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The ISPE Matters Delaware Valley Chapter newsletter is created by the Marketing and Communications (MAC) Committee. For information on how you can contribute, please contact:

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www.ispe.org/delaware-valley-chapter

FROM THE PRESIDENT'S DESK

By Marvin "Guy" Royal



As we sail through the summer months, we come to the end of another Delaware Valley Chapter program year. While it has been an absolute joy serving as the Chapter President, this brings my term to an end. We have had many successes this year and some of these event details are below. However, the work does not end and we need your help carrying our mission forward. Our goal is to continuously improve the delivery of quality content and experiences to you, our members.

Our business year began in August with the uncertainty of continued COVID restrictions. However, the Delaware Valley saw the necessary improvements to allow the beginning of restrictions to be lifted and began opening up for face-to-face interactions. In September, we hosted our Annual Golf Outing, which had been rescheduled from spring 2021. It was a spectacular event. This event sold out in record time, indicating we were well on our way back to some normality in our lives.

Moving through the fall months, we continued with various committee events, having both a virtual attendance component and in-person, when possible. It was determined we should maintain a virtual connection for our members whenever possible to reach more attendees, especially as

we experience a shift in how business operates post pandemic. It has become clear we will not return to the same industry routine we knew before, which will require more virtual connectivity.

Our **Women In Pharma** committee has continued to grow its presence in the community and offered multiple events this year, from walks in the park to diversity discussions and book reviews. These events are geared toward their goal of supporting the success of women in the pharmaceutical industry.

Our **Education Committee** held a three-part series on statistics over a three-month period. In addition, prior to the start of our Annual Symposium & Exhibition, the team held a three-hour session focused on Cell & Gene Therapy Viral Vector Process Development and Facility Design. They concluded the year with an event on Third Stage Product Life Cycle: Cleaning Validation Maintenance.

In addition to the annual golf outing (which was moved from the 2021 program year) the **Programs Committee** hosted a second golf outing in May, which realigns our regular event date. Further, the team hosted a plant tour at Busch Vacuum Solutions, an event on Oral Solid Dose, cGMP fundamentals into facility design requirements, and a program on Cell Therapy Facility Design. This was a busy and successful year for this committee.

(continued on page 2)

FROM THE PRESIDENT'S DESK (CONT.)

By Marvin "Guy" Royal

Our **Membership Committee** not only sponsored one bus to Interphex for our members but two, since Interphex was held in October 2021 and also May 2022. The annual membership Holiday Party is typically held in January but was moved to March due to a bump in COVID numbers in Philadelphia. Another reminder of the challenges needed to overcome while hosting events during a pandemic!

Emerging Leaders (formerly Young Professionals) expanded their connection to their members by hosting two happy hour events, one during the fall and the second during our Annual Symposium & Exhibition. Connecting is part of the equation,

but delivering content was also accomplished by hosting an Intro to GxP event and Single Use vs. Stainless Steel presentation. This committee continues to grow their presence in the community.

Our virtual connection to area university engineering students through our **Student Affairs Committee** continues to develop through Instagram ([take a look here!](#)) Our long-term plan is to develop a forum for these students to stay connected with ISPE events, create a profile to help them connect to opportunities within our industry, and provide a portal to have their questions answered through a mentor network.

I am proud of our team for providing a very full year of content with a diverse offering of event types. We truly enjoyed being back in-person and spending quality time with our peers. The future in the Delaware Valley pharmaceutical community looks bright. Moving beyond the pandemic and learning new paths to our members has been challenging and rewarding. We wish you a wonderful summer and look forward to seeing you in September!

Respectfully,
Marvin "Guy" Royal
President 2021-2022
ISPE Delaware Valley Chapter

If you have any comments, questions, or concerns about ISPE DVC, or would like to make a suggestion about future programs events or topics, please feel free to e-mail me directly at: president@ispedvc.org



Attendees at the 30th Annual Symposium and Exhibition. Read more about the event [HERE](#).



Board members at the 30th Annual Symposium and Exhibition.



Attendees at the education event prior to the Symposium. Read more about the event [HERE](#).

