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

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## FROM THE PRESIDENT'S DESK

By Danielle Rebori

As we kick off the 2018-2019 program year and reflect on our accomplishments, I am delighted with the continued progress of offering varied networking, educational and social opportunities for our community. I am thrilled with the momentum and direction of the Chapter. You can read more about all the Chapter offered in greater detail in the next few pages.

Every year, chapter leadership looks for ways to improve the presentation of content so that it is current and of interest to the industry. The goal is attracting professionals, young and seasoned, with opportunities to interact, as well as, share ideas and experiences.

None of this could be accomplished without the Chapter's volunteers. On all levels - Board of Directors, the Committee V.P.s, and their individual committees - everyone works tirelessly to strive to deliver content in new ways and at a number of new locations throughout the Delaware Valley area.

With that said, I would like to congratulate the newly appointed 2018-2019 Board of Directors and wish them a very successful year, under ISPE

DVC President Kristina Pumphrey's leadership. I know they will continue to strive for excellence. ISPE DVC is always looking for eager members that would like to get involved.

Please check the ISPE DVC website and your emails for upcoming events. Remember to register early and often!

Danielle Rebori  
Senior Associate  
JacobsWyper Architects

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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 at: [drebori@jacobswyper.com](mailto:drebori@jacobswyper.com)**

## BOARD OF DIRECTORS

### 2017-2018

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##### VP, Symposium

Marvin Royal  
STEQ America



## 2018-2019 LOOK AHEAD

### Upcoming Events

SPE DVC is well into planning exciting program and education events for our members in the coming months. Keep an eye out for more information on what's to come!

- Regulatory Impact on GMP Manufacturing Facilities in King of Prussia, PA | Tuesday, October 9, 2018 | [Click here for more information or to register!](#)
- ISPE Annual Meeting & Expo, Philadelphia | November 4-7 | [Click here or image below for more information or to register!](#)
- ISPE Annual Meeting Boston/DVC Joint Social Event at the Hard Rock Cafe Philadelphia | Monday, November 5
- November Education Program | **More information coming soon!**
- ISPE DVC Annual Holiday Party at the Mutter Museum of The College of Physicians of Philadelphia | Thursday, December 13, 2018
- 26th Annual ISPE DVC Annual Golf Classic | Monday, April 29, 2019

2017-2018  
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## STATISTICS FOR CMC PART II: MANAGING CHANGE AND PROCESS VARIATION

February Education Program | Held at GlaxoSmithKline Upper Merion

On February 22, 2018, ISPE DVC hosted an education event titled Statistics for CMC: Managing Change and Process Variation. The event was held at the GSK Upper Merion facility and despite the rainy, wintry weather nearly everyone was able to attend.

The event was presented by Julia O'Neill, a statistics expert who has taught the FDA how to use statistics when auditing manufacturers. Back in May 2017, Julia had given Part I of the Statistics talk, and it was so informative and well done that everyone asked Julia to return and give the second part, which focused on managing process and assay changes, and on assay and reference standard issues.

A popular part of her talk focused on "pulling signal from noise." In this part, Julia focused on a real

life case study where a biologics process resulted in product outside the potency specifications. Many experts had tried to determine the root cause with no success. Julia and a team of experts were brought in to apply various statistical techniques to the data from finished lots, and they were able to successfully determine that multiple shift points had occurred, each with its own cause, and therefore one root cause alone was not the answer. Changes were recommended to the process based on statistical projections, the resulting lots met the projections, and the day was saved.

Not just anyone could break such a complicated topic down in a way that makes it understandable, but Julia shines at doing just that and with a sense of humor too. Keep your eyes tuned for future topics by Julia, she knows how to

make complicated topics interesting and relatable!

**Thank you to all our regular attendees who were able to be there, and welcome to all the new folks who came out. If you haven't come out for one of ISPE DVC's education events, be sure to come try us out. We have good food and a chance to network with your peers in the industry, and excellent presentations by experts in their fields.**

**Attendance at our events can be used to meet your continuing educational requirements for professional certifications. Requests for future topics are always welcome!**



## EVENT RECAP & PHOTOS

### Night at the Urban Axes

Hosted by ISPE DVC's Young Professionals Group

A friendly competition of axe throwing and networking was held in one of Philly's most hipster neighborhoods, aka the "New Kenzo." Participants met at Urban Axes for an evening of camaraderie, delicious gourmet sammies, exquisite summer sides, refreshing beverages, and a round of friendly competition.

