From the President’s Desk

By Kristina Pumphrey

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

ISPE-DVC had a busy fall and is already halfway through our program year. A few highlights:

• September’s Plant Tour of Sanofi Pasteur in Swiftwater, PA
• November’s education in conjunction with the Rockwell Automation fair. With their support, we were able to offer the event free of charge!
• Annual Holiday Party which was a night to remember at the Mutter Museum.

I encourage you to read on to learn more about our recent events.

I would also like to highlight a few of our committees that contribute to the success and operations of our Chapter. The Marketing and Communications (MAC) Committee has streamlined our meeting notices to go out on set days and provide links to all our events with a highlight on one each time. They have been recognized by national as having the most active chapter website. Membership has been soliciting feedback from active and recent expired members. They have also organized local roadshows at area companies to spread the word about our great chapter. Please contact us if your company would be interested in hosting an information session. The symposium committee is also working hard to organize this year’s event which is taking place on Thursday May 16th.

In addition to events, we have also strived to use funding and volunteer time to give back to our community. We contributed to Habitat for Humanity with a volunteer event in December and upcoming again in April. We also presented Habitat with a check at our Holiday Party and contributed to Toys for Tots. The Chapter sponsored the local Future City’s competition and judged a special award entitled the Chuck Clericuzio Award for Innovation in Healthcare. We also took part in their engineering fair where we presented 3D modeling vs. 2D drawings to help middle school students learn more about engineering.

I am thrilled with what the Chapter has accomplished so far and I am honored to be serving as President of the DVC this year. A list of upcoming events are outlined in the newsletter and our events page.

VISIT THE ISPE-DVC WEBSITE HERE

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
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2018-2019 LOOK AHEAD

Upcoming Events
ISPE-DVC is working hard to continue offering unique, educational and fun events. Keep an eye out for more information on what's to come!

- March Education: Critical Utility - Pharmaceutical Water Generation
  March 4, 2019 | 5:00 - 9:00 pm
  Register HERE!

- March Plant Tour: CIP: Tank Cleaning Innovations & Technologies

- Save the date! 26th Annual ISPE-DVC Annual Golf Classic
  Monday, April 29, 2019

- Save the date! ISPE-DVC 29th Annual Symposium and Exhibition at Lincoln Financial Field May 16, 2019 | 3:00-9:30 pm

2018 ISPE-DVC Annual Holiday Party
Held at the Mütter Museum

Our 2018 Annual ISPE-DVC Holiday Party was held at the Mütter Museum in Philadelphia on December 13. It was a fabulous event at an incredible venue.

We would like to thank all of those on the event team who made this such a special night. Special thanks to Laura Ann Chin for capturing the evening with fabulous photography. We also thank everyone who attended. It was a wonderful night of food, music and camaraderie!

We would like to congratulate IPS for being selected as the ISPE-DVC Sponsor of the Year and Bob Matje for receiving the coveted Buz Lange Award.

As an organization, our chapter was also able to provide generous support to both the Toys for Tots drive and Habitat for Humanity.
On October 9, 2018, the ISPE-DVC gathered at the Crowne Plaza Hotel in King of Prussia to learn about aging facilities and their associated regulatory impacts. The evening opened with beverages and networking with about 40 members in attendance. After networking, the members sat down for dinner and the beginning of the presentation. Over the course of two hours, our guest speakers Linda Kramer and Terry Ward walked the attendees through the challenges associated with keeping aging biological manufacturing facilities cGMP compliant, the complications with new construction and retrofits, and the possible impacts of future regulatory compliance.

Governing bodies, such as the FDA or EU, have extensive guidelines for operating manufacturing facilities. Whether the owner is interested in the modernization of an existing facility or building new, it is critical that regulatory guidelines are followed. Failure to do so can lead to delays in schedule, leading to product shortages. Both Linda and Terry have vast experience in regulatory compliance, including laying out the challenges that companies face and possible paths to rectification. Linda and Terry’s presentation also provided useful information on hot topics related to potential FDA changes in the future. Many of us are aware of regulatory bodies but are less familiar with the challenges in maintaining compliance.

On behalf of all of us at the Delaware Valley Chapter, we thank Linda and Terry for taking time to share their lessons learned and also their accomplishments. It was a great evening for networking and education.

