

ISPE NJ Newsletter

Coming Events

March 28, 2019
Professional
Development
Meeting

Prolong Pharma South Brunswick, NJ

REGISTER HERE

April 16, 2019
Student Poster
Competition
& Educational Event
Rutgers, Piscataway, NJ

REGISTER HERE

May 20, 2019 Golf Outing & Winery Tours

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Volume I, Issue I

March 2019

President's Message by Mike Kelliher



Welcome fellow ISPE NJ Chapter members to our first newsletter of 2019! I hope that since our Q4 newsletter, you were able to unwind over the holidays before getting back into the swing of things. As I compose this note on a relaxing "Sunday Funday", a recurring pattern seems to parallel business matters. My wife and I just went to the farmer's market with our cheerful dog, picking out some fresh produce for homemade fruit crepes this morning (I'm one lucky guy!) and then supporting some type of concoction that I'll muster up later. However, an ominous forecast is ahead in the midst of this gorgeous, balmy

March day that will transform into yet another Winter storm watch this season.

It's been fairly incredible: from the "carmageddon" episode where 6 inches of snow turned 30 minute commutes into 3 hour-plus journeys, to the arctic blast that pushed rare subzero temperatures, and finally to yet another anticipated delayed start time or site closure tomorrow due to potentially dangerous driving conditions. This certainly wreaks havoc upon both our personal and professional lives. From my end, it presents an unwelcome obstacle towards meeting production demands. Nature seems to remind us of the importance to adapt to changing landscapes. Similarly, we put forth strong efforts on the Board to change our chapter approaches based upon feedback.

Case in point, I'm excited about the new series of Professional Development Meetings (PDMs) this year that will start later this month. We've reformatted the approach from the former Professional Development Days as member feedback has dictated that there are often obstacles to reserving an entire day, preferences for a variety of topics, and concerns with accommodating cost. Of course, weather has also had its say the last 2 years, leading to rescheduled events. Spreading these educational events throughout the year seems to best prepare the venture for success. We believe these sessions will be popular and informative for changing hot topics within our industry, including our first two upcoming events on Data Integrity and Artificial Intelligence.

In addition to the PDMs, we have the student research posters contest, golf and winery networking, member appreciation event in the works, and a couple YP gatherings that will all take us to Summer.... Ah yes, the season where baseball can be played here with far less chance of snow and there's a reduced risk of static shock when touching doorknobs in dry workplaces! In this newsletter edition, we address recent events including:

Student plant tour at BMS and stellar performance in the National poster competition
Holiday party at Princeton's Nassau Inn. It never fails as during the gift exchange a gentleman who
possess perhaps "slightly less hair than most" always seem to unwrap the hair dryer!
FOYA presentation at Sanofi where the sustainability category winner from Pfizer elucidated the
hurdles involved towards achieving a Platinum LEED certification.

In closing, I wish to reemphasize from the past that this is YOUR chapter. Please don't hesitate to contact a board member with ideas on industry topics, events, venues, or any other business of interest. We do our best to keep everything fresh, but I believe some of our best ideas over the years have come from our members. Additionally, we always embrace volunteers with open arms so don't be bashful! Thank you to all of our volunteers and sponsors who truly make our Chapter the best that it can be. I wish everyone success in your current endeavors and look forward to seeing you at a future event.

