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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 approach the half-way mark of our program year, I am thrilled with what the Chapter has accomplished so far. We have held a number of networking and program meetings, which we have tried to deliver in new ways. I am honored to be serving as president of the DVC at this exciting time.

Every year during the summer months, chapter leadership gathers for a full day retreat to define our goals and lay out our plans for the year. And every year we talk about how to best deliver on the value proposition that we offer to our chapter members and how to build that membership. We look for ways to improve the presentation of content so that it is current and of interest to the industry and attract those professionals, young and seasoned, with opportunities to interact and share ideas and experience.

To this end we, along with the ISPE International office, are implementing some changes that will update the way we do these things. Locally we have changed the model for planning and coordination of our events, taking some of the burden off of our committee volunteers

and allowing them to focus more on identifying timely and topical programs from industry leading speakers. You can read more of our event recaps in the coming pages but I'll point out a few highlights as well...

We kicked off September with a fall program hosted by CECO Environmental Co. for an inside look at the advantages of Fybroc pumps and their unique manufacturing process.

October did not disappoint with another amazing tour opportunity at Eastern Controls. They hosted our members and presented two 30 minute sessions. We can't thank them enough.

November highlighted one of DVC and national's initiatives that launched during the 2016 annual meeting: Women in Pharma (WIP). ISPE's WIP mission statement is to:

*"Drive our organization's progress towards gender parity, assist with the growth and education of our membership and sponsor programs to assist women in various roles in the pharmaceutical industry. Target sponsorship and mentoring programs connecting leaders with rising talent; with networks*

*and forums to support our members to achieve overall potential."*

The Women Influencing the Industry: A Local Perspective on Developing Your Journey event, moderated by Shannah Falcone (CRB), was highly attended and a great success. Thanks to Hargrove Life Sciences for sponsoring!

New committee member, Laura-Ann Chin, has infused the board with a new level excitement. She kicked off the Young Professional (YP) events, with a YP hosted From Grain to Glass: Everything You Wanted to Know About Gin Distilling at Philadelphia Distilling. Members, young and seasoned, embarked on an exclusive tasting tour of Philadelphia's finest distilling company, maker of Bluecoat, while learning about the distillation process from grain to glass. We were happy to see several new faces who made the commitment to become members.

ISPE DVC celebrated our 30th anniversary during our annual holiday party. This year members were treated to the Barnes Foundation in Philadelphia, home to one of the world's greatest collections of impressionist, post-impressionist and modern European paintings.

## BOARD OF DIRECTORS

2017-2018

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## FROM THE PRESIDENT'S DESK (cont.)

By Danielle Rebori

During the evening, the board presented the honored Buz Lange Award to Shannah Falcone and Sponsor of the Year to CRB Consulting Engineers. Congratulations to both and thank you for your service to ISPE Delaware Valley Chapter.

Once again, ISPE DVC is excited to sponsor the local Future City's competition held each year. This year

several members met at Archbishop Carroll to judge around 40 local participating middle school students in a STEM based activity to create a new city. The chapter was happy to host a few of these students at our Symposium at Lincoln Financial Field on February 1, 2018.

We have several special events lining up for the 2018 calendar, listed and described

below. Please remember to register early and often!

Danielle Rebori

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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:

[danielle@jacobswyper.com](mailto:danielle@jacobswyper.com)



## 2018 LOOK AHEAD

Upcoming Program and Education Events

ISPE 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!

- Statistics for CMC Part 2: Managing Change and Process Validation | February 22 | [Click here to register](#)
- Single Use Technology Assessment & Implementation via
- Retrofit of a Clinical Manufacturing Facility | April 11, 2018 | [Click here to register](#)
- ISPE DVC sponsored bus to INTERPHEX in NYC | April 18 | Details coming soon
- Education Event: Overview of Robotics in Manufacturing | April 26 | [Click here to register](#)
- Sporting Clay Shoot | April/May 2018 | Details coming soon

- Habitat for Humanity Day of Service | May 18 | Details coming soon
- ISPE DVC 25th Annual Golf Classic | May 7 | Details coming soon
- ISPE Annual Meeting & Expo, Philadelphia | November 4-7 | [Click here or image below for more information \(registration coming soon!\)](#)

## YOUNG PROFESSIONALS | FROM GRAIN TO GLASS: EVERYTHING YOU WANTED TO KNOW ABOUT GIN DISTILLING

By Laura-Ann Chin | ISPE DVC Vice President of Young Professionals

On November 30, 2017, ISPE DVC Young Professionals hosted its first kick-off networking event at the 13,000 square foot warehouse in Northern Liberties, home to Philadelphia Distilling's production facility. This sold-out success story brought together 60 attendees involving members, young professionals, students, potential new members, and guests.