**Speaker bios:**

Linda Kramer is the Director of Global Regulatory Affairs at GlaxoSmithKline where she is responsible for inspection readiness for regulatory authorities, performing internal quality audits of the monoclonal antibody manufacturing facility and maintaining a state of compliance for the quality systems used in GMP inspections.

Terry Ward is the President and Owner of Ward Regulatory Compliance consulting where she provides independent consulting services for pharma, biopharma and vaccines companies. Prior to this venture, Terry was involved in regulatory compliance and quality assurance as a Senior Director at GlaxoSmithKline.

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**ISPE-DVC Membership Social**

The Membership Committee hosted a social at Yards Brewing in Philadelphia on September 27. The event featured opportunities to learn about the benefits of membership in ISPE as well as casual networking with our industry peers over craft beers and gourmet bites. A custom brewery tour was offered that focused on the canning line, an exciting feature of Yards’ new location at 500 Spring Garden Street. Current members were highly encouraged to bring a non-member as a guest to introduce them to what our organization has to offer and to earn a discount voucher for a future event. Notably, John Bournas, the CEO of ISPE, made a special appearance at the sold-out social.
SANOFI SWIFTWATER FACILITY TOUR
September Education Program | Swiftwater Campus

History of the Site
The Sanofi Pasteur site in Swiftwater, PA, formerly known as the Pocono Biological Laboratories, was founded in 1897 by Dr. Richard Slee. The laboratories later became part of the National Drug Company, then Connaught Laboratories, followed by Pasteur Merieux Connaught and Aventis Pasteur.

The Swiftwater site has nearly 120 years of vaccine experience and created its first influenza vaccine in 1947. Today the 500 plus acre campus has more than 50 buildings and is the global center of the scientific and industrial expertise. Sanofi Pasteur is the world’s leading seasonal influenza vaccine manufacturer. After doubling its global vaccine production capacity over the past 10 years, Sanofi Pasteur now produces over 220 million doses of seasonal influenza vaccine for worldwide distribution. That’s approximately 40 percent of the global influenza vaccine supply and a minimum of 65 million doses just for the United States.

The Swiftwater site produces, fills, formulates, inspect, and packages vaccines for seven diseases: Influenza, Pertussis, Diphtheria, Meningitis, Haemophilus Influenzae Type b (Hib) infections, tetanus, and yellow fever.

The ISPE Tour
Approximately 40 DVC ISPE members were treated to transportation to and from the Swiftwater site. Coffee and donuts and movies provided us with entertainment during the 90 minute bus ride. After our security check, we were able to enter the facility in Building 60 where our guests were treated to a buffet style lunch.

Our hosts were Tom Bryant, Mark Diehl, and Mike Killian. They provided several presentations to us on CFD (Computational Fluid Dynamics) implementation at Sanofi and its benefits. CFD is a branch of fluid mechanics that uses numerical analysis and data structures to solve and analyze problems that involve fluid flows to perform the calculations required to simulate the interaction of liquids and gases with surfaces defined by a boundary condition. Mark Diehl, Director of Engineering, presented how Sanofi has implemented this technology to study HVAC air flows in their process areas and minimize air flows to conserve energy.

Tom Bryant, Senior Director of Engineering Project Management, led a bus tour of the Swiftwater campus. The Swiftwater site is truly a beautiful campus. A winding, babbling stream traverses the site and it is truly picturesque. The natural splendor of this site doesn’t end there, as deer, turkey and other wildlife can be seen as one walks between buildings or to the multi-tiered parking lots. Sanofi still has the original laboratory utilized by Dr. Slee, which is a museum today, reminding us of how far the site has come.

After our bus tour, we were guided on a tour of their new QC lab. The QC lab was designed and constructed using a modular design. Pre-assembled piping and framing were utilized and the entire building was constructed in 18 months. One of the highlights was an automated multi-level stock storage system. Lab workers are able to get all their supplies at the touch of a few buttons. The entire system is enclosed and out of site and is accessed within an airlock area. Labs utilize portable work stations for easy re-configuration as needed. Common stationary utility stations for lab gases, water, etc. are available at each station.

Our last presentation was a virtual tour of the new Influenza Manufacturing Facility given to us by Mike Killian, Reliability Engineer. 3D modeling was used to illustrate the different areas of the 160,000 square foot facility. A new central utility plant was also constructed to provide the new building and other future site utility needs.

