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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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[MAC@ispedvc.org](mailto:MAC@ispedvc.org)

ISPE Delaware Valley Chapter  
[manager@ispedvc.org](mailto:manager@ispedvc.org)

[www.ispe.org/delaware-valley-chapter](http://www.ispe.org/delaware-valley-chapter)

## FROM THE PRESIDENT'S DESK

By Eleanor Small



**Eleanor Small**  
**Principal Scientist**  
**Johnson & Johnson**  
**Consumer, Inc.**

Welcome to 2021. While part of me wanted to celebrate that “we made it,” let’s level set. In this industry we know the turning of a calendar page does not magically cure a global pandemic, solve racial inequity and create inclusion, or fill the sorrows left by of those we lost. There is still much work to be done to achieve our new normal, and it is going to be uncomfortable at times. Despite 2020, or perhaps because of it, I found a renewed conviction in our power to create change for good.

When I reflect on 2020, I think about the truths we have learned about our industry and about each other. The past 12 months we have spent a lot of time in each other’s homes. We have been joined by children and pets at meetings, discovered new decorating tips from home “offices,” and learned that, yes, our senior leaders have bad hair days too. We have learned to stop apologizing for being human. Let us embrace this new, more authentic connection and keep this momentum going with humanity and heart.

At an industry level, we have also seen changes. The level of collaboration between leaders of the pharmaceutical industry is, dare I say it, unprecedented. For the first time competitors are

challenging each other from a place of support and celebrating each other’s successes. Imagine what our industry could achieve if this became the standard. Imagine what we will do for health inequity, sustainability, so called “incurable” diseases. Whether as individuals, as a chapter, or as an industry, when we work together imagine the innovations we can unlock.

This is my challenge to you for 2021: become a leader who drives innovation through collaboration. In my career, I have found the best tool to create a unified team is to lead with genuine gratitude. No matter how steep the challenge you face, take a moment to look up, not at the finish line, but at those around you. Reflect on how they have impacted you and share your gratitude.

I’ll start the challenge by expressing my gratitude to you, our members. You placed your faith in this board to guide you through another year, allowing us to establish new standards in digital programming, education and chapter administration. Through your support we welcomed six new members to our various committees, kicked off our Women In Pharma (WIP) mentor circles, and established a VP of WIP on our board structure. We are thankful to our sponsors, who stood by us as we ultimately had to cancel two major events and returned to support us again this year.

*(continued on page 2)*

## 2020-2021 BOARD OF DIRECTORS

### President

Eleanor Small, *Johnson & Johnson*

### Executive Vice President

Marvin Royal, *ValSource*

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### Treasurer

Amy Markey, *Cabeletta Bio*

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Bill Dugary, *Applied Control Engineering*

Glenn Lawrence, *Merck & Co.*

### Past President

Kristina Pumphrey, *Precis Engineering*

## FROM THE PRESIDENT'S DESK (cont.)

By Eleanor Small

Finally, I want to share my gratitude to our chapter Officers and Board of Directors. Our small group did not make it through 2020 unscathed. Like the rest of the world around us, we saw the impacts of 2020 up close and personal. Every one of you went all-in for one more term, and continuously tried new strategies to keep our programs running. I have never been prouder of this group, than when I witnessed how we rallied around one another in times of need, covering deadlines for each other and reaching out to each other.

As we enter 2021 with cautious optimism for a return to "normal," may we carry forward with heart and gratitude. From the bottom of my heart, thank you for your faith in me for this second year.

If you have any questions, please reach out to a member of our Board or directly to me at [president@ispedvc.org](mailto:president@ispedvc.org)

- Eleanor F. Small, Ph.D.  
President, ISPE Delaware Valley Chapter

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**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](mailto:president@ispedvc.org)**

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## NOT AN ISPE DVC MEMBER BUT INTERESTED IN JOINING?

Contact Laura-Ann Chin, ISPE DVC's VP of Membership, today at [Membership@ispedvc.org](mailto:Membership@ispedvc.org) or join our mailing list [HERE](#).

