2019

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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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www.ispe.org/delaware-valleychapter





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

ISPE-DVC had a busy fall and is already half-

way 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

2018-2019 BOARD OF **DIRECTORS**

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Greg Sabatino, Eisai / Morphotek

Past President

Danielle Rebori, Jacobs Wyper Architects



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**

March 12, 2019 | 5:30-8:30 pm Register <u>HERE!</u>

- 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.







AGING FACILITIES TO NEW TECHNOLOGIES:

REGULATORY IMPACT ON cGMP MANUFACTURING **FACILITIES & PRODUCT LICENSED APPLICATIONS**

October Education Program | Held at Crowne Plaza King of Prussia

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.



EVENT RECAP & PHOTOS

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 manufacture. 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, inspects, 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.



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



Financial Field.

29th Annual ISPE-DVC Symposium and Exhibition will be held on Thursday, May 16, 2019 at Lincoln



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





EVENT RECAP & PHOTO

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 adorned the Nick Foles jersey DVC Past President, Danielle Rebori, gave him! He took the opportunity to wear plenty of Women in Pharma pins and soldthem 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

International Products Corporation

William Entriken Wm Entriken Design

Will Elittikeli Desigi

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 Huttick

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

JacobsWyper Architects

Gregory Kratz

The Norwood Company

Maris Kurcina

AES Clean Technology

Whitney Kutney

Valsource Inc.

Jennifer Leonardi

Air Liquide America

Timothy Lisle

JacobsWyper Architects

John Loeper

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

Brian Metcalf

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

Krupesh PatelTemple University

Baris Polat

Mylan

Michelle Reyes

AstraZeneca

Cliff RisellGOJO 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 Schwait

CRB

Toshi Shant

Flowmetric Life Sciences

Benjamin Shapiro

SNC Lavalin

Carol Shultz Merck & Co.

Scott Sommer

E-Technologies Group

Ag Spurling

MHG Consulting Inc.

John Stewart

Lyophilization Technology Inc.

John Sturgis, Jr. Natoli Engineering

Robert Tarlo

David Taylor Chromalox

Arcadis

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

Lawrence C. Tiboldo Merck & Co Inc.

John A. Ververelli Dimitri J Ververelli Inc.

Peter T. Bigelow XCell Strategic Consulting, LLC

Ralph A. Blackmer **Vector Hana**

Richard A. Davis Girton Manufacturing Co Inc.

Robin E. Muench

Lawrence C. Tiboldo Merck & Co Inc.

John A. Ververelli Dimitri J Ververelli Inc.

25 Years

Donald C. Bockman Proconex

William H. Cagney Janssen Supply Group, LLC

Yvonne M. Duckworth **CRB**

John S. Holton

Kenneth S. Kovacs

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**

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,

Clara M. Gudolonis

Pharmatech Assocociates, Inc.

William Edward Hill

West Pharmaceutical Services

Raymond C. Horner

STERIS Corp

Saji Jacob

Ace Consulting

James W. Keaveney

Emerson Automation

Solutions

Stephen Kohlbrenner

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

Vincent P. O'Brien, Jr.

Precis Engineering, Inc.

David P. Oschwald

Ives Equipment Corporation

Mark A. Petrich

Merck & Co Inc.

Elizabeth Plaza

Pharma Bio-Serv

Stephen Rigby

Emerson Process Management

Todd M. Rohn

Precis Engineering, Inc.

David Schueck

American Alloy Fabricators

Sean H. Sommer

Jacobs Engineering Group Inc

Kenneth A. Stout

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

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

John Lagodney CRB

Monica Leahy CRB

Brian R. Lipko Hargrove Life Sciences

Samuel A. Litwack **Ashland Specialty** Ingredients

Richard C. Ohmott Janssen Pharmaceuticals

Ryan E. Ott Azzur Group, LLC

Chantelle M. Otto CSL Behring

Scott Overton Sanofi Pasteur Ltd

Justin A. Pagliaro Hargrove Life Sciences

Christopher Patten Compliance Technology Group Inc.

James B. Powers, Jr. **Bridge Associates** International

Roberto L. Rivera Pfizer

Mark J. Shaffer Domino-NA

Matthew R. Vazquez **Gannett Fleming**

Thirunellai G. Venkateshwaran Merck & Co Inc.

5 Years

William S. Aja Panacea Technologies Inc.

Sue Behrens IPS

William S. Cheyney Jennings Alberts Inc.

Theodore M. Cohen

David J. Colander Fisher Clinical Services

Simon Cote West Pharmaceutical Services

Mireille Deschamps EMD Millipore

Gregory S. Emmerliing

Susan Garabedian Janssen

Dan K. Gresens Bahnson Environmental Specialties

Richard D. Hahn

Chad Happ Barry-Wehmiller Design Group

David M. Harcar DMH Consulting, Inc.

David Harper, Jr. **Jacobs Engineering**

Doug A. Hupe Agua Filter Fresh, Inc.

Zuwei Jin **Emerson Process** Management

Michael Kennedy

Alysys Inc.

Kristopher Koch Schott North America, Inc.

Mike Libman Lehigh Valley Technologies, Inc.

Donald Mason Johnson & Johnson Consumer

Joseph J. Mauer CRB

Jayme L. Richter B Braun

Drexel Rothrauff Blue Mountain Quality Resources Inc.

Robert M. Rovinsky

Marvin Royal STEQ America

Eric M. Scatton Genesis Engineers Inc

Kevin Daniel Sexton RPA Engineering

Eleanor F. Small Johnson & Johnson Consumer

Michael Spagnola CRB

John Starcevic GlaxoSmithKline

Chris Stevens Spark Therapeutics

Abdelgader Zamamiri Regeneron Pharmaceuticals Inc.

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

























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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

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

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:





