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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 continue through uncharted waters, there appears to be a brightening light at the end of the tunnel. As the joke goes, let's hope it's

not a train. However, I feel the science has proven true and we are moving toward a safer environment from the risks of COVID. I am also very optimistic considering our industry proved its capability to successfully operate in a virtual business environment, while producing lifesaving vaccines in record breaking time. While performing in this virtual environment, we have decreased our carbon footprint and our need for brick and mortar business locations. This is a trend that can bolster the bottom line while improving employee work/life balance. My wish for our industry, because there should always be a silver lining, is for these improvements to continue.

While the challenges of COVID are trending in a positive direction, we begin to deal with the wake left behind. While it is still too early to predict whether our industry's business practices will go back to the way they were, our chapter is prepared to provide content and networking opportunities for the new norms ahead of us. We plan to continue offering virtual components with our in-person events and programming whenever possible, allowing us to reach more of our members. Since September 2021,

we have hosted more than 15 events/activities with over 500 in-person and virtual attendees. With this in mind, we are looking forward to even more in-person events, so please join us to meet your colleagues, catch up and stay current with industry happenings.

We hosted our **30th Annual Symposium & Exhibition** at Lincoln Financial Field in Philadelphia, home to the World Champion Philadelphia Eagles. We welcomed a record number of attendees (over 1,000!), which is amazing, considering this event was canceled the past two years due to COVID restrictions. The selling out of exhibition space in record time indicates that people want to get out and connect with clients and colleagues again. This year's event featured additional speakers, onsite job interviews and an outdoor after-party.

We will host our **Annual Golf Outing** at North Hills Country Club on May 9. This will put us back in our regular May timeframe for this annual event. We did have an event this past September, which was the rescheduled outing from the previous Spring; it also sold out quickly. This is another indication our society is moving past the pandemic. [Learn more about the golf outing here.](#)

Upcoming Initiatives

Below are two of the initiatives we are working on to continually improve our

(continued on page 2)

FROM THE PRESIDENT'S DESK

organization and content offerings:

- A content repository to allow members to access past education and program content. This would allow DVC members to access pertinent content as their technical needs arise.
- A virtual student chapter replacing our current university-based chapters, utilizing social media. This allows current students to stay connected to ISPE information and events and also reach out with questions and receive answers quickly. We also plan to create a mentoring component to better guide students toward careers in our industry.

In closing, I would like to thank the 2021-2022 Board of Directors and Committee Vice Presidents for their tremendous work during all the ups and downs caused by COVID. While we navigated new waters and changed course as required, this created schedule changes and marketing campaign rewrites with short notice and all of you performed flawlessly. Continuing through the program year, the future looks bright and we welcome all to a new beginning!

- Marvin "Guy" Royal

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

2021-2022 BOARD OF DIRECTORS

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ISPE DVC'S MAILING ADDRESS

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

ISPE INTERNATIONAL HONOR AWARDS

Eleanor F. Small: Max Seales Yonker Member of the Year Award



The ISPE International Honor Awards provide the opportunity for all of us to recognize and celebrate the dedicated professionals who are volunteering countless hours to support ISPE in its mission.



ISPE DVC's very own Eleanor F. Small, Ph.D. won the Max Seales Yonker Member of the Year award. This award honors the ISPE Member who has made the most significant contribution to the Society during the past 12 months. It

is named in honor of a dynamic woman who contributed to the Society in many different ways and served as a source of inspiration during her battle with cancer.

Our board members were not surprised of this award winner, given how much Ellie contributes to and engages with the ISPE community and beyond. It is a well-deserved recognition.

Congratulations, Ellie, from your entire ISPE DVC family!

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!](#)

EVENT RECAP

Women In Pharma (WIP) Walk and Talk

On Thursday, October 14, 2021 the ISPE DVC WIP committee met at the Artillery Park of Valley Forge National Park for the first Walk and Talk. In total nine DVC members, one child and one husband joined us on this beautiful day for a very casual meeting focused on networking and enjoying the outdoors! Members met at 5:30pm, were provided a brochure which included a picture scavenger hunt and then groups of two were sent on the trail to "walk and talk."

