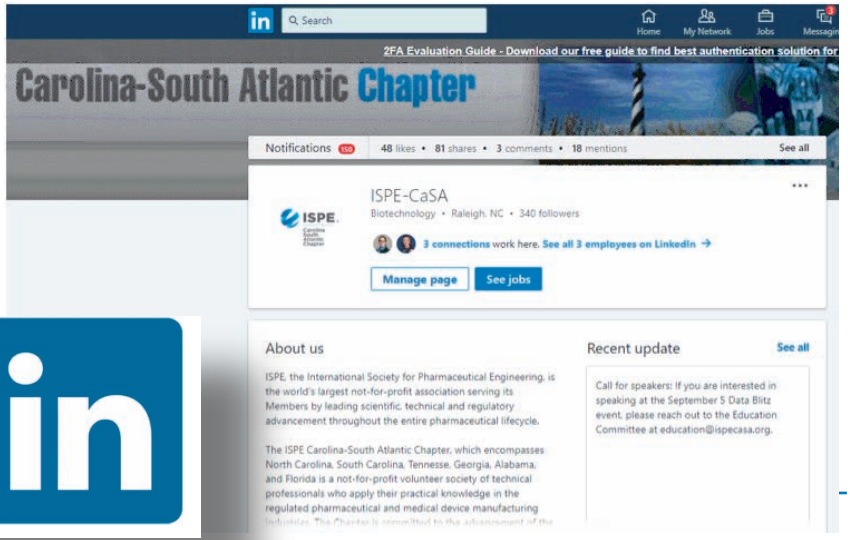
Social Media Committee

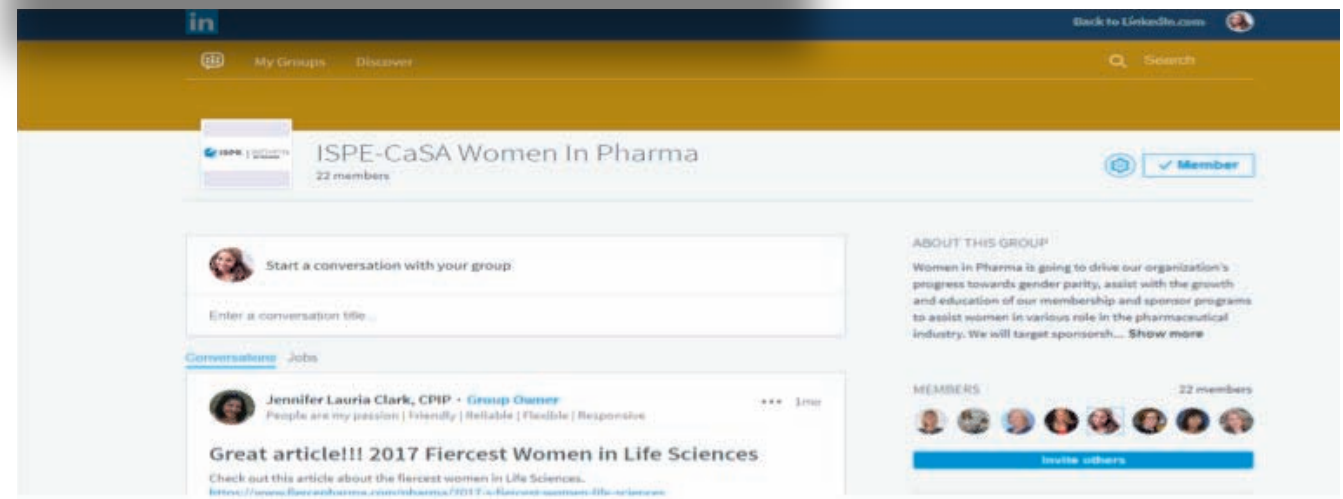
By Daniel Santarsiero, Chair

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/





Personalized Drugs Transform The Way Authorities Handle GMP

By
Monica Hueg
Global Technology Partner
NNE

"One-size fits all" no longer applies to the world of pharmaceuticals. With the increase of personalized medicine, manufacturers are pressuring regulatory authorities for faster product approval. But what else have personalized medicines changed in the GMP world?

Today, a better understanding of genetics as well as faster DNA sequencing allows doctors and scientists to provide better diagnoses, safer drug prescribing and more effective treatments. This is done by tailoring medicine to a single patient with personalized medicine [1], also known as "targeted medicine". These developments give individuals increased control over their health. But the road to effective and safe personalized medicine is filled with challenges related to good manufacturing practice (GMP).

GMP compliance is essential to ensure the quality of medicinal products. The intrinsic characteristics of personalized medicine, such as Advanced Therapy Medical Products (ATMP)[2] include variability of the starting materials, small batch sizes, short shelf life, and so on. These qualities pose specific challenges for the manufacturing process.