MAILING ADDRESS

ISPE Delaware Valley Chapter (DVC) | #142
600 West Germantown Pike
Suite 400
Plymouth Meeting, PA 19462

UPCOMING EVENTS

Now you can see all of ISPE DVC's upcoming events in one place, making it easy to register from one convenient website. Click [HERE](#) to see what's coming up!

2021-2022 BOARD OF DIRECTORS

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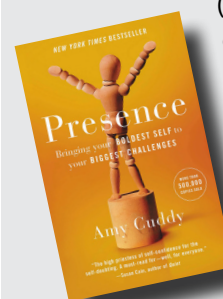
Bill Dugary, *Applied Control Engineering*

EVENT RECAP

Women In Pharma (WIP) Book Club Meeting - "Presence: Bringing Your Boldest Self to Your Biggest Challenges"

On April 28, 2022 the ISPE DVC WIP committee hosted a stimulating discussion of "Presence: Bringing Your Boldest Self to Your Biggest Challenges" by Amy Cuddy. Within the *New York Times* bestseller, Amy discusses useful tips for facing your biggest challenges. The group talked about the book and how some of the important elements effect our day-to-day lives and how our experiences have shaped our professional journey.

Since several attendees had not read the book in its entirety (due to time constraints), we may break the next book club review into several sessions and discuss a few chapters at time rather than the entire book. This way, the discussion can be more in-depth and reduce the pressure to read an entire book in a short timeframe.



WOMEN IN PHARMA (WIP)

WIP provides women in the pharmaceutical industry a forum for connecting and collaborating on technical and career advancement topics. Click [HERE](#) to learn more.

30TH ANNUAL ISPE DVC SYMPOSIUM AND EXHIBITION

Held at Lincoln Financial Field | Philadelphia

The 30th Annual ISPE DVC Symposium and Exhibition was **our largest event to date, with 126 exhibitor companies, 14 career fair suites, and over 900 attendees.**

As it has been three years since the last one due to the pandemic, it felt like a reunion for many. The halls were filled with joyful greetings and excitement to finally be back in person, make new connections, and see old colleagues. Not only was the floor flooded with attendees, both of our stages had excellent attendance, and the stadium tours, Emerging Professionals networking event, and after-party were packed.

Aside from the allure to attend a local, in-person event again, there were multiple changes this year that helped bring in new faces. **We put out a call for presentations and had over 40 submissions.**

We were able to expand the education sessions to two different stages. Many presentations were co-presented with end-user companies such as Merck, GlaxoSmithKline, Iovance, B. Braun, Autolus Therapeutics and Catalent. **We also had a great keynote this year, Audrey Greenberg, Co-Founder, Center for Breakthrough Medicines.** She discussed how the Greater Philadelphia region must build systems, support, services, and infrastructure to carry an idea from bench to lifesaving cure.

The Symposium committee increased communication about the event by sharing weekly eblasts, social media posts, creating a LinkedIn

event landing page where attendees could invite their connections, daily website updates, and emailed communication to exhibitors and attendees with details and maps.

The outdoor after-party in the new Miller Tent location was the largest party to date, with folks laughing, dancing, and making their networking rounds. As attendees are not allowed on the field's real grass at the Lincoln Financial Field, the relocation of the party off the show floor to a different outdoor space was a welcome change of pace.

To provide our attendees with more privacy when job searching, each company that participated in the career fair was in an individual skybox suite rather than a table in a shared space. Each skybox provided a secluded location to give prospective hires the opportunity to keep their interest in each company more discrete. Complimentary headshots were hosted in the previous career fair area to bring more attendees to the area. The photos were sent out just a few days after the event, to contact the photographer, you can reach Matt Romano via [email](#), his [website](#) or at 484-431-3051.

As with many companies, a staff shortage reduced the number of stadium tour leaders, food attendants and bartenders. Next year, we will request more tour leaders, more food and open both bars earlier. Although a sprinkle prevented the field games from being put out this year, we hope to have them out next year. We also

received feedback that while the band was great, it was a little too loud, so we will switch to a DJ. We also plan to add more education and start the show even earlier.

Nearly 70 percent of the post-show survey respondents would like the event hosted at the same location.