Sanofi Pasteur was an excellent host to our members and the tours were informative and information was readily shared within the boundaries of confidentiality.

On behalf of all of us at the Delaware Valley Chapter, we thank Tom and his team for being such gracious hosts, taking their time to share some of their experiences and accomplishments, and allowing us into their facility. It was a great day and great tour.

As a special treat with a limited audience, the Sanofi campus tour was an ISPE-DVC members only event.

Save the date!
26th Annual ISPE-DVC Annual Golf Classic will be held on Monday, April 29, 2019 at Philmont Country Club.

Save the date!
29th Annual ISPE-DVC Symposium and Exhibition will be held on Thursday, May 16, 2019 at Lincoln Financial Field.

Save the date!
HABITAT FOR HUMANITY VOLUNTEER DAY

By Bob Hoernlein

On December 7, 2018, it was a bitter cold morning, but that didn’t stop seven ISPE members from volunteering for Habitat for Humanity of Bucks County. Eve Phelps from RedKnight, filled in as head volunteer, for her father, Bob Hoernlein, who was away on vacation. After having some warm coffee and meeting the other team members for the day, the team got started on building the foundation for one of four homes that will be located on that particular work site.

The work site is located in Morrisville, a town in Bucks County, across the Delaware River from Trenton. The current lot is located in a residential neighborhood that is within walking distance of shops. With access to jobs in both PA and NJ, this location seemed perfect for four new Habitat homes. After a cold morning of mixing concrete, moving cinder blocks and operating wheelbarrows, the team warmed up for some pizza in an area pizza shop.

The afternoon warmed up a bit, the coffee continued to be poured, and the work went into late afternoon. All of the participants had a fun time meeting one another and working on a very meaningful project.

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

ISPE 2018 Annual Meeting DVC/ Boston Joint Social, Hard Rock Café Philadelphia

DVC and Boston joined forces to host a social at the November 2018 ISPE Annual Meeting in Philadelphia. Holding up their end of a friendly wager on Super Bowl 52 – Boston Past President, Jack Campion adorning the Nick Foles jersey DVC Past President, Danielle Rebori, gave him! He took the opportunity to wear plenty of Women in Pharma pins and sold them as part of a fundraiser. He also kindly gifted Danielle with a case of Harpoon IPA. Sports competition fun, food and drink made it a great evening to network and catch up with friends near and far.
WELCOME NEW ISPE-DVC MEMBERS!

July 2018 - January 2019

Sayaka Abe
Merck & Co.

Srinivas Addepalli
Caliber Infosolutions

Philip Albert
Greene, Tweed & Co.

Chris Altum
CRB

Maureen Andersen
Arcadis

Carlton Andrews
Meto Systems

Samantha Blanford

Zak Blazic
The Norwood Company

Mark Caldwell
Jacobs Engineering Group

Euler Da Cunha Santi
Laporte Consultants

Gautam Dalwadi

Rhonda Dodson

Jehad Elsaadi
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Dmitriy Fedorenko
Chromatan

Mark Fenstermaker
Jacobs

Shane Filer
Neal Systems

Daniel Finnegan
Covex LLC

Sayaka Abe
Merck & Co.

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Rhonda Dodson

Jehad Elsaadi
International Products Corporation

William Entrikey
Wm Entrikey Design

Dmitriy Fedorenko
Chromatan

Mark Fenstermaker
Jacobs

Shane Filer
Neal Systems

Daniel Finnegan
Covex LLC

Dan Galvin
NETZSCH Premier Technologies, LLC

Michael Gao

Timothy Garrett
Comecer, Inc.

Steve Goul
Sanofi

Dean Hammond
ABB Inc.

Lyndsay Handschuh
Genesis Engineers

Karen Harbison
Exyte

Agnes Hardy-Boyer
Sanofi Pasteur

Christopher Hope
Zoetis LLC

Samantha Hutwick
Drexel University

Janet Japzon-Salugao

Thomas Joos
Cook MyoSite, Inc.