*\*Use Promo code: JOIN2021 for \$40 off Industry Member Rate. For New Members only.*

*\*For existing members, don't forget to turn on the membership auto-renewal feature for ease of renewing membership yearly.*

## ISPE DVC'S MAILING ADDRESS

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

## 33rd Annual Holiday Gala

Reading *Between the Wines: A Virtual Wine Tasting* by Baldacci Family Vineyards, Napa Valley, CA

Once again, COVID could not stand in the way of ISPE DVC’s signature 33rd Annual Holiday Gala. This year, the highly anticipated gala featured an exclusive virtual Wine Tasting event showcasing Baldacci Family Vineyards of Napa Valley’s famous Stag’s Leap district. This sold-out virtual wine event brought together our members in the comfort of their home over Napa Valley’s finest libations and a carefully curated artisan cheese and cracker box sponsored by Genesis AEC.

ISPE DVC members got to learn firsthand from Michael Baldacci, himself, owner and winemaker of Baldacci Family Vineyards on the vineyard’s history, Stag’s Leap district and the craftsmanship behind each bottle of wine. Quinn Kraft, Hospitality Director, stirred up a spirit of friendly competition among members with a wine-themed live trivia followed by a series of biotech/pharma

questions. Congratulations to John Dearnaley of Verista for sweeping first place and winning a \$50 gift card to Baldacci!

Toward the end of the evening, members were graced by the angelic voice of professional opera singer, Amy Armstrong, featuring arias from Puccini, Mozart and Charpentier. Members bid adieu to 2020 and welcomed in 2021 by collectively singing acapella to the tunes of Auld Lang Syne. What an evening to remember!

**Special mention: This event would not have been possible without the generous support of Steve and Barbara Hall who introduced ISPE DVC to Baldacci, Genesis AEC for the cheese and cracker box sponsorship and to our event sponsors: Jennings Alberts and Johnsrud Architects, a Bergmann Company for your continued support!**

### EVENT SURVEY

#### WANT TO ATTEND IN-PERSON EVENTS?

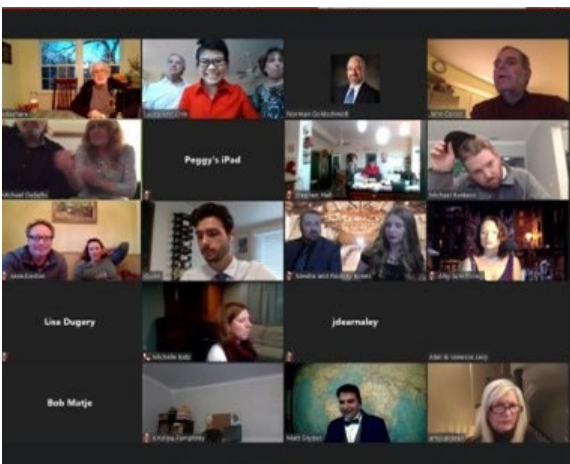
Tell us by filling out our [SURVEY!](#)

ISPE DVC is looking forward to hosting more great events in 2021! To help us plan for the year, we are asking our members to answer a quick, 10-question survey.

The survey asks if and when you might want to attend in-person events and how you’ve been enjoying our recent virtual events. Thank you for sharing your valuable opinion with us.

### EDUCATION TOPIC IDEAS?

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





## ISPE DVC WOMEN IN PHARMA (WIP) MENTOR CIRCLES

WIP Mentor Circles have started!

A concept developed at the international level, ISPE began promoting the concept of Mentor Circles at the end of 2018. The goal is to promote growing relationships and career development for people in pharmaceutical manufacturing and development.

For approximately one year, the mentor circles will meet at least three times; ISPE DVC has committed to meeting once a month! Time is spent networking, learning about mentorship, discussing technical topics and sharing ideas. While this program was initiated by the Women in Pharma (WIP) committee, both women and men are encouraged to attend.

For our first Mentor Circle meeting, held in October 2020, the team of interested ISPE members met via Zoom and got to know each other a little better. We are fortunate to have access to an ISPE Zoom platform, all courtesy of the platform sponsors: PharmaTech, IPS and PQE group. While we do hope to have a face to face meeting at some point in 2021, we are thankful we have technology at our fingertips to allow us to engage with our colleagues.

