2019

INSIDE THIS ISSUE

From the President's Desk1
Board of Directors2
ISPE Night at the Phillies2
A Risk Based Approach to the Management of Virus Risk in a cGMP Manufacturing Facility3
April Education Recap3
2019-2020 Look Ahead4
29th Annual DVC Exhibition and Symposium Photo Recap4
Habitat for Humanity5
ISPE DVC 26th Annual Golf Classic6
Welcome New Members8
Member Milestone Anniversaries9
Sponsor Spotlight11

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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www.ispe.org/delaware-valleychapter

FROM THE PRESIDENT'S DESK

By Kristina Pumphrey



Kristina Pumphrey, PE **Director of Process** Engineering Precis Engineering, Inc.

It has been an honor to serve as the DVC president over the past

year. I am so proud of all of our volunteers The education team provided some and appreciative for all the hard work they put in over the past program year. This newsletter summarizes all the events we put on during the second half of the year, but I would like to touch on what the committees have been up to.

Programs committee:

- January's program was a presentation by Dr. Anne Stokes on GSK's comprehensive viral safety program to ensure that products are supplied to patients free from virus contamination.
- March's program was a plant tour of Alpha Laval with a focus on CIP spray devices. This tour met one of ISPE DVC's goals to provide more hands-on content.

The programs committee was also responsible for the ski outing in January and the golf outing held in late April.

Education committee:

- March's event was a discussion on pharmaceutical water generation presented by Gary Zoccolante, an expert in the clean utilities arena.
- April's education focused on pharmaceutical engineering fundamentals, which covered an overview of process steps and

- equipment for typical OSD/sterile facilities.
- June's education was on the application of GMPs to support quality risk management based on integrated C&Q.

fundamental content this year for young professionals (YP) and professionals who work in different areas of pharma. We also did a Beta test on streaming our March education, which was a success. Be on the lookout for webinar options for this year's education events.

The annual Symposium was held in May at Lincoln Financial Field. A great time was had learning about the latest offerings from our suppliers, while networking with colleagues. We received good feedback on moving the event to May and I know I enjoyed the warm weather instead of the threat of snow.

I would also like to take this time to highlight one of our less publicized positions. Our treasurer, Amy Markey, along with Peggy Del Fabbro, have been working hard this year to streamline and track our finances. The tighter we are with the finances, the greater the opportunity to contribute to great causes like Habitat for Humanity, Future Cities and sponsorship of area students. I would also like to take a moment to thank Tony Macchia who has been our Chapter's financial controller for too many years to

(continued on page2)



2019-2020 BOARD OF **DIRECTORS**

President

Eleanor Small, Johnson & Johnson

Executive Vice President

Marvin Royal, STEQ America

Secretary

Dennis Gross, PA Drug Discovery

Treasurer

Amy Markey, Carisma Therapeutics

VP. Programs

Mike DeBellis, Jacobs

Co-Chair, Programs

Sawyer Romich, Hargrove Life Sciences

VP, Education

Brendan Bradley, Vanrx Pharmasystems

Co-Chair, Education

Dan D'Aquila, GlaxoSmithKline

VP, Marketing & Communications

Michelle Santoro, Skanska USA

Co-Chair, Marketing & **Communications**

Tieg Murray Rustam, Skanska USA

VP, Membership

Laura-Ann Chin, Genesis Engineering

VP, Young Professionals

Jenna Eicherly, Laporte Consultants

VP, Students

Jon Becker, RPA Engineering

Symposium

Jill Clark, CRB Sandra Bones, IPS

Directors

Michael Faia, Jazz Pharmaceuticals Greg Sabatino, Morphotek Peggy Del Fabbro, M Davis & Sons Bill Dugary, Applied Control Engineering Glenn Lawrence, Merck & Co.

Past President

Kristina Pumphrey, Precis Engineering

FROM THE PRESIDENT'S DESK (cont.)

By Kristina Pumphrey

Finally, I would like to congratulate our incoming President Eleanor Small and all of our elected board members. I am looking forward to another exciting year. A list of upcoming events are outlined in the newsletter and our events on page 4.