As the football schedule is still being determined, we have a tentative hold on a few dates in late May for the 2023 show at Lincoln Financial Field. April and May are the most popular times to host the show, with the least popular going back to February when it frequently snowed. The final date selection is based on its proximity to holidays and competing shows, such as INTERPHEX.

Unlike other annual chapter shows, the ISPE DVC Symposium is run by a very small group of volunteers working after hours to make the show successful. **If you are looking to join the committee, would like to volunteer the day of, or have some suggestions, please [email Symposium Vice President Sandra Bones, CPSM.](#)**

*Stay up-to-date on the latest event by following us on social media and signing up to receive our eblasts, so you never miss an event or deadline. **Thank you to everyone who attended the Symposium, and we look forward to seeing you there next year.***

Relive moments from the 30th Annual ISPE DVC Symposium and Exhibition by visiting the photo album [HERE.](#)

ISPE DVC SPONSORED BUS TO INTERPHEX IN NYC

Chartered Coach to INTERPHEX

ISPE DVC is always looking for ways to provide value to our members and this year's Interphex executive coach is no different. After a lull of low attendance numbers in 2021 due to COVID, ISPE DVC took a risk this year with a chartered executive coach in hopes that the decrease in COVID infection numbers and the rise in vaccination would lead to a more promising attendance to Interphex.

The response was 100 percent worth the effort! This year's executive coach, sponsored by [Genesis AEC](#), was an entirely sold-out event. The trip up to the Javits Center, NYC would not have been possible without the fearless leadership of our coach leaders [Lisa Dugery \(Busch Vacuum Solutions\)](#) and [Deirdre Garcia \(Torcon\)](#).

Both Lisa and Deirdre have continuously kept this annual fun tradition alive over the years and coordinated palate-amusing breakfast selections

paired with gourmet coffee and a selection of healthy accoutrement.

Every passenger was accounted for and all ISPE members, industry partners and guests got to enjoy the benefit of trekking to New York City without the woes of city traffic and parking. Networking among colleagues and rekindling of much-anticipated pre-COVID relationships were made.

ISPE DVC looks forward to serving our members in many years to come. **Please consider joining us next year for this wonderful convenience** to participate in the Life Sciences Industry Tradeshow of the Year: Interphex! Interphex 2023 will be held April 25-27.

Keep up with all things INTERPHEX 2023 [HERE](#).

THANK YOU, 2021-2022 ISPE DVC SPONSORS

The Delaware Valley Chapter of ISPE is committed to providing educational content, information on industry advancements, new and improving technologies, and social and business networking events for the local and regional pharmaceutical industry.

Since our chapter is operated entirely by volunteers, we require financial support to accomplish these activities. Some of this funding comes from our much appreciated Annual Chapter Sponsors.

From our long-standing relationships to our new supporters, we appreciate your support in affording us the opportunity to continue our contribution to our industry.

In addition to financial support, these companies collaborate with our team on technology, industry trends and new equipment. They also provide support in allowing their teams the time necessary to convey this information and get it out to you: our community.

Again, thank you to all of our sponsors in helping us succeed! If interested in becoming a chapter sponsor, please [send us an email!](#)

INTERESTED IN ISPE MEMBERSHIP?

Click [HERE](#) or [send an email](#) for more information.



EDUCATION TOPIC IDEAS?

What topics would you like to see covered at future education programs? Click [HERE](#) to send your ideas.

CELL AND GENE THERAPY VIRAL VECTOR PROCESS DEVELOPMENT AND FACILITY DESIGN

April Education Event at the Symposium

Prior to the start of ISPE DVC's 2022 Symposium at Lincoln Financial Field, the education committee held a three-hour education event focused on cell and gene therapy process development, technology and facility design. This theme was in keeping with the 2022 Symposium's focus which was on the unprecedented cell and gene therapy technology development in the Delaware Valley. **The education event consisted of four separate in-depth presentations; all conveyed leading-edge technology concepts in their respective areas.**

Kimberly-Ann Mattia from GlaxoSmithKline's (GSK) Biopharmaceutical R&D Process Technology team, took the attendees through a case study on the challenges of performing process technology transfers for viral vector manufacturing. She discussed the key aspects of transferring a process to scaled-up size at each unit operation and the corresponding challenge of meeting critical quality attributes.