**Additional photos from Urban Axes can be viewed here.**



## BOARD OF DIRECTORS

2017-2018

### Board of Directors (cont.)

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RPA Engineering

**Director**

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Greg Sabatino  
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**Past President**

Danielle Rebori  
Jacobs Wyper Architects



## DVC's 25th ANNUAL GOLF CLASSIC

By Mike DeBellis | Held at Philmont Country Club

Can you believe it? This year's Golf Classic marked the Chapter's 25th Annual Golf Classic held at the Philmont Country Club in Huntingdon Valley, PA.

I'm sure some of the founding Program Managers of this great event would be thrilled to know that what they started 25 years ago continues on. Ed Stanford and Frank Moran, may the Golf Gods smile upon you and know that you're not forgotten. Where has the time gone? We had a beautiful day at Philmont, once again, and I'm sure Ed and Frank had something to do with it this year. The North Course at the Philmont CC continues to go through some changes, but the service and attention to details has not. Thank you to everyone at Philmont for another great outing.

In what has now become our norm, prior to the shotgun start, golfers were treated to a logo'd umbrella door prize upon check in, designed to keep the rain away, and they were able to enjoy the Philmont's lunch buffet before getting started.

The practice areas were available to those who allowed enough time for warming up a bit at the driving range and putting areas. Getting prepared for the challenges that lied ahead on the unforgiving Philmont North Course is always helpful.

Thanks to our generous sponsors, this was another banner year for prizes and awards. Thank you all for your continued support, your generosity really makes our outings great each and every year. This year's Hole-In-One sponsors were **Brydges Group** who provided us with a chance to win a two year lease to drive a 2018 Alfa Romeo Stelvio SUV and **Bahnsen Environmental Specialties** who provided us with a chance at winning a glorious trip for two to the 2019 Masters in Augusta, GA. As you might have guessed, no one had a hole-in-one. Clearly we all need more practice. Maybe next year.

This year we also had **Dixon Golf** join us for a fund raising activity on the challenging Par 5, 9th hole. Participants who donated to the St. Jude's Children's Hospital were able to place their second shots at the 100 yard marker and really save strokes here. Dixon also made available chances to win an Amateur Sponsorship Package consisting of Dixon golf items and online offers for Dixon equipment. Thank you to all who donated as we raised \$1,000 for St. Jude's!

This year's ISPE DVC logo golf balls were from the Dixon line of golf balls and were made from biodegradable materials. So, if you were unfortunate enough to slice one or two into the woods, you can find peace of mind knowing that your ball will be environmentally friendly as it decays in the woods, lost forever.

Our Refreshment Cart Sponsor was **M+W Group** and the Refreshment Table Sponsors were **Evoqua Water Technologies** and **Herman Goldner Co., Inc.**

Trophy Sponsor was **Wick, Fisher, White.**

Inside the Philmont's banquet rooms, the party continued as everyone enjoyed the open bar cocktail hour and hors d'oeuvres while chatting with friends, colleagues, and clients. The dinner buffet included pasta, the "incredible" seafood bar, carved meats, and a dessert bar. Philmont Country Club also provided us with our ISPE ice sculpture at the raw bar.

After dinner, our chapter President, Danielle Vassalotti-Rebori greeted our members and in the DVC tradition, yours truly presented our out-going President with her very own Presidential Putter. It's a token of our appreciation for all their time and hard work performing the many duties required of them as President, serving the members of the Delaware Valley Chapter throughout the year.

*(continued on page5)*

### Save the date!

Thursday, December 13, 2018, ISPE DVC will be having our Annual Holiday Party at the beautiful Mutter Museum of The College of Physicians of Philadelphia!

## DVC's 25th ANNUAL GOLF CLASSIC (cont.)

By Mike DeBellis | Held at Philmont Country Club

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

Special thanks go to Susan Padien, our chapter manager, for all her hard work with registration and signing golfers up, and helping me keep track of everyone. Also thank you to all the many volunteers who helped with registration, handing out giveaways, setting up trophies, hole-in-one judging, 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.

