President's Message

I can’t believe this will be my last newsletter article as President. It has been an honor to serve the CaSA ISPE Chapter and I look forward to what the Chapter will do in the future. I want to thank our board for their time and dedication. I also want to thank our management firm, First Point, for the excellent job they do to support us and our events. We had our largest ever Life Sciences Technology Conference this year – thank you all for attending, sponsoring, speaking, and hosting booths. We also had record attendance for our Golf Event in Cary. Be on the look-out for upcoming information about our Golf Event in Georgia this Fall.

We normally slow down as a Chapter in the summer, but we are having an education session and tour of Novo Nordisk on June 26. We are bringing back a popular event – CaSA Night at the Durham Bulls Ballpark on August 23. Additionally, we will continue to have our Therapeutic Thursdays throughout the summer, so check our website for cities and locations.

Our newsletter theme is “Summer of Personalized Therapy.” Summer is my favorite time of the year because there is so much you can do outside with family and friends. I enjoy watching my son play baseball, going to the beach, having barbecues, playing corn hole, and taking walks with the dog. I hope everyone will have time to enjoy the heat of the summer doing your favorite summertime activity.

In closing, I truly appreciate the opportunity to serve as your President. I strongly encourage everyone to get more involved with our Chapter and help it continue to be one of the best in the country.

Wendy Haines, PhD
President, ISPE CaSA Chapter
The following advertisers are using our hyperlink feature in their ads, NNE, Gemu Valves, Burkert, PCI, and O3 Sterilization. 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!
Today, personalized medicine is already significantly advanced. Research now shows that with generic medicine, some patients benefit, others obtain no effect at all and some even experience adverse effects. The ability to differentiate treatment between patients – even patients with the same disease – is drastically changing the pharmaceutical drug landscape. And in doing so, it has shifted the way medicines are manufactured.

One example of tailored therapies for individuals are “autologous therapies” – where a unique patient is treated with her/his own unique in vitro modified T-cells. Autologous oncology therapies are a major game changer. For example, chimeric antigen receptor cell therapy (CAR-T) initiates a bioengineered immune system attack on cancer. A groundbreaking moment in the development of these drugs was when the FDA approved Novartis Kymriah CTL019 in August 2017, the first gene therapy to treat pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL).

The FDA has approved clinical trials for advanced therapy medicinal products (ATMPs), and now 13 cell therapies are officially approved. In fact, Donovan Jones from IIR Life sciences predicts that “The global market for cell-based therapies is expected to surpass $20 billion USD by 2025, with an annual growth rate of 21%.”

'One-size fits all' no longer applies to the world of pharmaceuticals. A growing understanding of genetics, the immune system and the potential for stem cells means more effective treatments and cures for severe diseases.
Although this new paradigm may not completely replace larger manufacturing operations, this shift in operations and manufacturing is here to stay. At this stage there is not yet an all-in-one package for a sustainable and future proof manufacturing concept, but manufacturing equipment is under development to fit commercial manufacturing purposes. Therefore, new or refurbished facilities for this segment need to be flexible, agile, future proof and extremely good at handling small numbers of precious batches at a higher frequency to cope with the manufacturing of unique, personalized drugs like CAR-T therapies.

“Manual processing is prone to errors and is expensive in operations – in fact, it is said that up to 80% of errors in a pharmaceutical production are down to human error”. -Henriette Schubert

Staying in compliance: GMP challenges in a personalized medicine world

If you have a cell therapy that you are waiting to put into commercial manufacturing, there are some big decisions to make. For instance, should you build your own manufacturing facility, use a CMO, or perhaps lease a cleanroom container until processes and equipment are developed further? Whichever option you choose, the first step on this evolutionary journey is to consider the GMP implications and implement a strong control strategy.

Manufacturing autologous therapies requires aseptic manufacturing suites, which means high GMP classification during manufacturing (unless manufacturing is conducted in closed processes). Additionally, most manufacturing is currently done by manual aseptic processing, which requires highly trained and qualified personnel. And as more therapies for more patients are produced, more manufacturing suites are needed to be able to produce batches in parallel. Instead of ‘scale up’, we need to think ‘scale out’ for commercialization.

The main issue here is that manual processing is prone to errors and is expensive in operations – it is said that up to 80% of errors in a pharmaceutical production are down to human error. This percentage hits particularly hard when you consider how these unique therapies use a patient’s own stem cells, so any unplanned shutdowns or faults can result in impurities in the cellular therapy product. This can be life threatening for the patient, particularly in cellular therapy facilities where treatment is often acute.

In addition to this, Annex 1, one of the most comprehensive updates in EU GMP regulations to date, will be finalized this year. Among other things, Annex 1 focuses specifically on a general risk-based approach, moving the operator away from the product and making sure manufacturing processes are digitally traceable.

A journey towards closed processes and full automation

So how do we deal with these challenges? Most importantly, we need a change in mindset. Although manual handling still dominates in the development of autologous therapies and the start-up of commercial manufacturing, the potential for product risk and the associated costs of high grade GMP environments logically points towards closed systems like isolators. Isolators are easy to scale out and mitigate cross-contamination risk, as “open handling” is performed in a closed primary barrier system.

Short-term, this solves many of the above issues. But long-term, we need to take this one step further. The FDA guidance on Aseptic processing points out that: “Automation of other process steps, including the use of technologies such as robotics, can further reduce risk to the product”.

To substantially lower the risk of operator contamination, the ideal environment would be a fully closed barrier system, no operator in contact with the product, and a robot that conducts all handling tasks. Alongside this, utilizing single-use technology and closed process philosophy would remove the hurdles of cleaning and decrease cross contamination risk.
**Technology Corner**

**Sustainability benefits: operational cost cutting and an improved working environment**

It may not be immediately obvious, but this shift towards closed manufacturing processes has many other positive implications. For example, downgrading the GMP room classification by using closed systems significantly reduces the amount of ventilation needed in a facility. Additionally, if the operator is separated from the product there is no need to go through a full gowning procedure several times a day. Both factors mean lean operations, reduced waste, and huge energy savings.

Shifting towards this model will also significantly improve the working environment for the operators themselves. Having to gown up and down several times a day and wear a full GMP Grade B cover suit and mask is a high impact on work environment (plus not being able to go to the bathroom or eat anything for several hours must take its toll). A better working environment means happier employees, which means less stress and less errors. Ultimately, it makes a company a more attractive workplace, and a more attractive option for highly sought candidates within a very competitive industry.

**Disruptive innovation in pharma?**

Game changing trends such as CAR-T cell therapy are sending waves across the manufacturing industry. ATMP facilities are moving away from manual handling and operators handling products in GMP grade A benches with grade B cleanroom backgrounds, to more flexible facilities with automated processes and operators separated from the product.

Just as disruptive innovation has affected numerous other industries over a short period of time (think LPs to CDs to Smartphones), disruptive innovation also affects pharma manufacturing. Currently the technology does exist – but is not yet available in a convenient “all-in-one” package. Yet the speed at which innovative technologies evolve has increased at an unprecedented pace, and pharma manufacturing technology is no different. The real question is not “if”, but when and how we will implement the changes.

Finally, to develop these concepts properly there needs to be a joint and coordinated cooperation between pharma engineering consultants, universities and hospitals, equipment developers, pharma manufacturers, CMOs, and regulatory bodies. Ultimately, with a collective effort, what seemed unrealistic only 10 years ago is now becoming a real possibility. With personalized medicine and autologous therapies taking the stage, the future vision of more sustainable ATMP facilities is now in sight.

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Henriette Schubert is an expert in architecture, biocontainment and GMP facility design. With an emphasis on GMP demands and interdisciplinary biocontainment engineering, Henriette’s key focus is on consulting assignments that target the basis for decision and basis for design, front-end studies, and facility design concepts.

Henriette Schubert qualified as an architect (Cand. Arch/Architect MAA) in 1992 from the Royal Danish Academy of Fine Arts in Copenhagen. She has worked with life science projects for most of her professional life and has acquired a profound knowledge and insight into interdisciplinary facility design for biocontainment and cGMP facilities. Today, Henriette also specializes in facilities for tailored therapies/personalized medicine, combining her laboratory operations experience with her insight into the synergies and conflicts between GMP and biocontainment.

Henriette Schubert has worked on pharma and biotech projects in Scandinavia, Europe, the USA, Russia, India, and China. She has been a member of ABSA since 2007 and is also a member of the Nordic Biosafety Group, IVBWG (International Veterinary Work Group) and EBSA. Henriette is a regular speaker at conferences and symposiums.

Contact Henriette Schubert at HSBT@nne.com.
The ISPE-CaSA Education Committee is seeking additional partners for the remainder of the 2018 programmatic year to help fund our educational events. We have many upcoming programs, including a Talk & Tour at Novo Nordisk, the 2018 Data Blitz, a Gene Therapy Seminar Series, and more. Events occur throughout the CaSA region but are focused in RTP and Atlanta.

There are many benefits for becoming a partner. Here are a few:

- Networking opportunities
- Marketing your company through advertising visibility at Chapter Education Events
- Influencing young professionals, peers, and students
- Community Outreach to generously support the people and companies of our biotechnology community

Partnerships are on a first-come, first-served basis – slots are limited! Various levels of partnership are available, including Platinum ($1,400), Gold ($900), Silver ($600), and Bronze ($250). See the Partnership Form for all partner benefits and other specifics.

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**Membership Corner**

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By Rachel Leahy, PhD, RAC

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Chapter Events

Networking Committee
By Kevin Debbs

24th Annual Golf Tournament Success!

The 24th Annual ISPE CaSA Golf Tournament was held on Monday, May 21 at Prestonwood Country Club. For the second year in a row, we occupied all three of the championship courses. The weather was awesome, and we had a great turnout for the event. Specifically, we had 243 players and 20 non-golfing participants, which was a record turnout. The event couldn’t have been possible at such a high quality without the dedication, participation, and commitment of all the players and sponsors. I’d also like to thank all of the sponsors that worked behind the scenes and inside the ropes to execute this event. The list is too long to recognize all of the volunteers individually; however, they know who they are. Thanks again to all of the volunteers for all your efforts throughout the day!

In addition to a great day of golf, we raised $11,395 for the Jane Brown Scholarship Fund. This was all made possible by your generosity by purchasing sponsorships, buying mulligans and raffle tickets, and participating in the Par 5 Ball Drop. The Jane Brown Scholarship Fund was formed several years ago to honor the legacy of Jane Brown and her contributions to ISPE and our Chapter. Through this program, the CaSA Chapter provides annual scholarships to undergraduate and graduate students that are pursuing careers in the Life Sciences.

Thanks again, and we’ll see you next year!

Thank You to the Generous Sponsors Who Made this Event Possible!

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Chapter Events

Thank You to Everyone Who Made Our 24th Annual Golf Tournament Such a Great Day!
Chapter Events

Therapeutic Thursdays…

and only in June in RTP… Therapeutic Tuesday!

Join colleagues and friends for an evening of networking and enjoyment on Therapeutic Thursday! The mix & mingles run from 5:30 to 7:30 p.m. There’s no need to register in advance. Just walk in the door and start networking. Sponsors will provide appetizers. Cash bar.

In June only, we’re having Therapeutic Tuesday in the RTP area right after the Novo Nordisk Talk & Tour.

June 26/28

Therapeutic Tuesday – RTP
June 26

Therapeutic Thursday – GA
June 28

June 26

July 26

RoviSys SouthEast Offices
480 Green Oaks Pkwy
Holly Springs, NC

Location: TBD
Atlanta, GA

Location: TBD
Fort Lauderdale, FL
Chapter Events

August 30

Location: TBD
RTP, NC

Location: TBD
Jacksonville, FL

Many Therapeutic Thursday sponsorship opportunities remain for 2018. Contact networking@ispecasa.org to sponsor an event.

Bring your Family out to a Ball Game!
It’s CaSA Night with the Durham Bulls.
Make plans to join ISPE-CaSA for a family friendly event
August 23, 2018
Registration is open now!

Women in Pharma Networking Event

Save the date, July 12 in Raleigh
More Information Coming Soon.
I recently attended the ISPE Quality Manufacturing Meeting in Arlington, VA. As the incoming International Young Professional Chair this was an amazing meeting, not only for my upcoming position but for the stellar content provided by ISPE.

The first two days were spent working hard with the current International Chair, Caroline Rocks (Pictured Below), and the North American Affiliate YP Leader, Tiffany Coleman. As Caroline prepared to pass on the responsibility of International Chair for YPs it was critical for us to spend this time (face to face) planning out the goals and future direction for this committee. We spent the time working on a new, soon to be announced, document for young professionals with the guidance of Chris Reid. Mr. Reid currently serves on the ISPE European Affiliate Council (EAC) and has been past chair for the GAMP Global Steering Committee.

It was a whirlwind of educational sessions covering a wide range of quality topics. However, I was most intrigued by the open discussions with representatives from the FDA, especially around their current priorities and industry critical quality initiatives.

Make sure you pick up the next edition of the CaSA Newsletter to see if there is a big announcement about the International Young Professionals!

In the future, we will have a call for member suggestions for the goals and direction for the years to come. As you can see, we have a great team, and we are just getting started.

I believe ISPE is at a crossroads. I believe we have a great opportunity to redefine ISPE as the global leader in educational content on quality manufacturing. It is up to the next generation of leaders to continue this journey and make ISPE the best organization it can be.

I am very excited about the future of ISPE. The ISPE volunteers I met during this meeting were an amazing bunch and I am confident we can achieve our goals with their support.

Make sure you attend the next ISPE meeting so you can be a part of the future of ISPE.
Save the date for the 26th Annual ISPE-CaSA Life Sciences Technology Conference. The date and venue have been set as March 12, 2019 at the Raleigh Convention Center. Stay tuned for announcements in the coming months about exciting new additions to the conference including Keynote announcement, new Networking Breakfast, modified Exhibit Hall schedule, Cocktail Hour(s), and more!

Exhibitor advanced deposits are now being accepted. Advanced deposits entitle you to a 10% discount off the cost of your booth or table, and you will be able to participate in the early selection process. The floorplan is being revised and finalized in the next month. Be sure to get your deposit in so you have the opportunity to secure the premier locations!

Submit your Abstract! The committee will be accepting abstracts for the 2019 Life Sciences Technology Conference until Friday, 19, 2018. Additionally, if you have a topic you would like to see, contact Jennifer Clark: jennifer.clark@cagents.com. We strive to include the most relevant topics impacting the Pharmaceutical and Life Science industry.

Any questions regarding the 2019 Technology Conference can be directed to Chris Small: csmall@clarknexsen.com.

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**Vision to Reality: Delivering Next Generation Therapies**

**2018 ISPE Annual Meeting & Expo**

4 – 7 Nov | Philadelphia Convention Center, PA

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Women in Pharma Networking Event

Save the date, July 12 in Raleigh

More Information Coming Soon.
To stay in immediate communication with your favorite professional organization, connect with us on our ISPE-CaSA Company page. Stay in touch with all the 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!

Join the movement and be part of the first 1000! Join us now! Don’t delay!
CaSA Member Spotlight:
Donald Stuck

Interview by Newsletter Committee

Q: What is your full name?
A: Donald Stuck

Q: Birth Place?
A: Sunbury, Pennsylvania

Q: College?
A: Penn College of Technology and University of Phoenix

Q: Tell me a little about your personal life.
A: Married with an 8-year-old daughter. Also have 31 and 35-year-old children and a soon to be 13-year-old granddaughter. My oldest daughter lives in Reading, PA while my son is in San Francisco, CA. My wife is French with her family living in Europe. Because of this, we like to travel both within the US and abroad. Pretty much required for visiting family.

Q: What is your present position? What do you do at your job?
A: I am the Associate Director of Facilities for bluebird bio in Durham, NC. As the Facilities Director, I’m responsible for overseeing the construction and startup of our manufacturing facility. I provide input on the facility and manufacturing design to manage all support services including maintenance, landscaping, housekeeping, and security.

Q: How long have you been with your current employer?
A: I have only been with bluebird bio for 3.5 months.

Q: Tell me about your career path, and how you ended up where you are today.
A: I spent 28 years with Smithkline & French, Smithkline Beecham and ultimately GlaxoSmithKline where I started as a Controls System Technician. I spent many years growing into various roles across facilities management, capital project delivery, and outsourced FM governance roles. After retiring from GSK a few years ago, I went to work leading a consulting team for a local Raleigh company where I was able to gain a greater perspective on the challenges smaller biotech and pharmaceutical companies are faced with. I spent this time learning and developing innovative solutions across the FM space for many clients across the US. The combination of a long and growing career at GSK in parallel with experience gained developing solutions for startup facilities paved the way for the role I have today.

Q: What is your favorite part of your job?
A: Waking up and knowing that what I do today will positively impact someone and their quality of life is empowering. I am very excited to know that I can make a mark and have significant input to the success of bluebird bio and the patients waiting for our therapies. This is my favorite part of what I do because in the long run it is not for me, but for the patients that need us all.

Q: How long have you been a member of ISPE/when did you first join ISPE?
A: I have been a member of ISPE since 1997 where I was part of the Delaware Valley Chapter for many years prior to relocating to NC.

Q: What benefits have you realized from being a member of ISPE?
A: ISPE has provided me both the opportunity to learn from the conferences and training and the opportunity to be a mentor and trainer myself. The value of networking with peers and discussing various ways to solve the same problem cannot be taken for granted. ISPE is a great resource across the industry for the baseline guides, GAMP guides, and other publications.

Q: Why are you still involved with ISPE?
A: When the opportunity presents itself, I am always eager to present on multiple topics to pay it forward for the younger generations just coming into this field of work. I stay involved to ensure my knowledge can be passed on and to keep learning from my industry peers.

Q: Any Mentors/Role Models that have helped to shape your life?
A: For over half of my career, I worked for the same individual. He was not only a role model and mentor at work, but also in my personal life. He had compassion that seems to get lost in the work environment as everyone thinks of themselves and their careers. This individual pushed me when I needed to be pushed, gave constructive criticism when it was needed, and allowed me to fail and learn from those failures. He also gave me the opportunity to succeed or fail by showing me that I was responsible for my own future. These failures and successes drove me to be who I am today, and I am eternally grateful.

Q: If you weren’t involved in pharma/biotech, what business do you think you’d be in?
A: That’s easy, I’d be a hair band rocker from the 80’s playing guitar. Or at minimum, I’d be working the sound and/or lighting on tour with major headliners.

Q: What is one skill you wish you had that you don’t?
A: Drums. I cannot play drums no matter how hard I try.

Q: Any hobbies? What are they?
A: I love doing home remodeling. I could buy a brand-new home and still rip it apart to make sure it has my handprints on it.

Q: Do you collect anything?
A: Tools. Even for the smaller jobs, I always buy myself a new tool. One thing I learned in the Facilities business years ago, is
always use the right tool for the job. This has a direct impact on both the safety and quality of workmanship.

Q: Finish this sentence – “I need more...”
A: Volume. The older I get the less my hearing is like it was. Cranking up my music in the car just requires more volume than it used to.

Q: Favorite Food?
A: That’s a tough one. Being married to a European woman, we like to eat different foods than the traditional “American” diet. I love to cook so will make dishes from all over the world. Currently Indian and anything with middle eastern spices will be found on our menus.

Q: What is something that people would be surprised to learn about you?
A: My favorite job ever was running the projectors at a movie theater. That was back when projectors were real and not digital. I saw Grease 119 times and Saturday Night Fever over 80. I used to sing in the projection booth and knew every word to every song in those movies. Best part is, nobody heard me.

Q: Last movie you saw?
A: The Shape of Water

Q: For those in the early stage of their careers, what advice would you give them?
A: Perseverance. Set a goal for yourself and always strive for that goal. Sometimes you need to make lateral moves or changes externally to gain a broader understanding of your profession. Also stay engaged with organizations such as ISPE and the wonderful members of this organization. There is a wealth of knowledge. And last, ask questions. There is nothing wrong with asking questions. The old saying, “No question is a dumb question,” is absolutely true. Speak up, make your mark. People will listen.

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

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919-573-5442
info@ispeCaSA.org

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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.
Advertising Opportunities in ISPE CaSA 2018 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.

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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 2018 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2018 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. **Deadline for 2018 advertisements, to start in the February 2018 issue is January 19th, 2018.**

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.

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