In November 2020, our second meeting focused on the topic of Artificial Intelligence and was led by Rodney Durban of ABB Inc. A smaller group gathered this month (11 members total), but robust discussion about the application of AI and new technologies to the pharmaceutical industry was enjoyed by all in attendance.

In late January, we heard Lauren Andersen's perspective on mentorship and the benefits she has experienced during her career at Merck. Currently serving as an Executive Director of MRL Development Quality, she is passionate about mentorship and credits her career success to the many benefits she has gained being both a mentee and a mentor.

In February, we are partnering with the DVC ISPE Education Committee to have a follow-up discussion with the speaker, Alexander Adams from GSK, on the topic of the environmental impact of biopharmaceutical manufacturing. **The seminar is scheduled for February 18 from 8-9am EST, and the WIP Mentor Circle discussion will take place on Wednesday, February 24 from 4-5pm EST.**

There is still space for additional participants. We have a core team of five people organizing the monthly sessions, so there is opportunity for up to 50 total participants (ideally break out discussions will have no more than 10 people).

If you are interested in joining ISPE DVC's mentor circles, please reach out to Michelle Batz at [michelle\\_batz@merck.com](mailto:michelle_batz@merck.com)

## WOMEN IN PHARMA

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



October 2020 WIP Mentor Circle Participants

# MAKING SENSE OF RECENT COVID NEWS

Emerging Leaders Committee (formerly Young Professionals Committee)

The Emerging Leaders Committee (formerly Young Professionals Committee) kicked off the 2020-2021 year with a lunch and learn on November 18, 2020.

During our fourth lunch and learn on a series about COVID-19, Dr. Dennis Gross provided attendees with an update on the fight against the virus.

The presentation began with a brief virology refresher (including debunking some myths related to COVID) and then transitioned into an overview of the clinical trial process. Of those drugs in clinical development at the time of the presentation, Dr. Gross accurately predicted that the mRNA vaccines seemed the most promising (38 percent of those in late-stage clinical) followed by traditional inactivated virus vaccines (22 percent).

The lunch and learn concluded with some best estimates regarding when vaccinations will be complete and when life can return to “normal” again. A big thank you to everyone who attended. The feedback we received was fantastic!

**Topics of the other three lunch and learns in the COVID-19 series included Immunology 101 for the Non-Biologist, Vaccines and Anti-Viral Agents.**

## 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 [execvp@ispedvc.org](mailto:execvp@ispedvc.org).

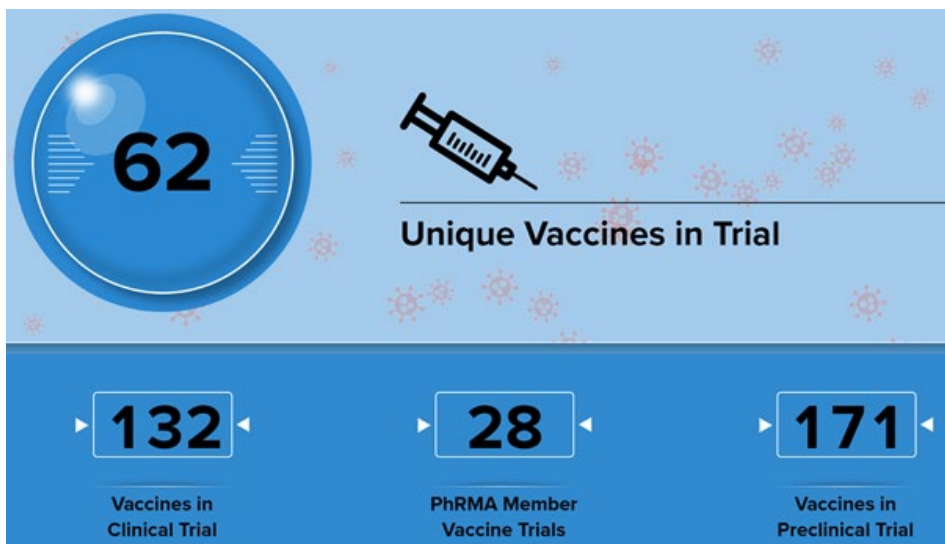


Image from [PhRMA website](https://www.phrma.org) // current as of February 16, 2021

## INTERESTED IN ISPE MEMBERSHIP?

Email [Laura-Ann Chin](mailto:Laura-Ann.Chin) for more information.

# PHILADELPHIA REGION FUTURE CITY COMPETITION

2020-2021 Future City Theme: Living on the Moon

The Philadelphia Regional Future City Competition is a 501(c)3 educational outreach program of DiscoverE.

It is one of 41 regional programs conducted throughout the country with the goal to introduce sixth, seventh and eighth grade students to the engineering profession. The program continues to be on the National Association of Secondary School Principals' National Advisory List of Student Contests and Activities.

## Future City Engages Kids in Engineering and So Much More...

This flexible, cross-curricular educational program gives students an opportunity to do the things that engineers do: identify problems, brainstorm ideas, design solutions, test-retest, build and share their results. This process is called the engineering design process. With the process at its center, Future City is an engaging way to build students' 21st century skills. Students participating in Future City:

- Apply math and science concepts to real-world issues
- Develop writing, public speaking, problem solving and time management skills
- Research and propose solutions to engineering challenges
- Discover different types of engineering and explore career options
- Learn how their communities function and become better citizens themselves

- Develop strong teamwork and project management skills

## Competition

Students in the Greater Philadelphia area work as a team from September to January with an educator and an engineer mentor to:

- Prepare a project plan
- Research and write solutions to an engineering problem
- Build a tabletop-scale model with recycled materials
- Present their ideas before judges at the Regional Competition in January

The Philadelphia Regional Competition draws schools from Philadelphia and surrounding counties including the Lehigh Valley, Southern New Jersey and Delaware. Students from middle schools and after school programs in the region form teams consisting of sixth, seventh and eighth grade students who work with a teacher and an engineer mentor from September to January.

## ***The 2020-2021 Future City Theme was Living on the Moon.***

At night, surrounded by stars or clouds, the moon looks distant and lifeless. However, it holds a place of unique beauty and dominance in the sky and has been inspiring humanity for eons. Dreamers of all kinds—artists, science fiction writers, scientists, engineers—have imagined a thriving city on the moon, one with healthy people and a resourceful,

sustainable ecosystem. New ideas are constantly being dreamed up and tested.

The mission of the DiscoverE Future City Competition is to provide a fun and exciting educational engineering program for middle school students that combines a stimulating engineering challenge with a “hands-on” application to present their vision of a city of the future.

## Program Impact

The Philadelphia Program has involved from 30 to 50 schools each year since its beginning in 1995 and has reached over 10,000 students. Many team members were introduced to engineering for the first time through Future City and have since become engineers. 98 percent of mentors and 91 percent of educators said they would recommend Future City.

## Awards

### Competition Award

The top six teams in the morning preliminary round compete in the afternoon regional finals, with the first place team going to the National Competition in Washington, DC during National Engineers Week in February. The Philadelphia teams have always placed well nationally and in 1999 took first place. The top national team gets a trip to Space Camp in Huntsville, AL.

### Special Award

In addition to the regional awards for the six finalists, the regional program also provides “Special Awards” in a number of areas related to the

# FUTURE CITY COMPETITION (CONT.)

2020-2021 Future City Theme: Living on the Moon

engineering of cities, provided by our many sponsors. These awards provide the students the opportunity to present their cities to more than just the competition judges and provide them with a feeling of accomplishment even if they were not a finalist in the competition. Last year, there were over 40 special awards presented and every team went home with at least one award. Additionally, all of the teams were provided with Future City t-shirts and various other items.

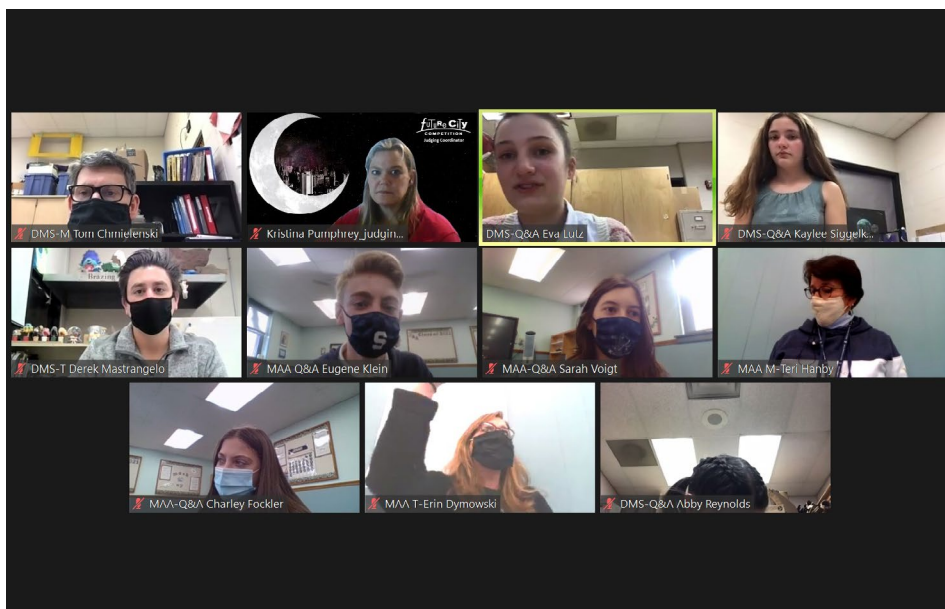
ISPE DVC is happy to continue our sponsorship of the competition and our special award:

**ISPE DVC Chuck Clerecuzio Award for Innovation in Healthcare:** The winner of this year's award was St. Hilary of Poitiers School

## Regional Competition Winners

The Winners of the 2021 Philadelphia Future City Competition are:

1. *1st Place* - St. Hilary of Poitiers School, Rydal, PA
2. *2nd Place* - Downingtown Middle School
3. *3rd Place* - Mount Aviat Academy
4. *Honorable Mention* - Saint Cecilia School
5. *Honorable Mention* - Queen of Angels
6. *Honorable Mention* - Lionville Middle School



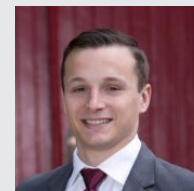
Future City Competition Participants

## UPCOMING EVENT

### ASSESSING ENVIRONMENTAL IMPACT OF BIOPHARMACEUTICAL MANUFACTURING WEBINAR

February 18, 2020 | 8-9 am

Consistent with the overall industry trend to reduce environmental impact in manufacturing operations, GSK's Biopharmaceutical Product Development and Supply team have implemented sustainability initiatives to assess the environmental impact of biopharm manufacturing.



Alexander Adams, GlaxoSmithKline

Mr. Alexander Adams, from GlaxoSmithKline, will present how impact assessment during the clinical development of product and

process lifecycle provides the best opportunity for reducing carbon footprint of a commercialized product. He will describe the assessment tools used by GSK and their relative strengths and weaknesses for assessing environmental impact.

Additionally, Mr. Adams will share conclusions on the opportunistic areas for all biopharmaceutical manufacturers to consider when assessing and reducing the environmental impact of their manufacturing activities.



## AGING ASEPTIC FACILITIES AND FIXING THEM

October Education



Herman Bozenhardt,  
Bozenhardt Consulting  
Services

In October 2020, the ISPE DVC Education Committee resumed virtual education events for our membership to continue to deliver relevant content and provide the

opportunity to earn Professional Development Hour credits.

Our first fall event featured a presentation by industry expert Herman Bozenhardt, President of Bozenhardt Consulting Services. Herman presented on the aging of aseptic facilities and how to fix them.

Evolving regulatory requirements—in addition to the current COVID environment—has created incredible pressure on existing aseptic filling capacity around the globe. This pressure

has increased the number of older facilities that need to be upgraded to bring therapies to patients.

During this lunch and learn attendees learned:

- What is an aging facility? What are its characteristics and flaws?
- How facilities age and deteriorate
- How to renovate existing facilities with a focus on reducing bioburden

This was a highly interactive presentation. Herman went through the lifecycle of existing facilities and used case examples from projects he has worked on in his 44 years working in the pharmaceutical industry as both an end user and as a consultant to end users.

Attendees walked away from this presentation understanding the main drivers of what ‘ages’ a facility, including poor plant management, lack of capital

investment for renovations and upgrades and regulatory quality standards outpacing the original design and facility purpose.

Through exploring past project examples, Herman found that problems across aging facilities are common. The vast majority of problems are with bioburden/contamination issues, outdated or processes, HVAC issues and problems with architectural layouts and finishes.

The presentation concluded with examples of fixes that were used during specific projects Herman has worked on to fix core processes, architectural layouts and HVAC utilities that brought facilities back into compliance and/or repurposed the facility for future, multi-product portfolio production.

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](#).

### 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, and Twitter or click below:



### 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 Michelle Santoro or Tieg Murray Rustam at [MAC@ispedvc.org](mailto:MAC@ispedvc.org)



# CMO SELECTION AND TECH TRANSFER CRITERIA

## Coffee Talk: December Education

In December 2020, ISPE DVC introduced Coffee Talk Education to switch things up in our ever-changing virtual world. From the comfort of homes or socially distanced offices, attendees grabbed their coffee and breakfast for an interactive panel discussion about CMO selection criteria and key aspects of a successful technical transfer to a CMO.

This was a unique presentation featuring both end user and CMO representatives. Gary Mills, Director of Sterile Drug Product Development at GSK presented on evaluating a CMO and Brent Lieffers, Senior Director of Operations at Singota Solutions presented on the criteria for a successful tech transfer into his CDMO organization.

During this 1.5 hour virtual coffee talk series, participants learned the following:

- Criteria for selecting a CMO
- Expectations of innovator and expectations of CMO
- What ensures a successful technical transfer of asset(s) into a CMO

Gary's presentation was from the perspective of the innovator and he defined the different contract organizations that innovators often use with a focus on Contract Development and Manufacturing Organizations (CDMO). He then did a deep dive on selection criteria, due diligence of a CDMO's capabilities and experience, regulatory status and



Gary Mills,  
GlaxoSmithKline



Brent Lieffers, Singota  
Solutions

quality record, process equipment and technical team experience and expertise.

Brent followed Gary's presentation and spoke to attendees from the position of the CDMO. He covered key criteria of a good working relationship between innovator and CDMO, expectations that the CDMO will have of an innovator as well as using his experience at Singota Solutions to describe the various services offered through a CDMO that can ensure a smooth and successful technical transfer of assets to the organization.

The panel presentation led to a very lively Q&A session and highlighted the value in having representatives from innovator and a service provider to fully discuss a critical evaluation that many of our attendees and members are involved in on a day-to-day basis.

## THANK YOU, SPONSORS

### ISPE DELAWARE VALLEY CHAPTER 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 with companies like **CRB, IPS, Jennings Alberts, MDavis** and **Precis Engineering**, to our new supporters including **First Pharma, Wick Fisher White** and **ValSource**, plus many others, 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!**

*(See page 16 for a list of all of our 2020-2021 sponsors.)*

## FALL MEMBERSHIP SOCIAL: 2020 BETTER 'BEER' OVER ALREADY

A Virtual Beer Tasting by Workhorse Brewing Company, King of Prussia | Hosted by ISPE DVC Membership Committee

2020 has certainly challenged the way we do things and ISPE DVC Membership events most certainly are no exception to that.

On Tuesday, November 17, 2020, ISPE DVC brought a little excitement to our members by hosting an online social gathering through a Virtual Beer Tasting by [Workhorse Brewing Company](#), King of Prussia. Prior to the event, members received a sampler pack of four 16oz cans featuring a Pilsner, Lager, IPA and a Seasonal Cranberry Wheat.

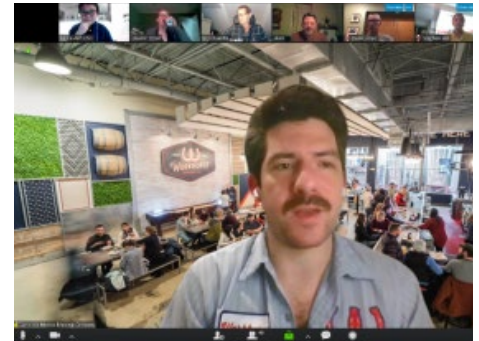
This virtual event began with Dan Hershberg, Co-Founder & Chief Branding Officer of Workhorse Brewing giving an overview and history behind the newly opened craft brewery and what separates Workhorse Brewery from all other craft breweries in the area. Three simple ingredients: Passion and

commitment to the final end product, To never compromise on quality and To Keep things Simple.

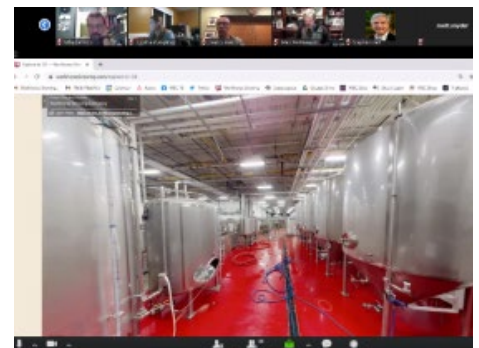
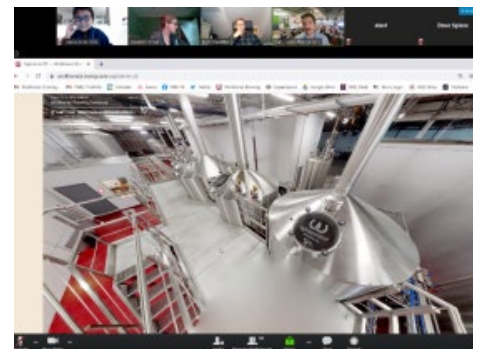
Our members got to explore Workhorse brewery in 3D through a virtual tour and *nerd-ed* out to the science of brewing through the many unit operations and processing steps involved.



Attendees also learned that anything from the balance of ingredients to varying brewing conditions result in beers with different hues ranging from pale, local lager to deep chocolate porter to ruby, amber IPA.





Dan was thrilled to answer the many questions from our attendees. At the end of the day, this sold-out event fostered a spirit of camaraderie and friendly banter among our members in the comfort of their home.



Dan Hershberg, Co-Founder & Chief Branding Officer of Workhorse Brewing







2020 Better 'BEER' Over Already!

A Virtual Beer Tasting Event by Workhorse Brewing Co., King of Prussia, PA  
Tuesday, November 17, 2020 | 5.15pm - 6.45pm  
Beers included with Event Registration

## EDUCATION EVENTS: LUNCH AND LEARN SERIES

Outsourcing vs. In-house Bioprocessing Operations, Data Integrity and F0 Equivalent Time

During the summer of 2020, the ISPE DVC education committee kicked off a series of virtual education events to continue to provide Professional Development Hours to our membership and deliver educational content relevant in today's pharmaceutical industry environment.

### Lunch and Learn Series #1 Cost Analysis: Outsourcing vs. In-House Bioprocessing Operations



Tia Lyles-Williams, Lucas-Pye Bio

We were excited to have Tia Lyles-Williams, CEO of LucasPye Bio present on the economics of "make vs buy." The economic exercise for those producing pharmaceutical

drug substance or drug product are often faced with this decision while trying to bring lifesaving medicines to market quickly. This economic exercise was emphasized in the wake of the global pandemic.

Tia walked attendees through the total costs of outsourcing versus building out in-house production facilities in addition to the core deciding factors end users should consider when making the decision. Various construction approaches including stick built, modular and pods were considered when evaluating the cost and timeline in building out a facility, in addition to the costs and timelines of selecting a CMO.

Using various examples and data from past facility construction projects of various methods, selecting a CDMO to get your molecule through phase I clinical trial oftentimes will be more cost effective and reduce project timeline risks.

### Lunch and Learn Series #2 The Journey of Data Integrity



Chad Wachter, GlaxoSmithKline

What is the guidance on data integrity from regulators, what does it mean and what are some processes and approaches to bring your organization to an improved state of compliance? These are just some of the common questions that we have been struggling with over the past few years across our industry. To help our community of professionals address these and other questions related to data integrity, ISPE DVC's education committee hosted a lunchtime webinar. It was led by Chad Wachter, Director of Product Quality & Compliance for Biopharmaceutical R&D at GlaxoSmithKline.

The event was well attended with participants representing owner organizations, consultants and suppliers from across the pharmaceutical/biopharmaceutical industry.

The Journey of Data Integrity discussed the compliance

expectations associated with the term "data integrity" from a perspective of the past, the present and the future. It was an excellent overview on how expectations of data integrity have evolved into what they are today, for example:

- Control framework for monitoring, data checking/ verification
- Risk-based audits
- Building and sustaining a data integrity culture

The overview also included potential areas of focus for the future, such as:

- Assessing data criticality across its lifecycle
- Data lifecycle management
- Process maps and control points

The attendees were walked through a discussion of the ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) principles and the data quality attributes associated with them. Included in this discussion was a review of the numerous types of data that are to be addressed in developing a quality control framework: raw data, original data, metadata, primary data, secondary data, derived data, important data, critical data, reported data, recorded data, statistical data, summary data, etc.

Accordingly, the webinar participants then reviewed the guidance and definitions used by both the U.K.



## EDUCATION EVENTS: LUNCH AND LEARN SERIES (CONT.)

Outsourcing vs. In-house Bioprocessing Operations, Data Integrity and F0 Equivalent Time

MHRA (Medicines and Healthcare products Regulatory Agency) and the U.S. FDA (Food and Drug Administration).

Conversation was then held around how data integrity supports data quality for the purposes of data consumers who need to apply the data. This understanding was applied within the context of today's regulatory expectations for a data integrity control framework: a framework which ensures an appropriate data culture through the use of assessments, monitoring, verification and audits.

Lastly, in a forward-looking view, Chad shared his views on potential future expectations for data integrity and quality.

The webinar was well received with much interaction and positive feedback. The ISPE DVC Board of Directors thanks Chad for his excellent presentation and leadership of this very important technical discussion.

### Lunch and Learn Series #3 What time is it? It's F0 Equivalent Time!



Samantha Kay, Fedegari Group

In August, the Education Committee wrapped up the virtual summer education series with a presentation by Samantha Kay from Fedegari Group.

In the presentation "What time is it? It's F0 Equivalent Time!" Samantha educated attendees on the ever-important topic of sterilization.

As drug products are delivered to market, it is imperative from a patient safety perspective that the therapies we are given are proven sterile. The content of this presentation focused on examples of terminal sterilization for injectable drug products.

Samantha covered the definition, application and calculation of equivalent time in determining the

sterilization cycle for a product in addition to the evaluation of several case studies.

Key questions answered during the presentation included:

- What is equivalent time?
- How is it used?
- What are differences in F-values?
- How are F-values calculated and what are the significance of the results?
- What are D and z-values?

In addition to definitions and example calculations of critical values to determine a sterilization cycle, attendees also learned what essential conditions need to be met for equivalent time sterilization and the differences for liquid loads versus porous loads. Regulatory guidelines were shared along with case studies for the sterilization of suspension product vials, syringe products taking into consideration temperature and pressure changes in the barrel for different cycles and IV bag loads.

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Sanofi Pasteur

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Group, Inc.

**Katie Brown**  
Azzur Group

**Lisa Casiello**  
CD & Associates, Inc.

**Jun Chen**

**Ryan Cochrane**  
Hargrove Life Sciences

**Justin Collins**  
Spark Therapeutics, Inc.

**Steve Coyne**  
CRB

**Liam Cummings**  
IPS

**Robert Cutler**  
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**Luis Dasta**  
Merck & Co.

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Bristol-Myers Squibb

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**Volkan Kart**  
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### 35 Years

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**Ernesto Renzi**  
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### 30 Years

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Services

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AIV Solutions

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Applied Control  
Engineering

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Precis Engineering

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IPS

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ILC Dover Inc.

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**Charles Gentile**  
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Merck & Co.

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Global Aseptic Process  
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GlaxoSmithKline

**John Weinheimer**  
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Jacobs Engineering Group

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