Light snacks and drinks were provided and everyone in attendance enjoyed the opportunity to meet face to face at the park. Attendees agreed we should try to do this event again in the Spring when the weather allows.

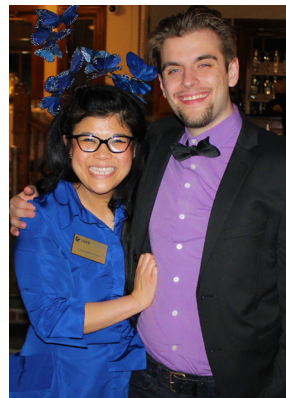


WOMEN IN PHARMA (WIP)

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

SPRING MEMBERSHIP BASH (AKA HOLIDAY PARTY)

Held at Knowlton Mansion in Philadelphia



ISPE DVC celebrates each and every one of our members through the many appreciation events held annually. This year was no different.

Friday, March 18 brought us together for the annual Spring Membership Bash: aka, the Holiday Party. We celebrated in style at Knowlton Mansion located in Fox Chase in Northeast Philadelphia. The weather was spectacular which allowed folks to wonder the mansion and grounds.

The evening graced about 80 attendees with a colorful serving of appetizers paired with sunset cocktails, followed by a hearty dinner and an evening of jolly good fun involving cash-free casino tables with live dealers and a live DJ to keep the tempo of the evening.

Raffle ticket sales benefited HAVEN Women, a 501c3 non-profit organization based in Philadelphia that works to house homeless women veterans. This year we raised \$750 to be presented at our 30th Annual Symposium & Exhibition held at Lincoln Financial Field on April 26, 2022.

Annual Awards

This year's prestigious **Buz Lange award** for outstanding contributions to ISPE and the pharmaceutical community was given to **Mike DeBellis**. Mike has over 35 years serving customer needs in the pharmaceutical industry. During this time, he has been an ISPE member for over 25 years. All 25 years he has managed the annual DVC golf outing. He has served for over 15 years on the Oral Solid Dose (OSD) CoP, Product and Process chapter team as Chair and Co-Chair, for the 2nd and 3rd Editions of the OSD Baseline Guide. Mike is also a past President of the Conshohocken office Employee Club for Jacobs Engineering Group, where he mentored many junior engineers. Mike has given his time freely to the Delaware Valley Chapter as an eight-year member of the chapter board of directors and past Vice President of the Programs Committee. Congratulations Mike, on this well-deserved recognition!

Also presented was a **Special Appreciation award** for outstanding contributions to the financial stability of our chapter. Over the last five

years, **Peggy Del Fabbro** has been an integral part of improving our financial processes, tax preparations and the financial mentoring of our junior board members. She navigated the uncharted waters of canceled events and carrying revenue forward due to COVID challenges. We would not be financially prepared for the future growth of our chapter without Peggy's dedicated service. Thank you, Peggy!

The 2021 Chapter Sponsor of the Year was won by ICQ.

Thank you again to all of our sponsors who donated gift baskets and to all who attended for a great evening. ISPE DVC looks forward to returning to normal and planning our 2022/23 Holiday Party in December or January.

Relive moments from this exciting 34th Annual Holiday Gala by visiting the photo album [HERE](#).

PANEL: DIVERSITY IN THE WORKPLACE

Presented by the Women In Pharma (WIP) Committee

On Thursday, December 9, 2021, attendees gathered at the Workhorse Brewery in Conshohocken, PA and enjoyed an evening of good food, excellent drinks and a very engaging panel discussion on Diversity in the Workplace.

While attendees enjoyed their food and beverages, Michelle Batz kicked off the panel discussion by welcoming everyone and briefly introducing the members of the panel: Kristina Pumphrey, Director of Process Engineering at Precis Engineering, Lise Schwartz owner of LiseSchwartz.com (Career Coach and Transition Specialist) and Christine Mineweaser, Senior Specialist in LVV Deviation Management at Merck.

The conversation focused on challenges they have faced in their careers, how they overcame those challenges and the lessons they learned. Key to the conversation was the concept of building a network of people around you that not only support your career but also offer advice and opportunities along your journey.

