JUNE 2019



ISPE New Jersey Chapter Newsletter

President's Message

Greetings fellow ISPE NJ Chapter members and welcome to our Q2 newsletter! As I write on the Summer solstice and we experience the longest day of the year, I can't believe the irony as the past term absolutely flew blew by as we're now near the sunset for your current Board. Hopefully you were satisfied and intrigued with the collection of programs that our Chapter put together as we attempted to find the most relevant educational topics, best atmospheres for networking events, and provide mentor/mentee opportunities within our chapter membership.



Michael Kelliher

As always, we're all chapter owners so communication of new event suggestions and feedback on prior events is encouraged. This mechanism led to our March educational event on Data Integrity hosted by Prolong pharmaceuticals. It was an energetic topic as witnessed by the multitude of questions during the presentation and the extensive conversations that took place well after program conclusion. In April, Rutgers hosted the student poster competition where it was impressive to hear about the latest undergraduate and graduate student research projects. I believe from this that our future medical advances are in good hands, which was further exemplified by a superb CAR T-cell therapy presentation which also garnered a high level of audience engagement. There was also time to enjoy a couple networking sessions this quarter as YPs and chapter members put on their bowling shoes at Bowlmor while later in May we had our annual Golf/Winery event where the weather actually cooperated!

As we kick back into Summer and the vacation season, we're repeating our popular member appreciation event on July 12th. This time, we'll be at the Sky Blue women's professional soccer match on Rutger's campus where family members are also welcome to register. Rain or shine (we have a tent option if needed near our reserved seating by the beer garden), the event is expected to take place. But sign up fast since we have an attendance limit and we've already eclipsed the halfway point! After elections are completed next month (thank you in advance to all who vote), the new Board goes on their Annual Retreat in August where the upcoming slate of programs is discussed as well as key chapter challenges and new ideas to ponder. Following that in September, we'll kick off the new term with the second iteration of our Women In Pharma event and are thrilled to spice up the format. We'll have a women's leadership speaker, author, and coach conducting the session who will elicit audience participation in a session that has received high acclaims from multiple industries.

In closing, it has been a distinct honor to serve as your President. Thank you to everyone who put in exhaustive efforts, especially our Board, Immediate Past Presidents, Chapter Manager, and all member volunteers. Without this complete team effort, we wouldn't have realized our past successes. I'm confident that Rich will have a successful transition in the upcoming term and believe he's already off to fantastic start with events planned in Q3 & Q4. I look forward to seeing everyone at future events where hopefully I'll now have more time to socialize and greater than a nanosecond to eat! Good vibes to all and enjoy your Summer.

- Mike Kelliher

Coming Events 2019

July 12, 2019

Member Appreciation Night

September 19, 2019

Women in Pharma

October 10, 2019

Professional Development Meeting

October 26-29

Annual Meeting Las Vegas

December 11, 2019

Holiday Party

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PAST EVENTS



YP Spring Social-Bowlmor Lanes

Spring Social Bowling Event, April 2018 By Dina Manfredi, ISPE NJ Board Member

ISPE New Jersey Chapter's Young Professionals held their Spring Social event at Bowlmor is Green Brook, NJ. We had great attendance at the event with a mixture of seasoned bowlers and beginners who all enjoyed the Bowlmor experience. The night included some snacks while network-

ing with practice rounds of bowling. Our final round of bowling was a competition, where best score took home a \$25 Amazon gift card, donated by GMP Systems, Inc. The winner was a new attendee, Luis Sosa, Jane Bedrossian with Pfizer won free attendance to the next YP event for encouraging two new YP to attend the event. Overall it was a very successful Spring YP Social! Keep an eye out for the next YP event this Summer!



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Data Integrity in the Life Science Industry March 23, 2019 Prolong Pharmaceuticals, South Plainfield, NJ By Neeraj Shah

On March 28^{th,} 2019, the ISPE New Jersey Chapter held its first Professional Development Meeting in 2019. Traditionally, professional development events were a full-day session in the past but starting this year the meeting format was changed from a single day annual event to a quarterly event and rebranded as Professional Development Meetings. The new format includes 60-minute networking opportunity with drinks and dinner followed by a 90-minute presentation or a panel discussion on an industry relevant topic held in the evening to enable active participation from busy professionals like yourself.