The next presenter, **Dr. Blair Roszell**, from GSK's Cell & Gene Therapy Process Development organization, provided an overview of autologous cell therapies, and followed up with in-depth discussions on the development of both viral vector manufacturing and the processing of patient's cells with the viral vector.

Brian Doub from GSK's Clinical Manufacturing Operations followed-up with a case study on operationalizing a bulk viral vector manufacturing facility within an existing mammalian cell culture facility. Brian's content included the work process for assessing bio-safety risk levels, performing Failure Mode and Effect Analysis, maximizing closed processing, and the ways of working that are key to the maintaining the operations control framework for quality and safety.

Lastly, **Steve Walter**, a Senior Process Technology leader from Hargrove Engineers and Constructors, led a discussion on the critical elements of facility design for both autologous and allogenic cell therapy manufacturing facilities. Steve addressed the key process differences, facility layout strategies, and the equipment required for each modality, providing a great overview on the design considerations that should be addressed during the conceptual engineering phase.



Across all three presentations, there were thoughtful questions and engaging discussions from the participants with

contemporaneous challenges in the technical areas presented. The attendance for the education event exceeded 60 people. The level of engagement, the attendance, and positive feedback received on the event were all indicative of the level of technology and manufacturing development that is presently taking place across this tech sector. **ISPE DVC will continue to bring to its membership more in-depth topics on cell and gene therapy in the future** as well as opportunities for Professional Development Hours (PDHs). This event provided 3 PDHs to all of the attendees.

Presenters for this event included:

- Kimberly-Anne Mattia, Manager Process Technology, GSK
- Blair Roszell, PhD, Manager Cell and Gene Therapy (CGT) Vector Process Development, GSK
- Brian Doub, Scientific Investigator Downstream Processing, GSK
- Steve Walter, Process Technology Leader and ISPE Certified Pharmaceutical Industry Professional, Hargrove Engineers and Constructors

YEAR END ISPE DVC BOARD OF DIRECTORS MEETING

Workhorse Brewing Company

Just as June brings an end to the Delaware Valley Chapter's program year, so comes our last board of directors meeting, held at Workhorse Brewing Company. This venue hosted successful events during the program year, and we believed it would be a good opportunity for the board to understand the differences and benefits of this type of location compared to a traditional hotel environment.

As we did last year, we invited all DVC board members, key committee members, Owner Advisory Group (OAG) members, and chapter sponsor representatives. This group provides a good representation of key stakeholders in our chapter.

During the board meeting, each committee vice president provided a summary of the events their team held in the past year. We provided a high-level view of the board's performance for the year and a glimpse into next year's team.



After the meeting formalities we had drinks and food while discussing strategies for the new year, past experiences and the industry's interests for future programs and events. **We welcome input from the industry in any form to maintain the pulse and needs of our local industry partners.**

Next up will be DVC's planning retreat to prepare for and kick off another successful year. We are hoping to continue moving out of the shadow of COVID and increasing event participation with new and innovative content delivery at exciting venues!

OWNER ADVISORY GROUP

ISPE DELAWARE VALLEY CHAPTER OWNER ADVISORY GROUP (OAG)

Being an effective contributor in an industry that operates in high-risk environments, under regulatory scrutiny and highly commercial competition, you need the support of industry leaders. We call upon these leaders to provide input on where they require specific technical and regulatory education (that may not be readily available) and collaboration with industry trends to help align the workforce.

We attempt this via regular meetings and working sessions. However, during the COVID pandemic, we have struggled to meet these objectives. As we begin to see light at the end of this long tunnel, we look forward to engaging our OAG team and advancing these discussions.

We would like to thank the contributions from our OAG team and are looking for additional members to join us and improve our capabilities.

If you are interested in joining the OAG team, please contact Marvin "Guy" Royal at president@ispedvc.org.