There was also discussion around how to find what makes you happy and how that looks like may be very different from the colleague sitting next to you. It also means everyone is entering into situations, either at work or at home, with different perspectives, abilities and interests. Meeting people “where they are” is so important in creating a workplace that welcomes everyone.



Thank you to everyone who supported this event. It was such an engaging night and the conversations lingered long after the panel discussion concluded!

More photos from this event can be viewed [HERE](#).

EDUCATION TOPIC IDEAS?

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

EVENT RECAP

Emerging Leaders (EL) Happy Hour

The EL committee held a well-attended happy hour in November at the Great American Pub in Conshohocken. Look for more networking events for emerging leaders soon. More photos can be viewed [HERE](#).



EVENT RECAP

ISPE DVC Sponsored Bus to INTERPHEX in NYC

In October, ISPE DVC sponsored a bus to INTERPHEX 2021. We departed from the parking lot behind IPS in Blue Bell. Approximately 20 people joined us for this no-hassle way to travel to NYC for the show. It was an excellent opportunity for our members to chat with old friends and meet/make some new friends in the industry.

Food and beverages were available for both the morning and the evening rides, as well as movies to pass the time. We hope more of our members will join us in 2022!

JOIN US ON THE ISPE DVC BUS TO INTERPHEX 2022! Sign up [HERE](#) before the bus fills up!

THE QUIET STRENGTH IN THE PHARMA INDUSTRY

November Program

On November 17, 2021, the Programs Committee hosted at Maggiano's in King of Prussia, PA a presentation on oral solid dosage (OSD), entitled The Quiet Strength in the Pharma Industry.



Although there is a lot of press coverage regarding new and innovative technologies, from vaccine production to cell therapy, OSD remains one of most effective means to administer many pharmaceutical drugs. OSD technology has been around for generations and is still considered to be the most cost effective and patient friendly forms of drug delivery. In fact, submission approvals by the FDA for new drug applications (NDAs) include many drugs based on OSD, so the impact of this tried-and-true delivery system will continue for many years to come.

Delivered by a panel of Mike Rooney of Marinus Pharma, Terry Jacobs of JacobsWyper Architects, Jamie Frizzell of Freund-Vector Corporation, and Mike DeBellis of

Jacobs, the presentation covered the basics regarding OSD products, development, equipment, and facility design. Also discussed was a broad overview of the value of the dosage form, latest trends, technologies, and impact to facility design.

This presentation was best-suited for a pharmaceutical professional who would like to broaden their understanding of OSD technology but it was well-received by a room full of industry professionals with varying roles, backgrounds and experience levels. We look forward to continuing to feature oral solid dosage in feature presentations and technical content.



To see more photos of this successful event, click [HERE](#).

AN INTRODUCTION TO GxP

Presented by Emerging Leaders

At the virtual Emerging Leaders event on January 20, Dr. Dennis Gross presented an Introduction to GxPs.



Dennis Gross, MS, PhD, SSYB, SFC

From inception to implementation, Dr. Gross dove into the history of the FDA and the programs it has developed throughout the years to adapt to an evolving industry. Touching on the key components of each GxP (GLP, cGMP, cGCP, cGVP), Dennis discussed each topic with concrete examples at each level to illustrate the regulation that is required to adhere to the FDA and the significance in doing so.

Furthermore, Dr. Gross also discussed the future of GxPs and what is on the horizon for the FDA. It was a fantastic stage setter for our event on February 8: cGMP 101: Translation of cGMPs into Facility Design Requirements.

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!

HOW ARE YOU MANAGING DURING THE PANDEMIC

Presented by the Women In Pharma (WIP) Committee

On Thursday, March 3, 2022, the ISPE DVC Women In Pharma (WIP) committee hosted the first event of 2022. The Mentor Circle format was revisited as a lot of positive feedback was received for these events held in 2021. This format offers an informal approach to networking and discussing real issues in the workplace and our world.