Additionally, early phases of research may take place in a hospital setting operating under a different quality system than those typical of the pharmaceutical sector (as given in the ICH Q10). This creates a gap of adequate systems in which to evaluate the quality of starting and raw materials. This is when personalized medicine changes the healthcare industry game – not only in the way many severe diseases are treated, but also in the way medicine is developed, approved, produced, and marketed.

Focus shift in personalized medicine

A keen focus – and a challenge – for advanced therapy medical products is GMP compliance within research, development, and manufacturing. However, recently, this focus has shifted. In 2015, GMP regulatory and compliance was all the industry could talk about. Later, in 2016, the main focus was on primary manufacturing of ATMP and secondly on GMP regulatory topics and challenges. Today, the trend leans towards manufacturing, new concepts and technologies rather than solely GMP.

The evolution of new concepts for future ATMP facilities and processes centers on the same trends we see in the large-scale pharma industry: closed systems and processes that move operators away from direct product contact and minimize product quality risk, and automation that enables the downgrade of GMP levels.

"Personalized medicine changes the healthcare industry game – not only in the way many severe diseases are treated, but also in the way medicine is developed, approved, produced, and marketed."

– Monica Hueg, Global Technology Partner

Technical Corner

Towards the batch of one

When using the patient's own cells to create a treatment for that specific patient, only one batch is used. This is due to both the use of the patient's unique cells and the patient's illness, which strictly limits the opportunities to re-do the procedure. This paradigm creates challenges on how to make these therapies commercially viable and GMP compliant, such as:

- Manufacturing capacity
- Manufacturing reliability
- Manufacturing cost
- Manufacturing flexibility/scalability
- Comparison of test results
- Classification of rooms
- Patient related logistics
- Regulatory approval of processes and product
- Cleaning
- Cross contamination / mix-ups
- Quality control
- Safety for the operators
- Safety for the patient
- From lab to the market
- Batch release
- Traceability

Full cGMP compliance is a requirement throughout every process step for manufacturing facilities for personalized medicine. However, it is important to note that today's GMP regulation was born out of pharma blockbuster manufacturing scale and does not conform to personalized medicine production. For example, personalized medicine requires much faster approval. Authorities are working with a set of regulations that are more flexible and can embed the production of personalized medicine.

The European Medicines Agency (EMA) drafted a stand-alone guideline with special focus on ATMP in 2015 Consultation Document – Good Manufacturing Practice for Advanced Therapy Medicinal Products. The revised framework aims at introducing flexibility for ATMPs.[3]

In 2013, the US Food and Drug Administration (FDA) published a report, ***Paving the way for Personalized Medicine: FDA's Role in a New Area of Medical Product Development***, reaffirming the agency's ongoing commitment to this emerging area of medicine by addressing personalized medicine from regulatory perspectives. There is still much to be done, but the agency strives to evolve its regulatory processes in response to and in anticipation of scientific developments that are critical for the development of personalized medicine.

Progress has not been swift, but the authorities are giving significantly more attention to personalized medicine and how to overcome inherited GMP obstacles in the current regulation. There will be many more regulatory changes in the near future to keep up with the expanding market, and the way GMP challenges are tackled globally will be a key influence over the future of personalized medicine.

[1] A broad term covering many different areas, no commonly agreed definition of the term yet but widely understood personalized medicine refers to three main categories; biomarker-based drug with co-diagnosis, gene therapy and cell-based therapy

[2] Advanced Therapy Medical Products include, among others, cell and gene therapies

[3] Per EU regulation 2007 (EC 1394/2007) all ATMPs are regarded as medicinal products and must therefore comply with current EU drug legislation including GMP requirements. The last contribution had the deadline of September 2016. The final version is in progress, but no deadline is published.

Monica Hueg has more than 17 years of experience with construction and verification/qualification/validation of biotech, pharmaceuticals and medical device facilities and their related production.

Monica's focus is on facilitating strategic business decisions with special attention to quality, compliance, and lean qualification such as implementing ASTM E2500. She consults on strategic planning for future production and quality improvements, often in connection with compliance gap analysis/assessments.

Monica has a master's degree in social science from Roskilde University, Denmark, and extensive theoretical insight and practical experience within GMP and compliance. She is involved in the analysis, planning, implementation, and completion of a wide range of projects within the pharma industry globally.

Monica regularly teaches courses within GMP and compliance and she has developed a number of courses within the topic.

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:	
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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 _____

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ISPE CaSA 2019 Annual Sponsorship Program

ISPE | Carolina-South Atlantic Chapter

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

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

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

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