All the best,

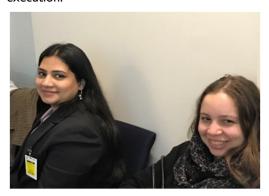
Mike

Bristol-Myers Squibb NJ Chapter Student Tour—Fall 2018

by: Monique Sprueill, Ernst & Young, ISPE NJ Student Activities Chair

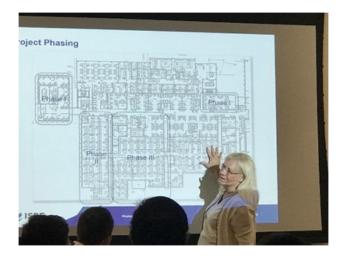
The ISPE NJ Student members had an opportunity to tour the renovated labs in Building 9 at the Bristol-Myers Squibb Hopewell NJ facility. We began with a presentation that described the project plan, building design, construction and qualification/validation strategy. This project team also presented at the 2018 Annual Meeting. Beth Starr (BMS), Luke Gong (PS&S), Joseph Delfs (BMS) and Jonathan Landis (Bancroft) provided an overview of the project and explained the importance of project management. They redesigned the laboratory and office space to facilitate a more flexible working environment and promote collaboration. Clean room space was also provided for additional

They discussed the challenges of working with an existing structure that was still in use for GMP activities during project execution.



Cell Line Development Robotics.





After the presentation, the students went on a tour. Sonia Pravasi (BMS), April Smith Torhan (BMS) and Evan Schlaich (BMS), the Subject Matter Experts (SMEs), educated us on the research and development activities as they guided the student through the renovated areas. The tours guides provided a great description of their everyday activities, how various processes are linked and dependent on each other and showed the students which equipment are used to support those processes.

The students in attendance were from Kingsborough Community College, New Jersey Institute of Technology, Rowan University, Rutgers University, and Stevens Institute of Technology.

The ISPE NJ Chapter extends a big thank you to all for actively engaging with the students and providing an experience that was greatly appreciated.



ISPENJ Holiday Party/Toys for Tots Drive December 13, 2018



By Neeraj Shah, Programs Chair

The holiday party held at the Nassau Inn in Princeton was well attended. The party is a great networking opportunity and people took it to heart. The pre-dinner cocktail hour was used to meet with old friends and colleagues and to meet and make new ones.

This year the holiday party had an additional event to it, the Toy Drive. Marines from Fort Dix were at the party to collect toys for the Toys for Tots drive.

The hotel did their usual great job of preparing the buffet. The buffet was quite varied with plenty hot and cold foods for everyone's taste.

Dinner was followed by "Yankee Swap" gift exchange, where stealing somebody's gift is not only permitted but encouraged. A good time was had by all, there were plenty of laughs.

See you in December 2019.





ISPE 2018 Annual Meeting Student Poster Contest

by: Monique Sprueill, Ernst & Young, ISPE NJ Student Activities Chair

The Student Poster Contest at the 2018 ISPE Annual Meeting was amazing. Students representing affiliates from around the world presented on research topics that will impact the Pharma/Biotech/Medical Device industry for years to come. The presenters were very knowledgeable about subject matters that ranged from robotic devices to the production of better vaccines.



Nicole Rosselli (Rowan University) represented the NJ Chapter in the Undergraduate segment of the competition. She presented on the "Biocompatible and Biodegradable Ionic Liquid Polymer Composite as Electrolyte". Her research presents possibilities of harnessing energy with biodegradable and biocompatible materials for future implantable medical devices.

Martin Burns (Stevens Institute of Technology) represented our chapter for the Graduate Student Poster Competition. He presented on the "Muscular Control of HEXOES, A Multidimensional Hand Exoskeleton". His project leverages machine learning and kinematic hand synergies to help patients achieve hand extension and improved dexterity.

Both of our NJ Chapter Student Poster winners were well prepared to meet the challenge and gave excellent presentations. However, there could only be one Undergraduate and one Graduate overall winner.

We are proud to announce that Martin Burns won the ISPE Annual Meeting Student Poster Competition overall for the Graduate category.



2018 Facility of the Year, February 21, 2019





By Arina Gerasimova, Programs CommitteeOn February 21st, 2019, the ISPE New Jersey Chapter held its first educational event for 2019 at Sanofi Bridgewater site. This year's event was a presentation by Pfizer's Director of Global Engineering, Paul Chiu, on the design, erection and commissioning of Pfizer's Consumer Health Suzhou Greenfield Facility that was the winner of Facility of the Year Award in 2018 for Sustainability. The event was a great success attracting over 60 attendees, including representatives of the leading pharmaceutical companies and industry professionals from New York and New Jersey areas.