For this event, the focus was “How are you managing the COVID-19 pandemic? The 13 participants discussed the social limitations of the pandemic and how that has impacted their mental health at points along the journey. Feeling isolated, not engaged and burying yourself in work because no boundary between home and work exists were all challenges. In addition, the great reshuffle is occurring as more job opportunities are available and people are looking for the most flexibility and greatest growth potential. Losing experienced colleagues creates a gap that takes more time and effort to backfill. There

was also a lot of discussion around setting boundaries, creating focus time on your calendar and finding the ability to say no when more and more tasks are funneled your way. Self-care is also an important area to focus on, as it’s proven that engaging in exercise, meditation, yoga, reading and other activities that reduce cortisol are critical for maintaining your health.

This conversation continued on April 28, 2022, when a book club discussion focused on “Presence: Bringing Your Boldest Self to Your Biggest Challenges,” by Amy Cuddy. The last two years have certainly presented challenges, so through the discussion on this book, we hope to learn a bit more about ourselves and how to support our colleagues, friends and loved ones.

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.

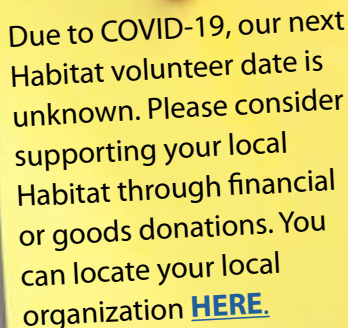
We would like to thank the contributions from our OAG team and are looking for additional members to join us and improve our capabilities. If you are interested in joining the OAG team, please contact Marvin “Guy” Royal at president@ispedvc.org.

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 below:

INTERESTED IN ISPE MEMBERSHIP?

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



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 27TH ANNUAL GOLF CLASSIC

Held at North Hills Country Club on September 7, 2021

Hello, fellow golfers! Well, we did it, despite COVID and unusually difficult times since March of 2020. We had a great turnout at a new venue for our long overdue ISPE Delaware Valley Chapter's 27th Annual Golf Classic. Our guests enjoyed a beautiful day at the North Hills Country Club (NHCC) in Glenside, PA. The staff at NHCC were top notch and ran the check-in process like a well-oiled machine. 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 new home for our outing.

As golfers arrived at the registration area, they were treated to our ISPE-branded cooler packs, filled with water bottles by our sponsor **CAI**; golf towels by **CPS**; golf balls by **Genesis AEC**; and ball markers by **Boundless**, who also provided our golf trophies and our Presidential Putter awarded to our outgoing chapter president each year. 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.

Once again, our Golf Classic was well supported by our generous sponsors. Sponsorships included door prizes, tee box sponsors, hole sponsors, trophy sponsors, and refreshment station sponsors. This truly was another banner year for our outing's prizes, giveaways

and awards. **Thank you to all our sponsors who continually amaze us with their generous support of our golf outing.** You make our outings great fun each and every year.

This year's Hole-In-One sponsor—**Belimed Life Science**—provided us with a chance to win a two-year car lease to drive a 2021 Mercedes GLC. A second Hole-In-One sponsor was **Bahnson Environmental Specialties**, who provided us with a chance to win a golf trip for two to Pebble Beach. Sadly, we had no winners of these incredible prizes. Clearly, we all need more practice with our hole-in-one shots. There is always next year, so never stop believing!

Refreshment Station sponsors were **Herman Goldner Co., Inc., CAI**, and **First Pharma Consultants, LLC**.

This year's trophies were a Classic Bronze Cup, sponsored by **Wick Fisher White**. The trophies went to the top three foursomes using a modified Callaway scoring system to determine winners in three flights, as determined by our club pro, and longtime friend to our outing, Mickey Sokalski.

This year's foursome photographs were taken by our volunteer photographer Laura-Ann Chin. **All photos are posted for our golfers and others to enjoy [HERE](#).**



Winners

A Flight	Rick Aulenbach Jon Becker Miranda Richter Todd Seidel
B Flight	Curt Biehn Katherine Clark Mike Lemons Mike DeBellis
C Flight	James Lowell Joseph Bravo Dave Lyon Dov Shevich

Congratulations to our Straightest Drive winner **Sarah Gumina** and our Closest to the Pin winner **Henry Ip**.

Somehow, we forgot to acknowledge this year's highest scoring foursome, but I promise we will not allow this to happen again. Remember, there are no losers at our golf outings; everyone who attends is a winner.