SOCIAL NETWORKING

DVC members are invited to join our group on LinkedIn for event notifications, networking and information sharing. Find us at ISPE-DVC on LinkedIn, Facebook, Instagram and Twitter or click the images below:

Due to COVID-19, our next Habitat volunteer date is unknown. Please consider supporting your local Habitat through financial or goods donations. You can locate your local organization [HERE](#).

ISPE DVC 28TH ANNUAL GOLF CLASSIC

North Hills Country Club | May 9, 2022

Greetings fellow golfers, duffers and hackers! We all had another great day of golf with excellent weather, great friends and business associates, food and beverages, and we managed to do it in true ISPE DVC style. We had a great turnout, and this marked our 28th ISPE Delaware Valley Chapter's Golf Classic. We hope to continue it annually once again. Our hosts at North Hills Country Club (NHCC) in North Hills, PA knocked it out of the park again this year. The staff at NHCC was top notch. Our guests were treated like members of the club throughout the day.

Special thanks to Jack Connelly and his team at NHCC for providing us with a wonderful venue for our outing and introduced us to a new 50/50 event with the golf ball toss. Our participants had a ball—tossing golf balls that is—into a preselected hole on the practice green and our winners who managed to get one of them into the cup made some decent cash too.

Thank you all once again for attending and supporting our outing the way you do. We simply couldn't make this happen without you.

As golfers arrived at the registration area, they were treated to an ISPE DVC duffle bag door prize. After checking in, golfers were able to enjoy an outdoor lunch buffet, the driving range,

and the practice putting green before the start of the golf outing.

This year's winners, based on the best scores in three flights, established based on arbitrarily selected holes determined by our pro were:

Winners

A Flight (score = 65)	Mike DeBellis Curt Biehn Bill Nesti (open)
B Flight (score = 65)	Jack Lenoir Sterling Minter Bryan Overbeck Pete Scarpati
C Flight (score = 66)	Mike Alexander Wyll Cass Dave Cockran Matt Thompson
*Highest Score (score = 83)	Sidney Biddle Mike Brennan Chris Fell Terry Jacobs

Liberty Bell wall plaque trophies and pro shop gift cards were awarded to our winners in each flight as well as gag gifts to our highest scoring foursome—all in good fun. The whiffle ball and bat sets were carefully selected to help develop their hand eye coordination and improve their golf game for next year! With some practice, we may get to see them up for some of the golf awards next year.



Once again, our Golf Classic was supported by our generous sponsors. We were able to offer another year of our Golf Clinic led by our NHCC golf pro. Lessons learned were utilized in our putting contest and our winner was awarded with a trophy of their own to commemorate their accomplishment.

Sponsorships also included door prizes, tee box sponsors, hole sponsors, trophy sponsors, and refreshment station sponsors. This was another banner year for our outing. The prize table was abundant with great raffle items, giveaways, prizes and awards. Thank you to all our sponsors who continually surprise us with their generosity and support of our golf outing. You really make our outings great fun each year.

Refreshment station sponsors were **Herman Goldner Co., RPA Engineering** and **Hargrove Life Sciences**. Special thanks for keeping our golfers hydrated with a variety of beverages and snacks throughout the round. And this year, NHCC kept us well stocked.

ISPE DVC 28TH ANNUAL GOLF CLASSIC (CONT.)

North Hills Country Club | May 9, 2022

Hole Activities and Prizes

1	Straightest Drive (men/women)	His and hers putters (Sponsored by Bahnson Environmental Specialties)	Anthony Coochimiglio and Sidney Biddle
3	Closest to the Pin	Eagles Logo Golf Bag	Frank Haughey (7'-0")
7	Closest to the Pin	New Driver	Rich Hylinski (8'-6")
9	Closest to the Pin	Wingman GPS System	Jack McGinley (13'-5")
11	Closest to the Pin	No. 3 Fairway Wood	Jason Foos (7'-4")
14	Closest to the Pin	Vizio 32-inch TV	Pete Scarpati (16'-10")

Once again, our very own photographer **Laura-Ann Chin** was out on the course and taking photos of us all. [See all of the event photos here.](#)

Out on the course our golfers competed for prizes on several holes throughout the day. Competitions and winners included:

The North Hills banquet room provided us with an open bar cocktail hour and hors d'oeuvres while chatting with friends, colleagues and clients. The dinner buffet included an incredible seafood raw bar, with succulent shrimp and crab legs, carved meats and salads. Everyone was well fed and enjoyed the cuisine.