This kick-off event aimed to integrate a solid networking opportunity while including an educational portion on touring Philadelphia's renowned craft distillery producing Bluecoat Gin, Vieux Carré absinthe, The Bay Seasoned Vodka and most recently their first limited edition malt whiskey in collaboration with Yards Brewing Company.

ISPE DVC has always been intentional about gaining momentum on events that give back and provide value to its members and this distillery tour was no exception. Many repeat attendees from the Women in Pharma event, held a month before, came to support this tour.

Jared, Philadelphia Distilling's very knowledgeable, engaging tour guide, journeyed the audience on the distillery's age-old craftsmanship portfolio paired with evolving modern techniques to create a unique selection of premium spirits from grain to glass. Jared covered the entire life cycle of gin distilling from sourcing the grains all the way through the bottling and labeling process. A very enthusiastic audience had their curiosity and questions answered.

The event seamlessly transitioned to a tasting of all the premium spirits including Bluecoat American Dry Gin, Bluecoat Barrel Finished Gin, Penn Vodka and Vieux Carré absinthe, to name a few. Gourmet hor's doeuvres featuring tempeh and pork belly bahn mi complemented the attendees' cocktails. More networking quickly followed throughout the evening and maple bacon bread pudding bid the attendees a sweet adieu for the night!

**Full photo album from the YP Distillery Tour Kick-off event can be viewed [here](#).**

### MORE EVENT PHOTOS!





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## ISPE DVC 30th ANNUAL HOLIDAY PARTY

At the Barnes Foundation in Philadelphia

December kicked off the holiday season and the DVC's 30th Annual Holiday Party. This year, it was held at the Barnes Foundation in Philadelphia.

Our guests were able to view Albert C. Barnes' incredible art collection, considered to be the world's greatest collection of impressionist, post-impressionist, and early modern paintings. Paintings from Cézanne and Rodin and other artists were on display.

The DVC also took time to honor our Military and each of our guests provided toys for the Marine's Toys for Tots program.

This year's Buz Lange award winner was Shannah Falcone of CRB. She exemplifies the character and dedication to our industry, community service and educational promotion. Her work with Women in Pharma and her dedication to ISPE, having served as Chapter President, made Shannah an obvious choice for this year's winner. She embodies the spirit and ethics of one of the finest members in our chapter's history, Buz Lange, who we continue to honor each year with this award in his name.

CRB took home the well deserved Sponsor of the Year award. We thank them for

their continued support of the DVC.

Thank you to our event sponsor M. Davis.

**Additional photos from the DVC Holiday Party can be viewed here.**



January's Ski Trip to Blue Mountain was great success. Thanks to our sponsors at EVOQUA Water Technologies, LLC and Vanrx for helping with the costs to feed our skiers. Once our folks were fed, it was all downhill from there.

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## PUMP MANUFACTURING PLANT TOUR

September Program & Tour Event Summary | Hosted by CECO Environmental

The CECO Environmental plant tour began with a brief presentation on the pump manufacturing technologies, followed by a plant tour.

The visit to CECO Environmental's Fybroc division included several stations so throughout the afternoon, all participants were able to visit each station on the tour. Participants learned about CECO Environmental and specifically about the Fybroc pump division, including types of pumps and their unique manufacturing process. Fybroc specializes in fiberglass

reinforced composite centrifugal pumps utilized in corrosive and other difficult liquids.

The groups were led on a tour of the manufacturing plant, which was fascinating to see as the manufacturing of pump components is still largely done by hand. The pump assembly and testing facilities were also visited on the tour.

It was followed by a networking hour at McCool's at the Historic Red Lion Inn in Telford. Special thanks to the event sponsor, Sunair Co.

## INSTRUMENTATION & CONTROLS IN FLUID SYSTEMS

October Program Event Summary | Hosted by Eastern Controls

Eastern Controls in Edgemont, PA hosted our members and presented two 30 minute sessions, one on Sensing Technology and the other on Process Instrumentation in a workshop / classroom environment to learn about instrumentation and controls in fluid systems.

Speakers included:

- Sensors: Ketan Pandit, Saunders Aseptic Diaphragm Valves for Americas, Regional Business Manager

- Process Instrumentation: Mike Hourigan, Owner and Managing Director of Horizon Controls Group

It was a very educational evening from one of the leaders in the field, followed by dinner at LaLaconda in Newtown Square.

## WOMEN INFLUENCING THE INDUSTRY

November Program Event Summary

The Women in Pharma (WIP) event, titled Women Influencing the Industry: A Local Perspective on Developing Your Journey, was moderated by Shannah Falcone of CRB. Panelists were women who have achieved significant success in their careers and shared their experiences, their journey, and offered their advice to the student women and men attending. The panelists included: Lisa Haflett (Merck), Ricki Chase

(Lachman Consultants), Melissa Sherman (Mobillon), and Michaela Simianu (Merck).

The program, hosted at Maggiano's in King of Prussia, was very highly attended and a great success. The event sold out and we had a great representation from industry, academia, both young and mature professionals, existing ISPE members, as well as many new faces!

### WIP EVENT

What an exciting evening with great discussions. Here are a few #womeninpharma tweets about the night:

**"Before you HAVE, you need to DO. Before you DO you need to BE."** (panelist Mihaela Simianu )

**"Make and develop connections and mentor each other early in your career."** (panelist Lisa Haflett)

**"We don't slow down and take the time to be introspective and know ourselves; there's a lot of value in just being still."** (panelist Ricki Chase)

**"Outwit, outlast, outplay, be your own advocate."** (panelist Melissa Sherman)





## DOOR PRIZES

Door prize winners included:

- Eagles Tickets - Jill Smith, Hydro Service and Supplies
- Eagles Tickets - William Dugary, Applied Control Engineering
- Autographed Carson Wentz Jersey - Nathan Marcus, Siemens



## 28th ANNUAL SYMPOSIUM & EXHIBITION

Hosted by ISPE DVC

Another year and another great event for the local ISPE community. Total attendance was a record 881! With new and past exhibitors on hand, we again increased our show size by double digits, continuing our goal to provide more for our members. Maybe everyone came out to see the NFC Championship trophy? Clearly the excitement and momentum carried through as our Philadelphia Eagles won the Super Bowl on the heels of our show. What a great time in Philadelphia!

Another repeat highlight was our Career Fair, which all attendees could pass through on their way to the exhibit floor. We had 16 companies participate!

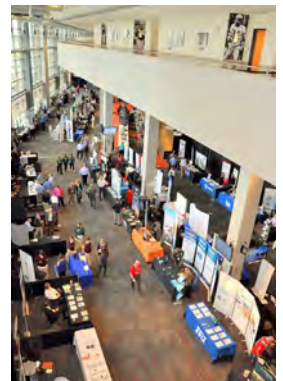
The Demonstration Stage was a great success this year, offering the latest in innovation and technology DURING the show, for attendees and exhibitors.

Our rockin' networking party was held inside the exhibit hall, at the conclusion of the show. "Right Turn at 40" was amazing as everyone wound down and relaxed after a very busy day. We would like to thank Dave DiProspero and

crew for keep us jamming.

We would like to thank all of those who attended, participated and volunteered to make this another great event, hosted by ISPE DVC. A special thank you goes to our Symposium Show Committee: Jill Clark, Mainstay Engineering Group; Ted Cohen, IPS; Ira Reese, Astro Pak; Mike Lanasa, Merck; and Peggy Delfabbro, M. Davis.

**For more photos of the event, [click here.](#)**



## QUALITY AND CONSISTENCY IN THE BREWING INDUSTRY AT YARDS BREWING CO.

January Program Event Summary | Hosted by Invisible Sentinel

January's program, held at the Yards Brewery in Philadelphia, featured Invisible Sentinel's co-founder and Chief Business Officer, Benjamin Pascal. Invisible Sentinel offers a means to determine the quality and consistency in the brewery industry. Their brewPAL product provides a

consistent testing approach for testing bacteria in beer and has reduced detection from days to hours. Ben reviewed the different types of pathogens that are responsible for beer spoilage and discussed how this is a growing concern in the brewing industry with recent product recalls

and customer's growing demands of a consistent taste profile in beer. He concluded with the different areas this technology can be applied and that they are in partnerships to apply this technology to pharmaceutical companies.



## MEMBER NEEDS SURVEY RESULTS

By Sawyer Romich, PE

In early January, the membership committee distributed a Member Needs survey in order to ensure that members are getting the most value from their ISPE membership. The focus of the survey was to understand the top reasons why members joined the organization, how satisfied they are with the benefits provided, and what benefits they would value if included with annual dues.

Results revealed that the majority of DVC members joined the organization either for professional growth or networking. Access to meetings, conferences, and training was also a popular response that closely followed the first two.

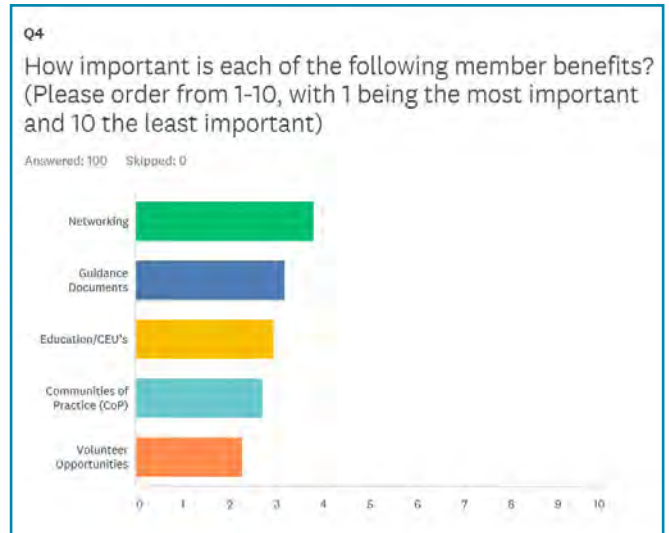
Not surprisingly, networking surfaced again as the member benefit that is most important and with which members are the most satisfied. Guidance documents was the second most popular response in both of these categories.

When asked which benefits would interest them if included with annual dues, DVC members most often responded with a subscription to guidance documents, virtual

industry education for career development, and a weekly email with pharmaceutical engineering news.

Perhaps the most intriguing question was which emerging topics are most likely to be of interest to you. A wide range of responses were received, but the most popular were continuous manufacturing, facility management, and operational excellence.

The membership committee is proud to report that the response rate and quality of responses received for the survey were both phenomenal. DVC is invested in making sure our members get the most value from their membership, and we look forward to taking action on your invaluable feedback.



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### Save the date!

The Delaware Valley Chapter's 25th Annual Golf Classic will be held at the Philmont Country Club in Huntingdon Valley, PA on May 7, 2018. Details coming soon!



## 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:



## HABITAT FOR HUMANITY

By Bob Hoernlein

On Friday, December 1, the Delaware Valley Chapter of ISPE 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 weather cooperating, the volunteers enjoyed a sunny, nearly 50 degree day on the job. When the sun gave its full effect, the jackets came off!

The team consisted of five ISPE DVC volunteers, two Habitat supervisors and one high school student. The five ISPE volunteers were Frank Artayet from Johnson & Johnson, Ed Bendzlowicz, a Johnson & Johnson retiree, Tim Hancock from BioPro Projects, veteran volunteer Brendan Bradley from Vanrx Pharmsystems, and myself, Bob Hoernlein. The high school student was Frank's son, Nicolas Artayet.

Currently under construction is a ranch style home at 1726 Prospect Avenue in Croyton, PA. The three bedroom, 1.5

bath totals 1,600 square feet and includes an attached 1.5-car garage. Previously, the lot had a house on it. A neighbor bought the house and had it demolished several years ago. Habitat for Humanity purchased the lot. The oversized wide lot accommodated a ranch style design.

The day we were there, the walls of the home were prepared for open cell spray foam insulation. The plywood floors were covered with plastic drop cloth material. The foam was mixed in a truck outside and two men wearing clean room suits and breathing piped in air from the outside, sprayed the foam in all the walls and roof rafters. After curing, the foam is trimmed to be even with the studs. According to one of the Habitat supervisors, there is only a 1 percent leakage rate using foam insulation.

The DVC team was split up into two groups. One group, Brendon and Ed,

raked and graded the entire backyard, removing rocks and construction debris, then seeded and laid hay down over the seed. The remaining volunteers were given instructions on how to stucco and then stuccoed the house perimeter foundation.

DVC supplied hot coffee and donuts to kick off the work day. Pizza and beverages were given out for lunch and were much appreciated by all present. Also, first time DVC volunteers received a volunteer sweatshirt.

This particular house will be completed in the spring, and presented to a working single parent and her two children.

If you have an interest in donating your time, or would like to make a contribution to our ongoing support of this worthwhile organization, please look for DVC notices of future volunteer days. The next event will be May 18, 2018. Mark your calendar, slots fill up fast.

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## WELCOME NEW ISPE DVC MEMBERS!

August 2017 - January 2018

**Tommy Byrd**  
Johnson & Johnson

**Peter Chu**  
Morphotek Inc.

**Jason Congdon**  
Morphotek Inc

**James Cotton, Jr.**  
PPCQA

**Bryan Cramer**  
Allegheny Surface  
Technology

**Keith Crouse**  
DC Beane and  
Associates  
Construction  
Company

**Christopher R.  
DiPaolo**  
ProTecs

**Aaron Duran**  
Amec Foster Wheeler

**Conor Flynn**  
Amec Foster Wheeler

**Shaun Gannon**  
IPS

**Matthew Gaus**  
Valsource Inc.

**Thomas Gaus**  
West Pharmaceutical  
Services

**Jack Gavey**  
Hargrove Life  
Sciences

**Barbara Groff**  
Precis Engineering,  
Inc.

**Kris Gucwa**  
Parker Biosciences

**David M. Hagan**  
Delaware  
Engineering &  
Design Corp.

**Jesse Hampton**  
Lannett Company,  
Inc.

**George Hannum**  
GSK- WREF

**Otto Hixon**  
Piramal Critical Care

**William Hood**  
RPA Engineering

**Jeffrey V. Horne**  
ValSource LLC

**Jacqueline Johnson**  
Merck & Co Inc.

**Oscar Jones**  
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**Robert W. Kozak**  
Mylan

**Paul Laub**  
IPS

**Christine Leu**  
Merck & Co Inc.

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Villanova University

**Brittany Macshane**  
Villanova University  
- Graduate Studies In  
Engineering

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**Samantha V. Marino**  
Wood PLC

**Kathy Maronski**

**Joseph McFadden**  
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**Nyle McIlvaine**  
Covex LLC

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**Michael McMurtrie**  
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**Matthew Micklin**

**Caleb Miller**  
Rowan University

**Daria Miller**  
Valley Forge Military  
College

**Amy Murnane**  
GlaxoSmithKline

**Linda Jean Nichols**  
GlaxoSmithKline

**Cory Perelman**  
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**Jennifer Peszek**  
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**Trip Wilson**  
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**Tom Wocklish**  
Chromalox

**Enkang Carol Yang**  
Genesis Engineers  
Inc.

**Alec Zaborowski**  
Morphotek Inc.

**Josh Zimmer**  
Fujirebio Diagnostics,  
Inc.

## UPCOMING EVENT

### Statistics for CMC PART 2: Managing Change and Process Variation

February 22, 2018 | 5-9 pm

Julia O'Neill, Principal, Tunnell Consulting, an expert in the pharmaceutical application of statistics, will provide Part 2 of her well-received presentation on Statistics in CMC. Julia has given this presentation to the FDA to train them on pharmaceutical statistics and their applications. Part 2 will cover managing process and assay changes, special challenges for vaccines and biologics, significance and equivalence, assay and reference standards issues, and evaluating assay and process contributions to variation. The evening will begin with an hour of networking with food and drinks, followed by the presentation.