For the March 2019 PDM, the topic was "Significance of Data Integrity in the Life Science Industry" which turned out to be a very engaging and interactive discussion from attendees representing both experienced and young industry professionals. The session had two speakers to highlight different perspectives and a facilitator to engage the audience to an interactive discussion. The following professionals were speakers and facilitators for the event.

Lorrie Schuessler, Sr. Director -Computer Systems Quality & Data Integrity, Syneos Health.

Neeraj Shah- Director -Clinical Supply Chain excellence -Celgene Corporation

James Canterbury, Principal at EY (Ernst & Young LLP)

Laurie Schuessler presented the purpose of data integrity and the role it plays in establishing trust with the regulators. She explained the concepts of ALOCOA + and the regulatory impact of not meeting the ALOCOA+ requirements. She also highlighted the key practices like data life cycle management, data governance best practices and data integrity maturity model. Neeraj Shah focused on the significance of data in driving transformative innovation in the life science industry. He talked about the current and future digital trends and the significance of data integrity and data quality in driving the digital innovation and transformation of the industry.

The event was a great success because it attracted over 50 attendees from the New York and New Jersey areas. The presentation was followed by a highly interactive and engaging Q&A session facilitated by James Canterbury, where the audience actively participated in asking great questions and sharing insightful answers to real life issues related to data integrity in small and large organizations.

If professional development is important for you and you like to improve your knowledge about the opportunities and challenges in the life science industry or just like to network with industry professionals, you should consider joining us for the upcoming events.



Lorrie Schuessler



Neeraj Shah

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ISPE NJ Student Poster Contest 2019

By: Monique Sprueill, NJ Chapter Student Activities Chair

On April 16, 2019 the ISPE NJ Student Poster Competition took place at Rutgers University Busch Campus in the Richard Weeks Hall of Engineering. This is an amazing building and was the perfect setting for our event.

All presenters were quite impressive. We received seven (7) Graduate and six (6) Undergraduate submissions from Rutgers University, Stevens Institute, Rowan University and New Jersey Institute of Technology. The research topics presented will have major impacts on areas such as drug delivery systems, neuromuscular pathologies, granulation and digital manufacturing solutions.

Our Graduate winner is Sean Sanford (Stevens Institute). He and his team focused on the use of visual feedback to optimize rehabilitation for patients with spinal cord injuries. Our Undergraduate winner is Daniel Maldonado Herrera (Rowan University). He and his team studied drug delivery by microfluid devices.

Our Chapter will sponsor their trips to the Annual Meeting in Las Vegas where their posters will be displayed in the Exhibit Hall. They are also candidates for participation in our first Annual Meeting Hackathon. Students and Young Professionals will compete on industry-relevant case studies.

Humberto Vega, PhD (Celgene) was our Technical Speaker. His topic was CAR-T: Technology, Process and Validation. He provided an overview of the science, manufacturing and performance qualification. This gave the students a great foundation on this topic while also providing relevant information to the professional attendees.

We are grateful to our hosts at Rutgers University for assisting with event planning and escorting our presenters. We thank our judges who reviewed the material, listened to our contestants and provide feedback. Our Chapter Manager and volunteers make our event a success by engaging the attendees and supporting the members. We also thank the Industrial Advisors who support our students and encourage them to achieve.

We are proud of all the NJ Chapter Student Poster Contest participants. You can review the abstracts on our chapter website. Congratulations to the 2019 Student Poster Contest Winners!



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2019 Annual Golf Outing & Winery Tour By Rich Smith & Ray Roggero

On Monday May 20th, the New Jersey Chapter held our annual golf outing at Neshanic Valley Golf Course in Neshanic Station, NJ in Somerset County. The weather cooperated and almost 80 golfers enjoyed a beautiful spring day on one of New Jersey's top public courses. This year we had a new caterer for the event and everyone agreed that the food was the best we have ever had.