Pfizer is a leading multi-national biopharmaceutical company and its award-winning Suzhou facility is one of the 6 manufacturing facilities located in the eastern part of China, 60 miles west of Shanghai. The topics discussed included project objectives, process design, site and facility model specifics, project safety and even cultural differences pertaining to the practices by local design institutes versus standards of the West.

This world's first LEED Platinum pharmaceutical plant boasts CO2 reduction, water conservation, solar electrical generation, green roof and walls, nitrogen and phosphorous removal system all of which have led to earning China energy 2 stars. This project is a great contribution to the China and world environmental journey.

You can be part of these history-changing and educational discussions by joining us at upcoming events.

















YP Member Spotlight—Dan Obercon

What is your full name?

Daniel Obercon

Where did you grow up?

Duanesburg, NY (about 30 miles outside of Albany, NY)

Tell us something unique or interesting about yourself.

My first job out of college was as a mechanical engineer for Electric Boat; the submarine division of General Dynamics. I worked on seawater fluid systems for the Virginia Class nuclear submarines. Due to my position, I had the opportunity to attend sea trials for one of the new boats I was working on. Three days at sea in a submarine was a very cool and eye-opening experience.



Where did you attend college?

Undergraduate - Clarkson University Graduate - Worcester Polytechnic Institute

What degree(s) did you earn?

B.S. Mechanical Engineering M.S. Systems Engineering

What is your current position?

Senior Project Engineer at GMP Systems, Inc.

What do you like most about your job?

My job is never boring, every day brings about different tasks, challenges, and circumstances. I get to work with many different pharmaceutical and healthcare companies and see an array of facilities. Each facility is always different than the last and that keeps my job more interesting.

Why did you join ISPE?

My boss has been involved in ISPE and suggested I join in order to take advantage of the educational programs, books, etc., as well, as for networking purposes.

Which ISPE activities have you participated in? Please describe the activities and you opinion of the experience. I have been to the ISPE NJ Vendor Showcase, ISPE Young Professionals Events, and some of the educational events. All of the events have always been good. Each of the events gets a diverse group of pharma professionals and it's a great way to meet people and learn more about the industry.

What advice do you have for students who are considering a career in your field?
Keep an open mind! There are many different facilities and career opportunities in the pharmaceutical industry, each special in their own way. Never turn down an opportunity for a job interview, even if you don't know the job will be the right fit for you. You may be surprised. If not, at least interviews serve as a learning experience in both interview and people skills and may also give insight into other careers which you had not considered.

Industry Member Spotlight—Brad Todd, DPR

What is your full name? Bradley Todd, please call me Brad

Where did you grow up? Port Jervis, NY

Tell us something unique or interesting about yourself.

I have a knack for travel planning, I love to research different areas and experience how people live. Some of our self-guided travels have included Oregon, Washington, Belgium, Italy, France, Spain, Ireland, Andorra in the Pyrenes mountains. I love to feed and watch birds in my back yard in Pennsylvania. I'm an avid reader, history buff, Jeopardy fan since I've been a kid. My wife Alicia and I adopt shelter pets.



What is your current position? Senior Project Manager at DPR Construction in Edison, NJ

What do you like most about your job?

I enjoy the interaction with the craft I meet on every project. I really enjoy problem solving and coming up with innovative solutions. I'm forever grateful for the investment of training given me. I have learned so much and made lifelong friends from some very talented clients, engineers, and co-workers.

I'm very proud of the projects I have had a role in, including vaccine manufacturing facilities, hospitals, surgery centers, higher education. I know the work is important and makes a difference in our local community and our society. I enjoy mentoring younger co-workers.

Why did you join ISPE?

I have joined the NJ Chapter to get to know some of the brightest engineers in a new area. We have recently moved from PA. I really enjoy talking shop and comparing notes with people from different companies and backgrounds. My goal is creating a new network of professionals with expertise in an area I have dedicated my career to. I enjoy following the online technical discussions and the collaboration and sharing of knowledge and experiences.