Kathy Junod
Synergy Pharmaceuticals

Mia Kiistala
Biogen

Brian Kirk
CRB

Tim Kline
Johnson & Johnson

Richard Kobylinski
Cooney Coil & Energy

Seth Kodner

Judy Kozak
Jacobs Engineering Group

Victoria Kramer
Stantec

Magda Krapf
Jacobs Wyper Architects

Gregory Kratz
The Norwood Company

Maris Kurcina
AES Clean Technology

Whitney Kutney
Valsource Inc.

Jennifer Leonard
Air Liquide America

Timothy Lisle
Jacobs Wyper Architects

John Looper
Arcadis

Roger Luhiriri
University of Pennsylvania

Alex Lukacs
Catalent

Heather Mack
Lonza

Ifte Mahmud
Merck & Co.

Bradley May
Advance Clinical (Morphotek/Eisai)

Peter McCormick
Mylan

Ashlin Miller
Pentec Health

Charles Mina
Sanofi Pasteur

Shannon Morris
Synergy Pharmaceuticals

Michele Nathan Borek
BDC

Kyle Nedlik
Stantec

Liz Opsitnick
Greene, Tweed & Co.

Dominic Orlando

Emily Ormsby
Stantec

Baris Polat
Mylan

Michelle Reyes
AstraZeneca

Cliff Risell
GOJO Industries Inc.

Dan Rudolph
Emergent BioSolutions

Kelly Ruff
Pace Analytical Life Sciences

Amy Rupp
CSL Behring

Aitor Sanchez-Prado
EwingCole

Robert Sassa
W.L. Gore & Assoc Inc.

Elizabeth Sassano
Greene, Tweed & Co.

Prakash Sattiraju
Caliber Infosolutions

Amy Schriver
Sheridan Group

Craig Schweit
CRB

Toshi Shant
Flowmetric Life Sciences

Benjamin Shapiro
SNC Lavalin

Carol Shultz
Mylan

Scott Sommer
E-Technologies Group

Ag Spurling
MHG Consulting Inc.

John Stewart
Lyophilization Technology Inc.

John Sturgis, Jr.
Natoli Engineering

Robert Tarlo
Arcadis

David Taylor
Chromalox

Michael Thomas
Arcadis

Michael Tracey
Arcadis

Michael Treacy

Renny Varghese

Joseph Weaver

Joseph Zarkoski
Synergy Pharmaceuticals
MEMBER MILESTONE ANNIVERSARIES
August 2017 - January 2018

30+ Years
Peter T. Bigelow
XCell Strategic Consulting, LLC
Ralph A. Blackmer
Vector Hana
Richard A. Davis
Girton Manufacturing Co Inc.
Robin E. Muench

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Ralph A. Blackmer
Vector Hana
Richard A. Davis
Girton Manufacturing Co Inc.
Robin E. Muench

Lawrence C. Tiboldino
Merck & Co Inc.
John A. Ververelli
Dimitri J Ververelli Inc.

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Proconex
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Janssen Supply Group, LLC
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CRB
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W. Daniel McChesney
Integra Lifesciences
Aimee Penko
CRB
Jeffrey W. Sallack
ILC Dover
Lou S. Schmukler
Bristol-Myers Squibb

William H. Spicher
Lee Industries Inc
Daniel J. Tisak
Bala Consulting Engineers Inc
Joseph A. Tyska
Bristol-Myers Squibb
Peter T. Vishton
Terrence P. Walsh
TransCelerate BioPharma Inc
Gregory A. Wharton
Lee Industries Inc
James J. White, IV
JJ White Inc
Stephanie A. Wilkins
PharmaConsult US Inc
Jenny N. Wong
AstraZeneca Pharmaceuticals

20 Years
Jeffrey M. Beck
Jacobs

EVENT RECAP & PHOTOS

Congratulations to Eleanor Small, Ph.D., DVC Vice President on her recognition as Young Engineer of the Year from Delaware Valley Engineers Week Committee of the Engineers’ Club of Philadelphia!

The Engineers’ Club of Philadelphia is dedicated to relationship building and networking among technical professionals, communication and collaboration among engineers, raising the awareness of engineering in our society, and the professional development of its members.
MEMBER MILESTONE ANNIVERSARIES (cont.)
August 2017 - January 2018

Russell R. Booth, Jr.
Elizabeth-Hata International

John J. Burke
Johnson & Johnson Consumer

Charles F. Calitri
Pfizer

Bernard J. Carroll
Genesis Engineers, Inc.