**SPONSOR SPOTLIGHT: AQSEPTENCE GROUP, INC.**  
 By Philip Crincoli | Industrial Segment Sales Manager

**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)

AQSEPTENCE GROUP / VACUUM TECHNOLOGY SYSTEMS DIVISION

**“Industrial Vacuum Liquid & Waste Water Conveyance Systems Within Cleanroom Syringe Washing Operations & other Applications”**

*An overview of how indoor & outdoor vacuum wastewater conveyance systems create value within industrial settings including FDA regulated properties*

Philip Crincoli & Clint Hawn  
 January 2018



Aqseptence Group / Vacuum Technology Systems Division

involve customized pre-treatment steps for wastewaters prior to conveyance to the onsite industrial wastewater treatment plant, while following all FDA regulations and protocols.

**CONCLUSION**

While vacuum wastewater collection systems may not be a perfect fit for every application; one must look past the initial material cost to judge the overall cost savings of a vacuum system. The savings during installation, including a significant decrease in construction project schedule and labor, reduced water usage and cost, and the reduced treatment cost, will continue to save money both in the short- and long-term. For a typical project budget of \$100,000 or greater, the overall cost savings of a vacuum system over a gravity system is minimally 10% for any project, with the cost of materials within 20% by comparison, but the labor and project schedule (a larger portion of budget) costs are 60% less with our vacuum wastewater conveyance system.

**Industrial Vacuum Liquid & Waste Water Conveyance Systems Within Cleanroom Syringe Washing Operations & Other Applications**

Philip Crincoli and Clint Hawn

**BACKGROUND**

As Airvac evolved in the late 1960's, they quickly became known as the entity responsible for modernizing today's Vacuum Wastewater and Sewer Technology Systems. Today, Airvac™ is considered the industry standard as both the U.S. EPA and the Water Environment Federation feature our patented system in their published technical manuals. In the 1970s, our company began applying their vacuum wastewater conveyance technologies in Cleanrooms and other industrial settings including FDA regulated companies such as Merck, Avara, Bayer, Eli Lilly, Upjohn (Pfizer) and Roche.

**ADVANTAGES**

Liquid collection systems in FDA & USDA environments require flexibility & reliability. With the capability to vertically lift liquids up to 21 feet & transport them horizontally over long distances, vacuum technology liquid conveyance systems provide unmatched layout flexibility particularly in Cleanroom settings. Some of the features and benefits of installing a vacuum powered wastewater conveyance systems include:

- Shorter construction duration as labor and project schedule is significantly shorter up to 60%
- Piping in the wall, ceiling, attics and other confined spaces is more easily installed
- Design and installation with piping flexibility (vertically and horizontally). Most obstacles can be simply bypassed. Piping can go up and around obstacles up to 20 foot vertically
- Small pipe diameter (typically 1 1/4" - 4") can literally be installed anywhere
- No blockages- liquid transport at 15-18 feet per second scours out piping regularly
- No dual containment piping is required as the system is leak proof operating in a vacuum. Vacuum pulls air inward and there is no external leakage/contamination. Pipe punctures don't leak liquid but rather suck more air into the system.
- Safe and reliable separation of different classifications of wastewaters for specified treatment including biological and chemical contamination.
- Infrequent maintenance can be performed outside the Cleanroom or Controlled Environmental area limiting downtime.
- Ease of future renovations and extensions. The system can be expanded or modified at a later date should circumstances change.
- A number of the original systems installed have been operating since the 1970s with minimal maintenance. The systems have proven to be reliable, safe and meet FDA requirements

**CASE STUDIES**

Various case studies will be discussed with an emphasis on FDA Regulated solutions and applications particularly at Bayer, Eli Lilly, Avara, Pfizer, Roche and Merck West Point. The Merck West Point case study is of particular interest as it is part of a syringe washing operation in the production of different products including the Hep-C and Gardasil vaccines. Product changeover and sterilization techniques



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## MEMBER MILESTONE ANNIVERSARIES

August 2017 - January 2018

### 30+ Years

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**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

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