During the awards portion of our evening, we presented our chapter President, Marvin "Guy" Royal, with his very own Presidential Putter. It's a token of appreciation for the time and hard work he put into performing the duties of President and keeping our chapter running smoothly with educational and social events throughout the year. Thank you again, Guy. It's been a pleasure working with you over the years and I am proud to call you a friend as well. Best of luck in your retirement. Some of us only dream of sailing off into the sunset, but you and Marie are actually doing it.

Again, none of this could happen without our chapter manager, **Susan Padien**. She works

tirelessly with registration, billing, cancellations, chasing payments, and keeping track of everyone. Thank you so much, Sue, for another great golf classic event.

Also thank you to all the committee volunteers who helped us with registration, preparing our door prizes and

(continued on page 10)

2023 GOLF OUTING: SAVE THE DATE!

Our 29th Annual Golf Outing is scheduled! The event will be held on May 8, 2023 at North Hills Country Club.

ISPE DVC 28TH ANNUAL GOLF CLASSIC (CONT.)

North Hills Country Club | May 9, 2022

handing them out, setting up trophies and the prize tables, out on the course monitoring our hole-in-one competitions, taking photos of our foursomes (with champagne, I might add), and countless other little details. I thank every one of you for your time and contributions to the outing; we couldn't do this without you. I would also like to acknowledge and thank **Bill Nesti** who was there to help me at the last minute when my other right hand came down with COVID. Thank you, my friend.

To all our incredible sponsors, on behalf of everyone on the DVC Board of Directors, the programs committee, our golfing members, and their guests, we sincerely thank you for your continued support, not only at our golf outing, but for all our programs throughout the entire year.

This year's outing was another huge success and attendance was even better than expected. We hope this will continue for our future outings and all of our chapter events. **We will see you again at our 29th ISPE DVC Annual Golf Classic to be held at the North Hills Country Club in Glenside, PA on May 8, 2023.** We are already looking forward to it!

So, until we meet again, hit 'em long, and hit 'em straight! Stay safe!

Mike DeBellis, 2022 Golf Outing Program Manager



WE ARE LOOKING FOR AN IT VOLUNTEER TO ASSIST OUR CHAPTER!

The purpose of this volunteer role is to assist our board members and committees with IT support at events and meetings. Responsibilities could include, but are not limited to:

- serve as the first point of contact for board or committee members seeking technical assistance, either virtually or in person
- visit venues prior to events to confirm the technology set-up is suitable for ISPE DVC presentations and panels

- work with venues and meeting spaces to set up technology the day of chapter events and meetings
- troubleshoot any issues that may arise during an in person or virtual event or meeting
- provide accurate information on IT products or services and/or recommend any additional technology the chapter should invest in to provide the best possible presentations to our members.

Please reach out to president@ispedvc.org or execvp@ispedvc.org for more information!

CELL THERAPY FACILITY DESIGN - LOOKING BEYOND AUTOLOGOUS: TRANSITIONING TO ALLOGENEIC

June Programs Event

On June 1, 2022, the programs committee hosted at Plymouth Meeting Doubletree a presentation on cell therapy facility design entitled "Looking Beyond Autologous: Transitioning to Allogeneic."

Many cell therapy manufacturers are now investigating next gen allogeneic replacements for their existing therapies, resulting in the need for flexible facilities that can accommodate both processes.




It is key to be able to transition existing facilities and operations from autologous to allogeneic.

Delivered by a panel of Tyler Underhill and Daryl Kern of PM Group, the presentation covered the challenges and different attributes of the allogeneic cell therapy processes vs. autologous processes and how best to incorporate adaptability and/or flexibility in current and new facilities without

affecting the therapy quality. **This presentation was well-received by pharmaceutical professionals** as well as a variety of other industry professionals, which propagated a lively question and answer session addressing a span of technical design content.