Albert M. Cinciripino
Pfizer

Christopher L. Daugherty
GSK Biologics

Frank J. Davidowski

Michael Peter DeBellis
Jacobs

John S. Dinka
West Pharmaceutical Services

Rose Mary A. Dollard
Johnson & Johnson Regulatory Compliance

William D. Egan
Merck & Co Inc.

John B. Eshleman
Corium International

Curtis R. Firestine
CRB

Keith F. Gallion
CRB

Jessica L. Godshall
Hargrove Life Sciences

Stephen J. Heidel
Patheon

David B. Lerner
PA Consulting

David R. Melick
Precis Engineering

Michael Morley
New England Controls Inc.

Joyce L. Morrow
Merck & Co Inc.

Daniel O’Leary
GlaxoSmithKline

Mark Rodenberger
ALMAC

Brian K. Smith
SKAN US, Inc.

John K. Tagland
GlaxoSmithKline

Teresa Ward
Ward Regulatory Compliance Consulting LLC

15 Years
Jonathan Bailey
Janssen Biotech Inc.

Kenneth D. Baker
AdvantaPure

Brad D. Berkowicz
Shire

Joseph K. Berlingis
Yoh Validation, Quality, Compliance Services

Rebecca A. Brewer
Quality Executive Partners Inc.

Ted Buczacki, Jr.
Merck & Co Inc.

Eileen DeWald
Alcon Manufacturing Ltd

Pamela Bruen Docherty
Siemens Industry, Inc

Edi D. Eliezer
BioPrizM

Michael Faia
Jazz Pharmaceuticals, Inc.

Barbara Gallion
Barbara Gallion & Associates, Inc.

Clara M. Gudolonis
Pharmatech Associates, Inc.

William Edward Hill
West Pharmaceutical Services

Raymond C. Horner
STERIS Corp

Saji Jacob
Ace Consulting

James W. Keaveney
Emerson Automation Solutions

Stephen Kohlbrenner
DME

John E. Kurth
A/Z Corporation

Peter W. Lowry
Eisai/Morphotek Inc.

Michael J. Maurer
GlaxoSmithKline

Shaun McWeeney
Janssen Research & Development

Ronald Moritz
Interstate Technical Products

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Johnson Matthey

Scott A. Summers
Herman Goldner Co Inc

Mark D. Walkush
BioPharma Systems

Mary E. Waters
AES Clean Technology, Inc.

Thomas Zuno
Eli Lilly Inc.

10 Years
Perry J. Clemens
Sanofi - Westborough

Jason S. Collins
IPS

John D. Dearnaley
COVEX LLC

Mark DeLuca
Del Engineering

Susan E. Green
Johnson & & Johnson Consumer

Martin W. Hack
LB Bohle LLC

Timothy M. Knob, Jr.
Lee Industries Inc.

Glenn R. Kowalski
Arcadis
ISPE MATTERS

UPCOMING EVENTS

March Education: Critical Utility - Pharmaceutical Water Generation
March 4, 2019  |  5:00 - 9:00 pm
Attendees will learn about one of the critical utilities used on all pharmaceutical and biotech campuses, purified water. Gary will cover the different water standards required for various applications in biopharma environments, the technologies used to achieve different grades of water and the qualification for such systems.

REGISTER HERE

26th Annual ISPE-DVC Annual Golf Classic
Monday, April 29, 2019
Philmont Country Club
Huntingdon Valley, PA
SAVE THE DATE! MORE INFO TO COME!

ISPE-DVC 29th Annual Symposium and Exhibition at Lincoln Financial Field
May 16, 2019  |  3:00-9:30 pm
This is ISPE Delaware Valley Chapter’s 29th year of hosting this event. We are proud to be the originating chapter of Equipment Supplier Exhibitions. Again, our event will be located at Lincoln Financial Field which allows us to continue expanding our exhibition hall floor space. Our goal is to add value for our members and event attendees. To this end, we will continue providing education opportunities, a career fair, an academic pathway to our society and awesome networking event!

LEARN MORE HERE
THANK YOU TO OUR 2018-2019 SPONSORS FOR THEIR CONTINUED SUPPORT

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

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

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: