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Tuesday, March 9, 2021

8:30 am - 10:00 am OPENING GENERAL SESSION &

KEYNOTE ADDRESS:

"Leading Ladies in Industry -

A Panel Discussion"

10:00 am - 10:15 am **Program Break**

10:15 am - 11:00 am EDUCATIONAL SESSIONS I

USE OF (AI) ARTIFICIAL

INTELLIGENCE AND ADVANCEMENTS

IN TECHNOLOGY -

Virtually There: Replacing Physical Walk-Throughs with Virtual Environments for

a Travel-Restricted World

CELL AND GENE THERAPY —

Considerations for Multi-Product

Facilities for ATMP Manufacturing

11:00 am - 11:15 am **Program Break**

11:15 am - 12:00 pm **EDUCATIONAL SESSIONS II**

• CELL AND GENE THERAPY -

Flexible Universal CAR-T Manufacturing in Isolators - Closing the Process from

Upstream through Aseptic Filling

 PROGRAM MANAGEMENT IN A WARP SPEED ENVIRONMENT -

Expediting EPCMV for Warp Speed Projects in the Life Sciences Industry

12:00 pm - 12:15 pm DAY 1 - CLOSING REMARKS

CLOSING REMARKS

1:00 pm - 2:00 pm **Student/Emerging Leaders Career**

Development

ISPE-CaSA Emerging Leaders Panel

Wednesday, March 10, 2021

8:30 am - 10:00 am **KEYNOTE ADDRESS:**

"The Board's Point of View -

A Panel Discussion"

10:00 am - 10:15 am **Program Break**

10:15 am - 11:00 am **EDUCATIONAL SESSIONS III**

> CDMO DRUG DEVELOPMENT **TECHNOLOGY TRANSFER BEST**

PRACTICES -

Tech Transfer Program Management -

Best Practices in the Era of COVID-19

• USE OF (AI) ARTIFICIAL INTELLIGENCE AND ADVANCEMENTS

IN TECHNOLOGY -

Digitize the Batch Records with Pharma

4.0 Technology that Works

11:00 am - 11:15 am **Program Break**

11:15 am - 12:00 pm **EDUCATIONAL SESSIONS IV**

> PROGRAM MANAGEMENT IN A WARP SPEED ENVIRONMENT -

Efficiency Gains Through Cycle Time

Reduction

WOMEN IN PHARMA —

Applying Lean Execution Tools on a

Fast-Track Project

12:00 pm - 12:15 pm DAY 2 - CLOSING REMARKS

CLOSING REMARKS

1:00 pm - 1:45 pm **How UPS Executed Unprecedented**

Delivery of Fragile COVID Vaccines

Special presentation by Wes Wheeler, President, UPS Healthcare

Program Break

Take a break! Look around the virtual lobby, get a beverage, or sit back for a bit!

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ISPE-CaSA Presents Keynote Panels

Tuesday, March 9, 2021 8:30 am - 10:00 am

"Leading Ladies in the Industry"

The women on this panel have navigated their career on different paths. Leaders in their fields, they will share their insights on what it takes to thrive in the pharma/biotech/ medical device industries.

Moderator: Wendy Haines, PhD, ISPE-CaSA Past President, Associate Director of Scientific Services at PharmEng.

Panelists: Kelli Collin, Vice President, Head of Quality at Shattuck Labs; Monique Sprueill, Senior Manager, Strategy, Insights and Innovation, Enterprise Quality Strategy & Services at Johnson & Johnson; Christine Vannais, Chief Operating Officer at FujiFilm Diosynth Biotechnologies; and Sylvie St-Martin, Vice President, Quality Assurance at Medicago.







Sprueill



Vannais



St-Martin



Haines



Wednesday, March 10, 2021

8:30 am - 10:00 am

"The Board's Point of View -A Panel Discussion"

This esteemed panel, comprised of four ISPE-CaSA Board members, will provide their perspective on how the pandemic challenged their role, how their firm adapted to a new business model, and what they see unfolding for 2021.

Moderator: Rich Stanfield, ISPE-CaSA President and North American Vice President for Commissioning Agents, Inc.

Panelists: Tolga Musa, Director of Manufacturing, Biogen; Geoffrey Ramsay, Sr. Manager, Validation, Patheon, by ThermoFisher Scientific; Jennifer Popovich, Director, Validation, Mayne Pharma; and Daniel Williams, Regional Project Director, Americas, GlaxoSmithKline.











Stanfield

Musa

Ramsay

Popovich

Williams





Welcome to the 28th Annual ISPE-CaSA Life Sciences Technology Conference

A message from Conference Committee Chair Alma Montemayor

The ISPE Carolina South-Atlantic Chapter Technology Conference Committee is excited to welcome you to the 28th Annual ISPE-CaSA Life Sciences Technology Conference. On behalf of the planning committee, thank you for participating in our first ever virtual two-day conference. It's not ideal, but for the safety of our members, volunteers, and staff – it was the best decision for the chapter.

For many, last year's Tech Conference was the last conference, social event, or gathering they attended before mask mandates were enacted, social distancing became the norm and Zoom calls took over our work lives. We all had to adapt and stay focused to meet the challenges of COVID-19. That's why this year's theme is "Race to Recovery," spotlighting how, as an industry, we have been able to shift our attention to meet the challenges of COVID-19 through unprecedented collaborations and unparalleled focus on vaccine R&D while maintaining business continuity.

This year, we will start off each day with a panel discussion. The first panel, "Leading Ladies in the Industry" on Tuesday, March 9, includes a dynamic group of amazing women who will share insights on what it takes to thrive in their industry, and they'll share their journey including successes, challenges, and mentors/ allies along the way. Moderated by Wendy Haines, PhD, an ISPE-CaSA Past President who is Associate Director of Scientific Services at PharmEng, the panel includes Kelli Collin, Vice President, Head of Quality at Shattuck Labs; Monique Sprueill, Senior Manager, Strategy, Insights and Innovation, Enterprise Quality Strategy & Services at Johnson & Johnson; Christine Vannais, Chief Operating

Officer at FujiFilm Diosynth Biotechnologies; and Sylvie St-Martin, Vice President, Quality Assurance at Medicago.

For the second panel, "The Board's Point of View," on Wednesday, March 10, we have members of our illustrious board providing their point of view on how the pandemic challenged their role, how their firm adapted to a new business model, and what they see unfolding for 2021. Moderated by Rich Stanfield, ISPE-CaSA President and North American Vice President for Commissioning Agents, Inc., panelists are Tolga Musa, Director of Manufacturing, Biogen; Geoffrey Ramsay, Sr. Manager, Validation, Patheon, by ThermoFisher Scientific; Jennifer Popovich, Director, Validation, Mayne Pharma; and Daniel Williams, Regional Project Director, Americas, GlaxoSmithKline.

In addition, our committee and board did our best to provide value with 11 educational opportunities throughout the two-day event. We'd like to thank our sponsors and advertisers for supporting our chapter. I would like to thank all those who made this possible - the entire committee, the board, those who took time to review abstracts, other volunteers, and staff who made this virtual conference a reality! We hope next year will be different and this virtual event will be unique in CaSA's chapter history.

Thank you again for choosing to spend your time with ISPE-CaSA.

Alma Montemayor, 2021 Committee Chair

Save the Date - March 8, 2022!

ISPE-CaSA 29th Annual Life Sciences Technology Conference

Please contact ISPE-CaSA's office if you have questions: 919-573-5442 or info@ispecasa.org



Join Us in Celebrating CaSA's 28th Annual Life Sciences Technology Conference

A message from ISPE-CaSA President Rich Stanfield

On behalf of ISPE-CaSA Board of Directors, welcome to the 28th Annual Life Sciences Technology Conference.

It has been a challenging year of pandemic response, moving us into a virtual environment for much of our work, Chapter collaboration and Member Support and even our personal lives as many of us spent the holidays with our families via Facetime or Zoom, etc.

We hope you enjoy the collaborative education sessions in our two-day agenda. We are grateful for the many corporations, universities, and volunteers that contributed to development and delivery of the conference this year. Your sponsorships and our Member participants are inspiring representatives of the close-knit pharmaceutical community in the CaSA Chapter. We appreciate the opportunity to host such an amazing event.

Unfortunately, many of our Chapter events were cancelled in 2020 and much of 2021. We are, however, proud to offer a series of virtual educational seminars, Women in Pharma networking and engagement, our Emerging Leader committee's support to our Student

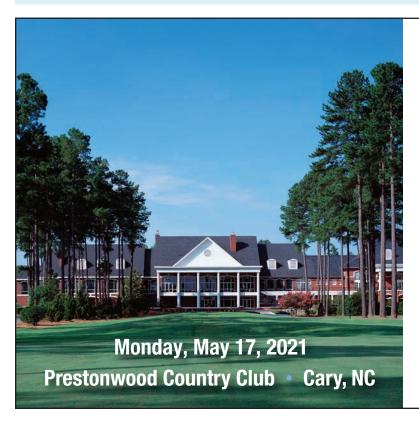
Chapters and professionals new to the industry and eager to shape their careers, and golf tournaments. Each of these events is made possible by generous sponsor companies who leverage CaSA's network to build brand awareness for their organization.

Thank you for your engagement, for your interest in and support of the Chapter and your attention to the hard work and time that our presenters put into each session today and tomorrow. If you are searching for help in solving a problem or training your teams, please send a note to info@ispecasa.org so we can serve your needs. We all volunteer to support our members!

Last, but not least, I want to thank our Technology Conference Committee, chaired by Alma Montemayor, for their hard work and nimble response to pandemic restrictions to produce this exciting event!

Thank you for joining us, and I hope you have a fantastic couple of days with us!

Rich Stanfield, President ISPE-CaSA Chapter



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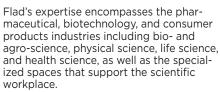
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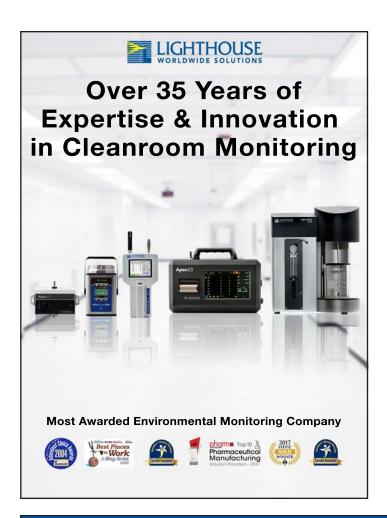
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IPSE-CaSA Past Presidents

Thank you, past presidents, for your dedicated leadership and valuable contributions to the success of ISPE-CaSA! We honor our past presidents for their substantial donation of time and talent through the years. ISPE-CaSA is one of the nation's top chapters, thanks to the visionary leadership and hard work of our past presidents.

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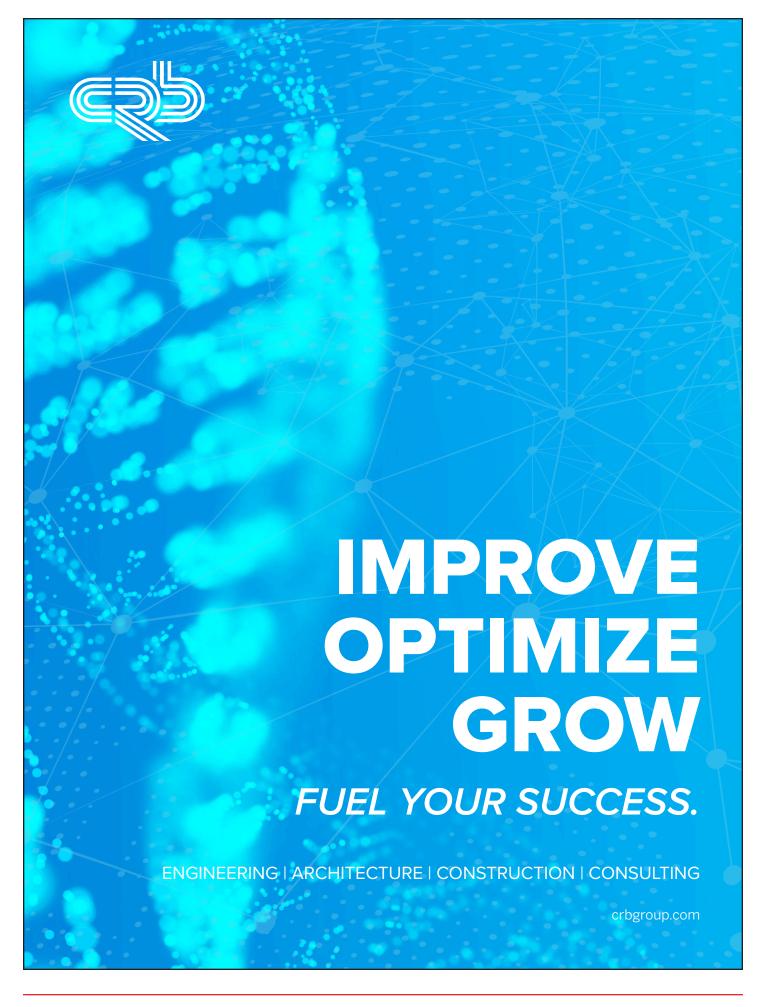
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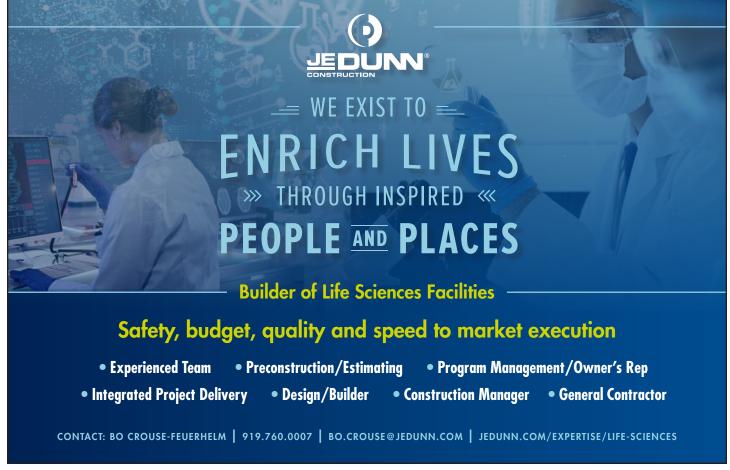


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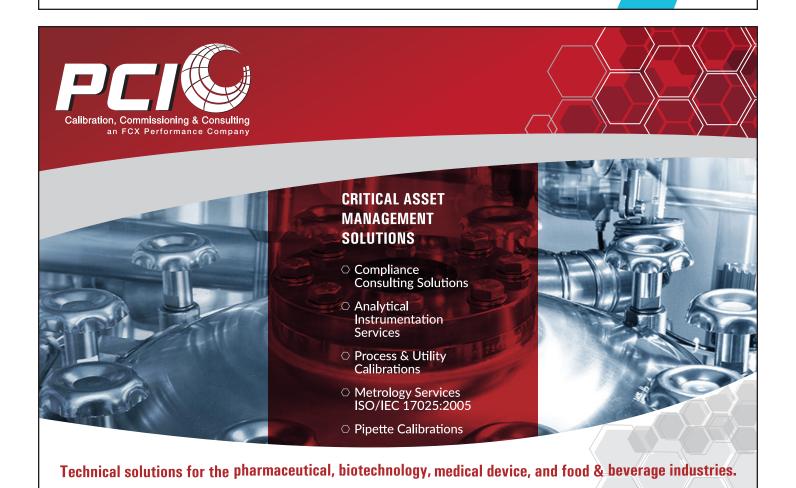
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Support ISPE-CaSA Education Efforts!

Support from industry partners is crucial to the success of ISPE-CaSA chapter education events, and the chapter is offering an opportunity to become a valued sponsor for the 2020 program year.

ISPE-CaSA presents seven themed education events, including two tailored to Emerging Leaders and Students in 2021. Sponsorships are available at \$200 for each of these events.

Among the many benefits of your support are:

- Education and career development for employees and clients
- Networking with industry leaders
- Marketing your organization through social media and visibility at Education Events
- Influencing young professionals, peers, and students
- Community Outreach to generously support the people and companies of our biotechnology community



Your sponsorship will also extend your company's brand throughout our marketplace and provide a valuable benefit to ISPE-CaSA.

Email info@ispecasa.org to learn how to support our Education Events.



ISPE-CaSA Life Sciences Technology Conference Fundraising Competition

Each year, ISPE-CaSA hosts a charity event at our Life Sciences Technology Conference.

As part of the 2021 Race to Recovery Virtual Tech Conference, our committees are competing to raise money for 5 adopted charities. From now until the end of the conference you can donate to help a charity you support to win the race.

Follow this link to our donation site:

https://www.eventbrite.com/e/ispe-casa-life-science-technology-conference-fundraiser-tickets-136951007149

and click on the box that says "tickets." From there, you can donate to the charity of your choice.

The ISPE-CaSA Board of Directors will give an extra \$1,000 to the charity that raises the most support.

Education Committee:

Raleigh Rescue Mission:

https://www.raleighrescue.org/



Membership/Outreach Committee:

Ronald McDonald House Foundation:

http://www.rmhcofnc.org/what-we-do/ ronald-mcdonald-houses



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https://foodbankcenc.org/



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ISPE-CaSA 28th Annual Life Sciences Technology Conference Planning Committee for 2021

Alma Montemayor Flad Architects **Technology Conference** Committee Chair



Theresa Leahey AEI | Affiliated Engineers



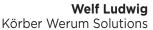
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