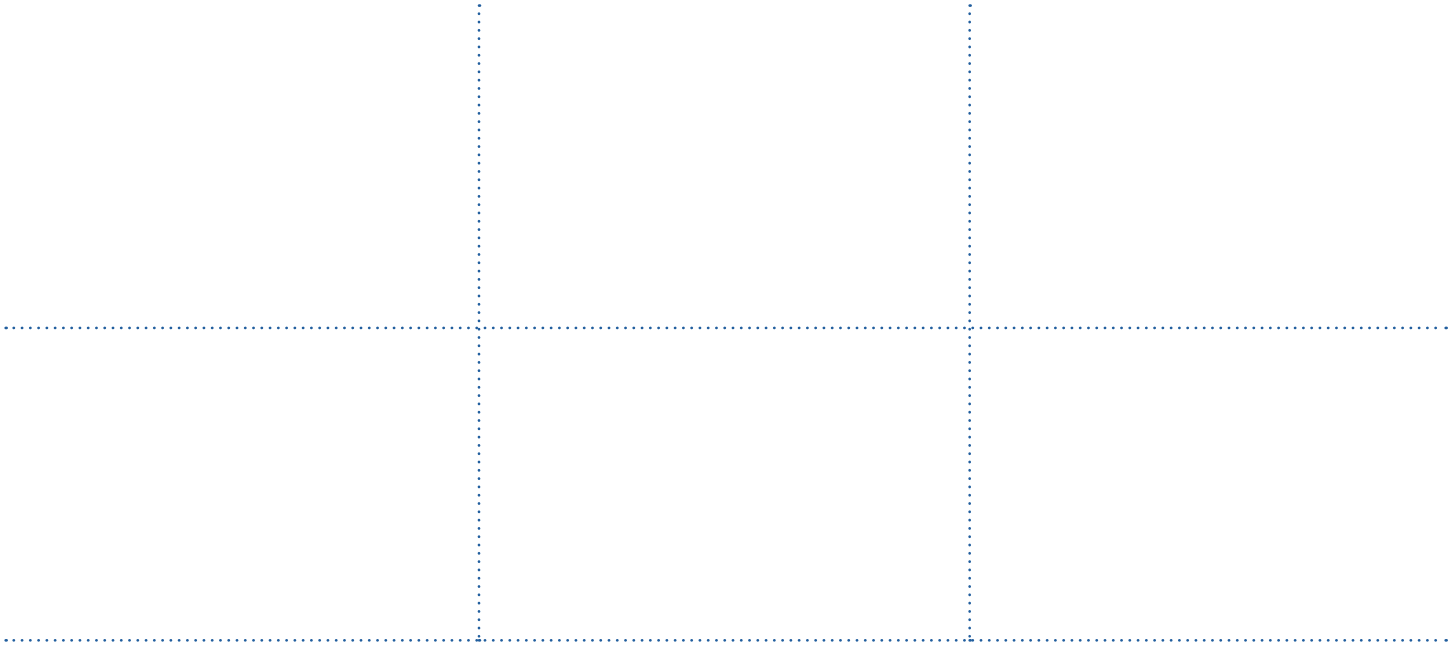
ISPE ACCEPTS VENMO OR PAYPAL FOR IN-PERSON EVENTS

We now accept VENMO or PayPal for walk-in events/onsite registration

PayPal QR Code (WITH PayPal Account)	PayPal QR Code (WITHOUT PayPal Account)	Venmo QR Code
User must have a PayPal account	User does not have to have a PayPal account (can pay with debit/credit card without PayPal account sign-in)	User must have a Venmo account
International Society for Pharmaceutical Engineering Inc.  PayPal		ISPE DVC @ispedvc  venmo

THANK YOU TO OUR 2021-2022 SPONSORS FOR
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WRITE IT DOWN!

If you would like to be published in ISPE Matters, please send your articles or ideas to us for consideration in the next issue.

All prospective articles should be emailed to Tieg Murray Rustam at MAC@ispedvc.org

CONNECT WITH US!

UPCOMING EVENTS

Now you can see all of ISPE DVC's upcoming events in one place, making it easy to register from one convenient website. Click [HERE](#) to see what's coming up!