New to this outing, we invited our non-golfing friends to join us for golf lessons given by club pros

ISPE DVC 27TH ANNUAL GOLF CLASSIC (CONT.)

Held at North Hills Country Club on September 7, 2022

Mickey Sokalski and Jack Connelly. The participants were taught the basics of the golf swing and at the end of the lesson, they were entered into a putting contest on the practice green. The winner of our putting contest was **Dean Hammond** and we hope to see him on the course with us at our next outing using his newly acquired skills.

The NHCC banquet room provided us with an open bar cocktail hour and hors d'oeuvres with chatting friends, colleagues and clients. The dinner buffet included an incredible seafood raw bar, reminiscent of the Philmont Country Club, with huge succulent shrimp and crab legs, carved meats and salads. My mouth is watering just writing about it again.

During the awards portion of our evening, we presented our outgoing Chapter President, **Eleanor Small**, with her very own Presidential Putter. It is a token of our appreciation for all the time and hard work she put into this position for two terms due to COVID. She took on all the responsibilities required of a Chapter President and then some. Thank you again, Ellie. It's been a pleasure working with you and watching you become a budding golfer!

Special thanks to **Susan Padien**, our chapter manager. Without her hard work with registration, billing, late registrants, cancellations,

chasing payments, and keeping track of everyone, we would have been lost. Thank you so much, Sue, for another great golf classic event.

Also, **a big thank you to the committee volunteers** who helped us with registration, preparing our door prizes, setting up trophies and the prize tables, monitoring our hole-in-one competitions, taking photos of our foursomes (with champagne, I might add), and countless other details. I thank every one of you for your time and contributions to the outing; we couldn't do this without you.

I also would like to acknowledge and thank **Lisa Dugery** who is always there to help me, whether I had a triple bypass surgery or a hip replacement, she has been there to help with getting the prizes and giveaways purchased and delivered to the club. So thankful for you, Lisa.

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

This year's outing was another huge success (despite COVID) and attendance was even better than we expected. We hope this will continue for our future outings

and all our chapter events. We hope to see you all again at our 28th ISPE DVC Annual Golf Classic to be held (again) at the North Hills Country Club in Glenside, PA on May 9, 2022. I am looking forward to it!

So, until May 9, hit'em long and hit'em straight!

Mike DeBellis, 2021 Golf Outing Program Manager



2022 GOLF OUTING: REGISTER NOW!

Our 28th Annual Golf Outing is open for registration! Click [HERE](#) to learn more. The event will be held on May 9, 2022 at North Hills Country Club.

cGMP 101: TRANSLATION OF cGMPs INTO FACILITY DESIGN REQUIREMENTS

February Program

On February 8, the Programs Committee hosted at Conshohocken Brewing in King of Prussia, PA an introductory course entitled cGMP 101: Translation of cGMPs into Facility Design Requirements. Current Good Manufacturing Practices, or cGMPs, provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.

This presentation was best suited for the mildly experienced pharmaceutical industry professional interested in broadening their understanding of cGMPs in facility design.

In this presentation, experts in cGMP facility design from Precis Engineering discussed the fundamentals of cGMPs and how they translate into pharmaceutical facility design requirements imposed by the FDA. The sold out panel was led Kristina Pumphrey, PE, who is the Director of Process Engineering at Precis Engineering and an accomplished Process Engineer with more than 20 years of experience in the pharmaceutical and biopharmaceutical industries.

Also included were Tim Lisle, AIA, an accomplished architect with more than 40 years of experience and John Volence, PE, CEM, a mechanical engineer with more than 14 years of experience who leads Precis' mechanical engineering department, overseeing project execution, quality control and department training.



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!

PRACTICAL AND VALUE-ADDED STATISTICS FOR THE NON-STATISTICIAN

Three-part Education Series

Accelerated timelines, complex supply chains, data constraints, evolving compliance requirements... These are just a few of the challenges of today's pharmaceutical industry. How can you leverage statistical methods to enable solutions to these challenges and become a more efficient developer and manufacturer?

Based on member survey responses, the Delaware Valley Chapter presented an educational series of practical and value-added statistical methods to apply across the product lifecycle to reduce timelines and resources, increase knowledge, manage risk, and assure ongoing product quality.

Session 1: Using Design of Experiments (DOE) to Define the Process Control Strategy

Presented By: Tara Scherder, Principal, SynoloStats

The September 30 event was the first in a series of three on the main topic of Practical and Value-added Statistics for the Non-statistician. This initial session was a three-hour onsite (with a virtual webinar option) presentation that consisted of ~2.5 hours of content and 30 minutes of Q&A. This was the chapter's first in-person event in over 20 months. The speaker (Tara Scherder) is considered an industry SME on the use of statistics in the pharmaceutical industry. Tara was energetic and engaging, which allowed the audience to maintain interest and attention

throughout. The presentation material was excellent and provided a general overview of the statistical approaches (DOE) that can be used as part of overall development of a process control strategy for various manufacturing processes and types of products. Detailed examples were provided that enabled the audience to understand how the interaction of parameters influence process design and development outputs toward deciding on an effective manufacturing control strategy. The presentation followed a logical order of what is DOE? Why use it? Following were examples of increasing complexity depending on the dataset.

The presentation demonstrated how the use of statistical methods can be applied across the initial stages of the product and process development lifecycle to reduce timelines, increase knowledge, manage risk, and assure ongoing product quality. The link to process knowledge and current regulatory expectations was highlighted as a key enabler to successful product development and future commercialization.

Overall, the topic resonated with the attendees, who ranged from owner companies to engineering firms to industry product supplier sales and account managers.

Session 2: Statistics for PPQ

Presented By: Katherine Giacoletti, Principal Scientist, Center for Mathematical Sciences, Merck & Co., Inc. and Tara Scherder, Principal, SynoloStats

Held as a virtual session on November 12, this session focused on statistics for PPQ.

Session 3: Statistics for Commercial Manufacturing

Presented By: Katherine Giacoletti, Principal Scientist, Center for Mathematical Sciences, Merck & Co., Inc.

In January, we held the 3rd event in the series. The one-hour webinar held over the lunch hour addressed risk-based strategies for using statistics in managing continue process verification of commercialized products. The presenter provided context in explaining the difference in requirements between Stage 3a and 3b as defined by the FDA. She also presented to the attendees an excellent explanation and treatment of the difference between Process Capability (Cpk) and Process Performance (Ppk) and why it is important to understand the difference. Both are statistical metrics that consider the variation of the process against its specification.

The presentation material and the presenter were both excellent and the Education Committee received good feedback from a few of the participants after the event.

WELCOME NEW ISPE DVC MEMBERS!

August 2021 - February 2022

Chris Wuertz

Genesis Packaging Technologies

Cameron Kantner

DPS Engineering

Caichen Zhong

Sara Eastman

EwingCole

Christian Swain

Kevin Zimmerman

PROTECTS

Colman Shouldice

Cognizant (Zenith Technologies)

Shawn Hoy

Genesis AEC

Brian Hershey

Lori Kohler

Spark Therapeutics, Inc.

Lauren Bubnis

PM Group

Suzanna Ho

Brian Goss

Fran DeGrazio

West Pharmaceutical Services

Hayley Crowe

Ecolab

Christopher Massey

WGS Equipment & Controls

Caroline Cinkala

Ryan MacKenzie

Merck & Co.

Matthew Russell

Che Lee

Cognizant Life Science Manufacturing

Zehra Zaybak

Eisai, Inc.

Amanda Lucarino

Steve Slavutsky

Draeger, Inc.

Felix Bryant, Sr.

Regeneron Pharmaceuticals

Andrew Kraemer

Pro-Quip

Emily Pantalone

Lawrence Pepper

Genesis Packaging Technologies

Tim Brewer

Yourway Inc.

Joshua Levy

Ballinger Co.

Scott Bierwerth

Louise Caughey

O'Neal Inc.

Vincent Keidel

Johnson Matthey

John Irwin

Daryl Summerson

IPS

Gargi Shahane

DPS Group

Randy Backich

ProMach Pharma

Sean Beatty

Lyophilization Technology, Inc.

Anton Soudakov

West Pharmaceutical Services

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