After a delicious BBQ style lunch on the terrace at Neshanic Valley Golf Club a small group of attendees departed for the annual ISPE wine tasting event. The first tasting was at Hopewell Valley Vineyards located at 46 Yard Road, Pennington, NJ. Owner Violetta Neri hosted the ISPE group and shared personal and interesting stories about where each wine comes from, why certain wines are made from grapes grown on their property and others are from different regions of the United States and even other countries. Hopewell Valley Vineyards is a winery dedicated to the creation of handcrafted wines by blending Old World traditions with New World flair. Their mission is to provide a relaxing, quaint, and beautiful environment to experience world class wines, enjoy the company of friends, and create long lasting memories. They have molded three generations of traditional European wine making experience with the challenges and excitement of establishing a state-of-the-art vineyard and winery in the heart of New Jersey. Their award-winning wines coupled with their renowned old-World hospitality has made Hopewell Valley Vineyards not only a place to purchase excellent local wines, but a destination in itself. Hopewell Valley was a delightful experience.

The second stop was Old York Cellars Winery located at 80 Old York Road, Ringoes, NJ. Old York Cellars offered more of a commercial visit. Upon entering the vineyard, after passing the iconic corkscrew sculpture installation and driving along rows of Marechal Foch vines, guests first encounter the Tank Room where the wine is made. Beyond the Tank Room on the left side lies the Vista Room that houses featured artist exhibits and indoor picnic area, but is mainly reserved for private events. Directly across from the Vista Room stands the Tasting Room where the ISPE guests lined the bar for the tasting.

A great time was had by all ISPE attendees and we made our way back to Neshanic Valley Golf Club for the awards dinner.

The golfing and tours were capped off by an hour of networking with passed appetizers and drinks followed by dinner and the prizes for golfing and our famous prize raffle.

Thanks again to our sponsors: Exyte, Hargrove Life Sciences, Lachman Consultants, Ecolab, Lend Lease, Cooney Coil & Energy, Whiting-Turner, Genesis, and Hydro Service and Supplies.

Once again it was another successful and enjoyable golf outing for the Chapter. Thanks again to all our sponsors and volunteers who helped make this event successful.

THANK YOU TO OUR FOURSOMES AT THE GOLF OUTING













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YP Member Spotlight—Jack Gavey, Hargrove Life Science

What is your full name?

Jack Gavey

Where did you grow up?

Fairfield, CT

Tell us something unique or interesting about yourself.

I decided to be a chemical engineer all because of my junior year chemistry teacher and his love for chemistry. I ended up hating orgo in college but enjoyed chemical engineering classes

Where did you attend college?

Villanova University

What degree(s) did you earn?

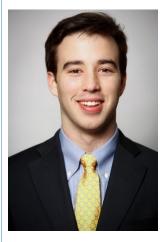
Bachelor of Science in Chemical Engineering with minors in Business and Finance

What is your current position?

Process Engineer

What do you like most about your job?

The People, no matter how busy or tough your day is going there are always people who are willing to help or give you advice or even just have a conversation.



Jack Gavey cont.

Why did you join ISPE?

I have been an ISPE member since I was in college and my favorite teacher was the advisor and she convinced me to join ISPE for all the great networking and development opportunities it has

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

I have participated in multiple ISPE events such as Brewery and Distillery tours, the Symposium, golf outing, Ski Trip, Christmas Party, and other various talks and presentations. Each event provides unique learning and networking opportunities. While I was a member of the Delaware Chapter, I was part of the Program Committee and assisted in the organization of a lot of these events which provided me a unique perspective into what it takes to make these events so great. My favorite event was the CAR-T Technology Process and Validation and Poster presentation. Not only did my colleague give a great presentation but he had the crowd really engaged on an up and coming drug therapy.

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

Get out there. Networking is a key to success in our industry. You would be surprised at how much you may have in common with someone or how they may play a role in your success. It may not even be career development but it could be project success based on who you meet and what they do.

Thank you to our Chapter Sponsor



Membership Message By Jamey Canterbury

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 opportunity to participate in our networking and educational events. We are looking forward to our membership appreciation night on July 12th at Yurcak Field on Rutgers Campus. This is a great opportunity for our members to connect and to kick off the summer with some fun and relaxation.

Our NJ chapter has over 800 active members but we are always striving to grow our community and help you expand your network; one of the best ways to do that is through word of mouth – so please do remember to take advantage of 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 join ISPE.

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



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