Which ISPE activities have you participated in? Please describe the activities and your opinion of the experience.

I have enjoyed many different ISPE events over the past 15 years or so, including events in the Delaware Valley chapter including Vendor Night at Citizens Bank Park, Golf tournament, visiting several of the area pharmaceutical facilities for technical presentations. Recently I have enjoyed the Holiday Party in Princeton and look forward the presentation of the Facility of the Year award and the Professional Development Meeting. I have enjoyed Interphex in NYC for many years and look forward to reconnecting with clients and vendors that I have had the pleasure of working with. I enjoy spending time with ISPE colleagues in a relaxed social setting.

What advice do you have for students and young professionals who are considering a career in your field?

I would encourage students to try hard to get in the field during summers and time off to get real life experience. Ask a local contractor to explain how their business works and where they see a need in their sector or specialty. A career in my field can be very rewarding and challenging. Every new project is an opportunity for growth. Take advantage of the knowledge and experience of your co-workers. Everybody has a unique skill set and style. Some of the solutions to complex challenges may come from unexpected sources. Ask questions and don't be afraid to take on responsibility.

"Industrial Vacuum
Liquid & Wastewater
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

By Philip Crincoli, Airvac

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 11/4" 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 STUDY

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 various vaccines. Product changeover and sterilization techniques involve customized pre-treatment steps for wastewaters prior to conveyance to the onsite industrial wastewater treatment plant, while following all FDA regulations and protocols. Merck, a BSL-I facility, is a good example of our system being installed in old infrastructure where renovation costs could potentially be astronomical. Roche, the equivalent of a BSL-4 facility, on the other hand, is an example of a new facility that was designed to include our vacuum wastewater conveyance system as part of the entire building.

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.

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member of ISPE
go to
www.ispe.org
and select New
Jersey Chapter!

Bring along a guest to a scheduled ISPE event and receive a \$25 gift card!

Member Message by Jamey Canterbury, Membership Co-Chair

Welcome to all new chapter members who have joined our community since the publication of our last newsletter. We hope that all members had an enjoyable holiday season and that the new year is off to a great start!

A special thank you to all of our members who were able to attend our holiday party on December 14th, at the Nassau Inn in Princeton NJ. This NJ Chapter tradition once again proved to be a night filled with fun, networking, and some great holiday cheer.

We are looking forward to the great programs that are lined up for this spring and summer, and look forward to seeing you all there. Please remember our member benefit of bringing along a non-member guest to a scheduled New Jersey chapter ISPE event and receive a \$25 gift card! It's a great way to reduce your own expenses, as well as offering an introduction and opportunity for a colleague to take advantage of the benefits of ISPE membership.

If you would like to become more involved in our organization, or have suggestions as to our program content or ways that we can improve our current offerings, don't hesitate to reach out to anyone on our chapter board. Be sure to check our website regularly for our scheduled events, including events specifically for our Young Professional members. Details on the board members, as well as upcoming events and member benefits can be found on our website: http://www.ispe.org/new-jersey-chapter

Happy Networking!

- Jamey



ISPE Young Professionals Committee of the Year 2018

ISPE has been making an effort to support members as they transition into the Pharma/ Biotech industry for several years.

Recently, a Committee was formed to drive the Young Professionals and Student interactions on the chapter level. It provides a forum for chapters to explore new ideas, discuss which initiatives are more successful and align on how to better engage members.

The collaborative spirit of the leaders and team members was recognized by ISPE at the 2018 Annual Meeting with the Committee of the Year Award.

I am proud to be a part of this awesome effort and look forward to continuing to contribute to this amazing team.

Monique Sprueill ISPE NJ Student Activities Chair Ernst & Young LLC (EY) Page 13 ISPE NJ Newsletter

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A vendor/display table at one event per year – excluding Holiday Party

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