In summary, this year's outing was another huge success as attendance was even better than last year and I hope this will be a trend for future outings, especially next year for our 26th ISPE DVC Annual Golf Classic to be held on Monday, May 6, 2019. We are looking forward to seeing you all again. So, until next year, hit 'em long, and hit 'em straight!

**For the Love of the Game!**  
**Mike DeBellis**  
**2018 Golf Outing Program Manager**

### EVENT PHOTOS



## Congratulations to all of this year's winners:

- 1 | Ernest Keeper, Harrison Ball, Jim Farrell, and Ryan O'Leary with a score of 61
- 2 | Jon Huggins, Bryan O'Toole, Jeff Graef, and Jeff Sidela with a score of 64
- 3 | Eric Silk, Mark Bellino, David Musto, and Josh Capperella with a score of 68

Closest to the Pin prizes were won by Steve Smith (3'3"), Pro Gaswami (1'9"), Ryan Kairis (7'10"), and Jeff Graef (3"6").

Longest Drive winners were Frank Artayet for the Men and Emilie Pelletier for the Women.

### Save the date!

26th Annual ISPE DVC Annual Golf Classic will be held on Monday, April 29, 2019.

## SOCIAL NETWORKING

DVC members are invited to join our group on LinkedIn for event notifications, networking and information sharing.

Find us on LinkedIn at ISPE DVC or click below:



Also connect to us on Facebook:



And Twitter:



## VOLUNTEER APPRECIATION DINNER

At Founding Farmers in King of Prussia, PA

A big shout out to the dynamic ISPE Delaware Valley Chapter Board of Directors for yet another successful year!

Thank you Danielle Vassalotti Rebori for your leadership throughout 2017-2018 and we have no doubt that incoming president Kristina Pumphrey will complement your leadership in many ways!

Thank you to all the spouses who have supported the involvement of the board members throughout the year! Looking

forward to an ambitious 2018-2019 calendar year!

**Additional photos from the Annual Volunteer Appreciate Dinner can be viewed here.**



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## WELCOME NEW ISPE DVC MEMBERS!

February 2018 - June 2018

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**Jack Dienes**  
University of Virginia

**Bill Diffendale**  
Emergent BioSolutions

**John Doran**  
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**Daniel Dry**

**Kym Faylor**  
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Eurofins NSC US, Inc.

**Laura Abrams Garver**  
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**Karen Hirshfield**  
Johnson & Johnson

**Shane Horan**  
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**Kevin Hutter**  
GlaxoSmithKline

**Abby C. Johnson-Schmitt**  
Sanofi Pasteur

**Tyler Jones**  
Cyma Builders and  
Construction Manager

**Hashem Khalifeh**  
West-ward Pharmaceuticals

**Andrew Klausman**  
WuXi AppTec

**Chris Koehler**  
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GlaxoSmithKline R&D

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**Daniel Napolitano**  
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**David M. Shannon**  
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**Diane Simon**

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Commissioning Agents Inc.

**John A. Walker**  
NIIMBL

**Douglas Watson**

## UPCOMING EVENT

### Aging Facilities to New Technologies: The Regulatory Impact on GMP Manufacturing Facilities & Product Licensed Applications

October 9, 2018 | 5:00-8:00 pm

The presentation will cover the complications associated with keeping aging Biological manufacturing facilities cGMP compliant; the implementation of novel technologies such as single use bags/connectors, in process analyzers, and isolator technologies in both aging and new pharmaceutical manufacturing facilities; and impacts of such regulatory compliance hot topics, i.e. validation/qualifications and data integrity on biological licensed product applications and regulatory inspections.

## ADVERTISE WITH US!

ISPE Matters is the perfect spot for advertising your business! We reach the heart of the pharmaceutical industry in the Delaware Valley. The standard ad cost is \$250 and will be printed in all issues this year.

If you are interested in advertising in ISPE Matters, please contact:

Michelle Santoro  
[Michelle.Santoro@skanska.com](mailto:Michelle.Santoro@skanska.com)



## THANK YOU TO OUR 2017-2018 SPONSORS FOR THEIR CONTINUED SUPPORT





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### WRITE IT DOWN!

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

All prospective articles should be emailed to:

Michelle Santoro  
[Michelle.Santoro@skanska.com](mailto:Michelle.Santoro@skanska.com)



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