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: kpumphrey@precisengineering.com

ISPE NIGHT AT THE PHILLIES

Membership Event

The Membership committee sponsored ISPE Night at the Phillies on Wednesday June 29. Festivities kicked off with a 90-minute private happy hour at the High & Inside Pub, which provided a platform for members to discuss and learn about the benefits of ISPE membership. In appreciation for their efforts, chapter volunteers, including board and committee members, were invited to attend the event with a plus-one at no cost.

Like any of our outdoor events, we plan them at the mercy of the weather, and, unfortunately, mother nature provided some of the worst storms we have had in our area since maybe Hurricane Sandy. According to VP of Programs, Mike DeBellis, "It was certainly what seemed to be a bad night for us, but what happened was wonderful for those of us who attended. We got to enjoy each other's company, reflect on the past year, meet some new contacts, and then wonder if we would have a home still standing when we did get home. But by the Grace of God, the weather let up and it actually turned out to be a great time and a really nice night for a baseball game."

Those who were able to endure the rain delay and stay for the game were treated to a runaway victory by our beloved Phillies. We hope attendees were able to make some meaningful connections and also just take a moment to give themselves a "pat on the back" for all the time and energy that they contribute to the success of our chapter throughout the year.

2018-2019 BOARD OF DIRECTORS

We recently held our 2019-2020 board members elections. We would like to thank the following board members for their service:

Past President

Danielle Rebori, Jacobs Wyper Architects

Rick Aulenbach, RPA Engineering

SPE MATTERS

A RISK BASED APPROACH TO THE MANAGEMENT OF VIRUS RISK IN A cGMP MANUFACTURING FACILITY

January Education Program | Maggiano's King of Prussia

Dr. Anne Stokes, PhD, spoke to our audience about a comprehensive viral safety program for the production of biopharmaceuticals which uses a threefold complementary approach: (1) control of raw materials, (2) in process testing and (3) demonstration of the capability of processing steps to clear virus. These and other considerations are tightly managed through a comprehensive risk management program that has resulted in confidence that the materials that are supplied to patients are free from virus contamination.

Dr. Stokes' presentation introduced a control framework for virus, TSE and novel microbial agents. She addressed why virus control is important during the manufacturing of biopharmaceuticals and the implications of virus/bacteria contamination to the pharmaceutical industry. We discussed the biopharmaceutical production of microbial or mammalian cells which are hosts to viruses or other microbial agents. Virus risk is addressed in the ICH Q5A guidelines which she discussed the three-pronged approach to virus safety. Dr. Stokes also presented on cell bank production, animal derived raw materials,

biopharm process equipment used in bulk drug manufacturing, single use bioreactors vs. stainless steel fermenters, monoclonal antibody production, virus (and TSE) life cycle of product and regulatory requirements, and safety approaches to manufacturing facilities. In conclusion, her message to us is that biopharmaceuticals are products of cells that have the potential to become infected with viruses, microbial agents, and TSE and the risk to the patient must be mitigated. Viruses (and TSE) can be carried for the lifetime of the product and evidence of clear mitigation of risk must be demonstrated to the regulatory agencies within the relevant dossiers.

Several questions and answers were provided, and Dr. Stokes received great feedback from our attendees. The family style Italian dinner contributed to a warm, receptive audience and it was a great evening for all. Thank you again, Dr. Stokes for sharing your expertise with our members.

Dr. Stokes' presentation was also made available on our website for all attendees to access HERE.

EVENT RECAP & PHOTOS

Intro to Engineering Fundamentals April Education Program

April's education program provided a refresher on the engineering behind some of the basic equipment and systems we use in the FDA regulated industries, such as pumps, filtration systems, water systems, fermentation processes, and more. This event offered a great opportunity for experienced engineers to gain new insight to the behind-the-scenes ways things get done.

Special thank you to our presenters Derek Phillips and Ed Mayo of Laporte Consultants.











EDUCATION TOPIC IDEAS?

What topics would you like to see covered at future education programs? Click **HERE** to send your



2019-2020 LOOK AHEAD

Upcoming Events Summary

ISPE DVC works hard to continue offering unique, educational and fun events. Below is the anticipated 2019-2020 Chapter Event Calendar. Keep an eye out for specific dates and topics for each event!

Draft Annex 1: What it Means to Sterilization and Moist Steam Quality September 23 in King of Prussia // Register HERE	January Program	Habitat for Humanity Volunteer Day Mid-April (member only event)
October Education	Annual Ski Trip January 2020	27th Annual ISPE DVC Annual Golf Classic May 4, 2020 at North Hills Country Club // Save the date!
Boston/DVC Joint Social Event October 27 at Margaritaville // Register HERE	February Education	ISPE DVC 30th Annual Symposium and Exhibition Mid-May 2020
ISPE Annual Meeting & Expo October 27- 30 in Las Vegas // Register <u>HERE</u>	March Program	June Education
Habitat for Humanity Volunteer Day Early November (member only event)	Membership: Spring Social (Students) Mid-March	Membership Appreciation Event Late June (member only event)
November Program	April Education	We target the second Tuesday of each month for program and education events (dependent on speaker availability)
NEW THIS YEAR! Holiday Party January 2020 (member only event)	INTERPHEX 2020 April 28-30, 2020 at Javits Center // Save the date!	

PROGRAMS VS EDUCATION

What is the difference between programs and education?

<u>Programs (Overviews and Inspiring Topics)</u>

- Cutting-edge science, inspirational speakers (i.e., CEO talks, new company/business models)
- Hot topics (i.e., newly announced governance policy changes, Geo-political ramifications)
- Tester/teaser for future education topics
- **Facility tours**

Education (In-Depth, Professional Development)

- Deep-dives of new guidelines and policies
- Engineering 101 refreshers (i.e., GMP, BiopharmE2E, etc.)
- Debates that impact the industry (i.e., single use-patient safety vs sustainability)







HABITAT FOR HUMANITY VOLUNTEER DAY

By Bob Hoernlein

On Friday, June 7, the Delaware Valley Chapter lent their services to the Bucks County chapter of Habitat for Humanity. The DVC has been volunteering for this non-profit organization for many years. With beautiful weather, the volunteers enjoyed a 70-degree day on the jobsite. parcel of land is a canal, many large

The team consisted of five ISPE DVC volunteers and two Habitat supervisors. The house we worked on was The five ISPE volunteers were Edward Chan of Amneal Pharmaceuticals, Youssef El-Bahtimy of Horizon Controls Group, Deirdre Garcia of HSC Builders, Tobi Mengle of tdmpe.com and myself.

Currently finishing construction is a two-story home at 213 Woodland Avenue, in Morrisville, PA. The threebedroom, 1.5 bath totals 1,800 square feet and includes a front covered porch. Previously, the lot was wooded, except for one home which was demolished by the previous owner. Some trees, including stumps, were removed in preparation for construction. The lot size is large enough to accommodate four homes; three of which are up and

in different stages pf construction. The house next to this one has a similar floor plan. Next to it is a two-story, four-bedroom, two bath house which will accommodate a handicapped child. Still in the foundation stage, will be a fourth ranch style house. Behind this trees and wooded area.

dedicated to Evita, a single parent, and her two school age children at the end of June.

Most of the team worked on finish painting molding, doors and wall touch-up. Tobi, a repeat volunteer, worked outside with a Habitat supervisor stuccoing the foundation.

DVC supplied hot coffee and doughnuts to kick off the workday. Pizza and beverages were given out for lunch and all were much appreciated by the seven-member crew. Also, first time DVC volunteers received a volunteer sweatshirt in appreciation for their service.

Photographs were taken and Youssef El-Bahtimy, chemical engineer, with Horizon Controls Group, presented the lead Habitat supervisor with a very generous \$200 check, as a company sponsorship for the event.

The house we worked on was dedicated to Evita, a single parent, and her two school age children at the end of June.

If you have an interest in donating your time or if you would like to contribute to our ongoing support of this worthwhile organization, please look for DVC notices of future volunteer days. The next event will be in early November.

We look forward to the next Habitat work day in November! If you are interested in working on a team, please contact Robert Hoernlein at: BobHoernlein@gmail.com



Save the date!

Look for emails announcing the date of our next Habitat for Humanity volunteer day in early November.

INTERESTED IN ISPE **MEMBERSHIP?**

Click **HERE** for more information.



ISPF DVC 26th ANNUAL GOLF CLASSIC

By Mike DeBellis | Held at Philmont Country Club

April 29 marked ISPE DVC's 26th Annual hole-in-one on either hole again this Golf Classic held at the Philmont Country Club in Huntingdon Valley, PA. We had a beautiful day at Philmont, which was a wonderful surprise since we had several rainy days before and after our event.

As golfers arrived at the registration area, they were treated to a logo'd towel by our sponsor **CAI** and the door prize this year was a ball cleaner. Golfers were able to enjoy Philmont's indoor lunch buffet before get-ting 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 your golf skills honed and dialed in for the ever challenging Philmont North Course is always helpful.

Thanks to our generous sponsors, this was another banner year for prizes and awards. This year's Hole-In-One sponsor was Brydges Group, who provided us with a chance to win a two-year car lease and drive a 2019 Alfa Romeo Guilia. A second Hole-In-One sponsor was **Bahnson Environmental Specialties,** who provided us with a chance at winning a glorious trip for two to the 2020 Masters in Augusta, GA. Golfers were greeted by the Bahnson reps and treated to some snacks during their hole-in-one attempt. As you may have guessed, no one had a

> Save the date! Same great event, new location!

27th Annual ISPE DVC Annual Golf Classic will be held on May 4, 2020 at North Hills Country Club.

year. Clearly, we all need more practice at our hole-in-one shots. But, I'm forever the optimist, there is always next year! Someday, someday...

Our Refreshment Cart Sponsors were Herman Goldner Co., Inc. and First Pharma Consultants, LLC. The Refreshment Table Sponsor was **Evoqua** Water Technologies.

Trophies this year were a classic golfer and awarded to the top three foursomes using a modified Callaway Scoring system and determined by the club pro.

This year's foursome photographs were taken by our volunteer photographer Laura Ann Chin, and are posted for our golfers to view **HERE.**

Congratulations to all this year's winners, including the winners of this year's highest scores: a twosome who shall remain nameless (Eric Silk and David Musto) to protect their reputations. Just kidding, they have nothing to be ashamed of. Remember, there are no losers at our golf outings! Everyone is a winner.

Inside the Philmont's banquet rooms, the party continued as everyone enjoyed the open bar cocktail hour and hors d'ouevres while chatting with friends, colleagues, and clients. The dinner buffet included pasta, the "incredible" seafood bar, carved meats, and a dessert bar where you could make your own ice cream sundaes... I gained 5 pounds just writing about it.

After dinner, we presented our chapter president, Kristina Pumphrey, with her very own Presidential Putter. It's a token of our appreciation for all the time and hard work our presidents put into this position, taking on all the responsibilities required of our chapter president, and for serving the members of the Delaware Valley Chapter throughout the year. Thank you again, Kristina. It's been a pleasure working with you.

Special thanks must go to Susan Padien, our chapter logistics manager, for all her hard work with registration, billing, late registrants, cancellations, chasing payments, and helping me keep track of everyone. Thank you so much, Sue. Thank you to all the volunteers who helped with registration, handing out giveaways, setting up trophies, hole-in-one judging, and countless other small details. I thank every one of you for your time and contributions to the outing; we couldn't do this without you. I especially couldn't have done this without the help of Lisa Dugery who was literally my right and left hands, making sure I didn't lift anything too heavy after my by-pass surgery.

Again, this year's hole sponsorships were generous and a special thanks to each one of them. 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.

Thank you to Philmont CC for providing a wonderful home to our outing for 22 years, where does the time go! It was another huge success as attendance was even better than last year. I hope this will continue to be a trend for future outings, especially next year.

(continued on page7)



ISPE DVC 26th ANNUAL GOLF CLASSIC (cont.)

By Mike DeBellis | Held at Philmont Country Club

We have a big announcement for our 27th ISPE DVC Annual Golf Classic: it will be held at a new venue. Next year's event will take place at the North Hills Country Club in Glenside, PA on May 4, 2020. We are looking forward to seeing you all again at our new location. Be sure to join us next year for a whole new golf experience. Meet Jack Connelly, former President of the PGA, and our old friend from Philmont, Mickey Sokalski, Golf Pro. It's going to be a great day of GOLF! So, until next year, hit'em long, and hit'em straight!

For the Love of the Game!

Mike DeBellis 2019 Programs Chair and Golf Outing Program Manager

Congratulations to all of this year's winners:

Ken Blankenship, Matt Snyder, Dave Thompson, and Marc Pelletier with a score of 63

Jeff Graef, Jeff Kasaczun and Jeff Pecsi with a score of 63 (a tie breaker determined 2nd place)

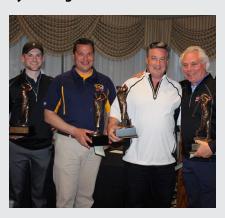
William Wiederseim, Andrew Signore, Joseph O'Donnell, and Bobby Crawford with a score of 64

Closest to the Pin prizes were won by Mike Wixted (4'6"), William Wiederseim (10'0"), Bobby Crawford (1'5"), and Jeff Matvienko (2"3")

Longest Drive winners were Joseph O'Donnell (men) and Melissa Barnes (women)

EVENT PHOTOS

This year's foursome photographs were taken by our volunteer photographer Laura Ann Chin, and are posted for our golfers to view by clicking the link below.









WFI COME NEW ISPE DVC MEMBERS!

February 2019 - August 2019

Andreas Abend

Merck & Co.

Danielle Adams

Merck & Co.

Chris Albeck

Jacobs Engineering Group

Parth Amin

Nagesh Bandi

Merck & Co.

Logan Bartholomew

West Chester University

Sandra Bones

IPS

Monique Brown

Achillion Pharmaceutical

Anna Burbank

Erin Maureen Burke

Mark Burke

Packaging Coordinators Inc.

John Chippari

West Pharmaceutical Services

Sunny Chipps

Mylan

Jamie Nicole Coia

John Costalas

CRB

Darrin James Cowley

Rajesh Dave

Merck & Co.

Joseph David

BLH-Nobel

Mark Diehl

Techno-Pro Solutions Inc.

Jeffery Downing

GlaxoSmithKline

Kevin C. Ellis

Siegfried USA

Rich Falkowski, Sr.

A&B Process Systems Corp

Dan Gower

Hargrove Life Sciences

Steve Graff

Kupper Engineering

Lorenzo Gutierrez

Jacobs Engineering

Uday Hardikar

B.Braun

Ryan Haugh

Hayward Gordon

Isaac Hayes

Siona Ho

Takeda

Huyen Hoang

Jonelle Marie Homa

Azzur Group

Cody Hopkins

M Davis & Sons Inc.

Melissa Howard

Merck & Co.

Charlie Hu

Merck & Co.

Rodrigo Isaza

Amec Foster Wheeler

Christine Jampo

Boston Analytical Inc

Christine Janizewski

ABEC

Chris Jones

Kemutec Group Inc.

Rachana Subhash Kelkar

University of Pittsburgh

Kevin Kincer

Mylan

Lisa Klein

Greene, Tweed & Co.

Tim Kriebel

Eastern Controls, Inc.

Andrew Kuroki

CRB

Samelyse Lees

GlaxoSmithKline

Nicholas Leight

ABEC

Dan Lesutis

Proconex

Lynn Lundy

West Pharmaceutical Services

Paul Lutz, Jr.

STERIS/CECS

Gerry Maybach

Cook MyoSite, Inc.

Christine McQuade

Shyam Mehta

Olivia Nicole Miller

Emerson Automation Solutions

Leo Milligan

Jacobs Engineering

Gina Norwood

Ryan Pearce

Merck & Co.

Eve Phelps

RedKnight

Leilani Rabanillo

John Renna

Jacobs Engineering

Dorothea Roberts

GlaxoSmithKline

Helen Roytman

Sharp Packaging Solutions

James Ruddell

Business & Decision

Ahsan Jamal Sarwar

Hikma Pharmacueticals

Levi Schenk

CSL Behring

Hillary Schuessler

GlaxoSmithKline

Russell Scola

Torrent Pharma Inc.

Keith Shannon

Precis Engineering, Inc.

Jacqueline Shiner

Horizon Controls Group

Peter Benjamin Toft

Merck & Co.

Robert Turok SPX FLOW US LLC

Alicia Urrutia

LifeAire Systems

George Wagner

George Wagner

Laura Wareham

Jacob Wargo

University of Delware

Karl Weiss

Sharp Packaging Solutions

Greg Wildgrube

Xyntek, Inc.

Tennille Williams

Estee Lauder Companies

Harry Wolfgang

Enkang Carol Yang

Sarah Loy Yeager

Janssen

SPE MATTERS

MEMBER MILESTONE ANNIVERSARIES

February 2019 - August 2019

30+ Years

James Banafato Mancel Associates, Inc.

Edward Tannebaum Strategic Planning Initiatives, LLC

Gary Wojcik DSM BioTechnology

Stephen Yu

Louis Angelucci, III Consultant

John Via, III **Drexel University**

Jozef Potters Jeffran Services LLC

Edward C. Bendzlowicz

25 Years

Michael Leader SNC-Lavalin Project Services

Dave DiProspero CRB

George Wiker

Michael Alexander MLA Associates, Inc.

Anthony Blandin Egalet Pharmaceuticals

Fred DiPasquale **Sharp Packaging Solutions**

Peter Henry Honeywell

Edward Ashare

20 Years

Barbara Begner

Kevin L. Koffke

AES Clean Technology, Inc.

Tim Guffey

Mark Szigeti Stantec Consulting Services

Hazem Eleskandarani Johnson & Johnson

Sean Illig Sanofi Pasteur

John Weaver Lee Industries Inc.

Mounir Azar Automation & Validation Solutions Inc.

Paul Heaps, Jr. Techniserv

David Stroup CRB

Robert Calvert Jacobs Engineering Group

Walter Matzmorr Tunnell Consulting

Jeff Wenner IPS

Kristen DeVito

Catalent Pharma Solutions

Patrick Toner Structure Tone

Matt Walczer Alexanderwerk Inc.

15 Years

Richard Gehring Applied Controls Inc.

Francesca McBride Jacobs, Life Sciences

Steven Walter

Hargrove Life Sciences

Alpana Desai

Emerson Automation Solutions

James Keane

Tracer Technologies, LLC

John Fay, Jr.

Dana Tilley Jacobs Engineering Group

Robert Finn GlaxoSmithKline

Ray Lockard **Ernst and Young**

Robert Mecke West-Ward Pharmaceutical Corp

Shannah Falcone CRB

Philippe Cini Turesol

Brian Peasley CRB

Katria Harasewych Merck & Co.

Laura DeLea IPS

Brian Egan IPS

Group

Joseph McCloskey Jacobs Engineering Group

Michael Earyes Compliance Technology

Stanley Whitman GlaxoSmithKline

EVENT RECAP

29th Annual DVC Exhibition & Symposium: Photo Recap









ISPE DVC Sponsored Bus to **INTERPHEX in NYC**

In April, ISPE DVC sponsored a bus to Interphex 2019. We departed from the parking lot behind IPS in Blue Bell. Approximately 30 people joined us for this no cost, no hassle way to travel to NYC for the show. It was a nice opportunity for our members to chat with old friends and meet/make some new friends in the industry as well. 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 next year!



MEMBER MILESTONE ANNIVERSARIES (cont.)

Reem Malki

Christine Boisrobert

American Air Liquide

Steve McDaniel

EwingCole

Neil Duser

Sanofi Pasteur

Lori Pfahler

Merck & Co.

Amy Markey

John Volence

Michelle Batz

Merck & Co.

Leo Krieg

CRB

AstraZeneca

Brendan Bradley

Ernest Keepfer

Theodore Shoneck

Elizabeth Blackwood

Johnson & Johnson

Maneesha Altekar

AstraZeneca

George Bass

GGB Services

ProPharma Group

Evoqua Water

Technologies

David Wargo

Mylan

Vanrx Pharmasystems, Inc.

Christopher Barbieri

Precis Engineering

Carisma Therapeutics, Inc.

Mylan

February 2019 - August 2019

Gary M. Logan

Takeda

Elizabeth Holden

Jacobs Engineering Group

Timothy Hancock

BioPro Projects LLC

Thomas McDonough

Matak LLC

Nathan Roman

Genesis Engineers

Jason Becker

Sanofi Pasteur

10 Years

Gary Wirt

Jacobs Engineering Group

Wayne Oyer

Emerson Fluid Automation/ASCO

John Knighton

Johnson & Johnson

Aaron Krause

Getinge USA Inc.

Tom Carroll

Nora Systems, Inc.

Glenn Lawrence

Independent Pharmaceutical

Consultant

Brian Marshall

RPA Engineering

David Schoneker

Colorcon

Bryan O'Toole

Teva Pharmaceuticals

Massimiliano Passerini

Angelantoni Life Science

David Cain

B.Braun

Frederic Le Pape

FPS America

Alicia Falls

Paul Valoret

Merck & Co.

Panos Boudouvas

ZenQMS LLC

Wendy Sunderland

Amicus Therapeutics

5 Years

Margaret L. Hindley

Johnson & Johnson

Genevieve Lampinen

Brian Weed

Controlled Contamination Services

Heidi Krueger

Xybion Corporation

Anthony Nicola

Jubilant Cadista **Pharmaceuticals**

Pete Yoder

GSK Vaccines

Christopher Arnold

Wick Fisher White

Bastien Peron

ABC-ACTINI LLC

Carl Forte

CSL Behring

Joseph Byrnes

Javan Engineering, Inc.

Henry Tom

DePuy Synthes

Joseph Tarnowski

GlaxoSmithKline

Martin Lipa

Merck & Co.

UPCOMING EVENTS

Draft Annex 1: What it Means to Sterilization and Moist Steam Quality

September 23, 2019 | 5:30 - 8:30 pm

The presentation, given by Walid El Azab, Technical Services Manager at STERIS Life Sciences, will highlight the different regulatory requirements regarding steam sterilization management, validation, and requalification against the draft Annex 1. This presentation will analyze the requirements for steam used for sterilization and approaches to steam sterilization of product, equipment, and packaging components.

ISPE DVC-Boston Joint Annual Meeting Social 2019 at Margarita Las Vegas

October 27, 2019 | 6:00 - 10:00 pm

Are you attending the annual meeting? If so, join Delaware Valley and Boston Area chapters for a joint social on Sunday October 27. This get together is a great opportunity for networking, catching up with old friends and connecting with new colleagues. Stop by for cocktails and hors d'oeuvres. Margaritaville is an upbeat, casual restaurant and bar conveniently located a short walk from Caesar's Palace! This casual event is FREE to attend but we ask that you pre-register.

SPE MATTERS

THANK YOU TO OUR 2018-2019 SPONSORS **FOR THEIR SUPPORT**















BUILDERS & CONSTRUCTION





MANAGERS













ADVERTISE WITH US!

Interested in advertising for our next program year? 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 or

Tieg Murray Rustam Tieg.Murray@skanska.com

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 Michelle.Santoro@skanska.com or

Tieg Murray Rustam Tieg.Murray@skanska.com

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:





