



# ISPE NJ Newsletter

Volume 1, Issue 4

October 2018

## Coming Events

### November 4-7

ISPE Annual Meeting  
and Expo  
Philadelphia  
Convention Center

[REGISTER HERE](#)

### December 12, 2018

Nassau Inn  
Princeton, NJ

6-10 pm

### February 21, 2019

FOYA 2019  
Pfizer Hangzhou

Project  
Sanofi  
Bridgewater, NJ  
5-8 pm

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## President's Message by Mike Kelliher



It is my distinct honor to greet you as the newly-elected President of the ISPE New Jersey Chapter for 2018-2019. On behalf of my fellow volunteer Board Members, thank you to all who voted and have illustrated your trust in our leadership for the upcoming year. I appreciate Jim Brinkman's leadership over the past year, handing over the Chapter with a solid path forward. Additionally, we're fortunate that our past 2 Presidents - Jim and Harry Segner - have agreed to provide their valuable guidance when solicited. Thank you Jim and Harry for your continued support of the NJ Chapter!

Summertime often provides a respite from hectic work and personal schedules. Were you able to get away from the frenetic pace to relax or perhaps take on a new adventure? Hopefully you were able to enjoy some time off to meditate or follow a life passion. I went on a vacation to pristine Newfoundland to get off the grid for a bit. I'm not sure if I was more impressed by the Viking settlement from 1000AD, a 7-foot moose waiting for our car to pass before crossing (yes every time I tell the story the moose is taller!), or the uber-rural environment where we visited an Irish settlement containing only 250 people. Experiences from this trip provided new perspectives and a fresh opportunity to reflect upon the past year. Recently, we had our Board Retreat and reviewed past events as well as presented new ideas. I've been asked by the membership about what's in store for the year that we have ahead. My focus is on what I consider to be the pillars of ISPE: Education, Networking, and Mentorship. However, most importantly, we should keep in mind that this is OUR Chapter. What industry topics would you like to explore in greater detail? Are there specific functional areas you're interested in or colleagues that you want to meet? I encourage everyone to reach out with ideas and voice if you wish to volunteer. This is most effectively done either verbally at an event (see the appropriate Board area representation on the following page) or by emailing our hardworking Chapter Manager, Bettyjane Watkins ([manager@ispenj.org](mailto:manager@ispenj.org)). Thank you to all who have already volunteered to help!

This newsletter speaks to recent events, starting with the educational "Top Trends in Pharmaceutical Regulatory Inspection" hosted by Prolong Pharmaceuticals. It was beneficial to energize the Regulatory/QA arm of our Chapter, further rounding out the reach of our program. Then we had the first-ever member appreciation free event at the Somerset Patriots stadium. Despite rain and heavy traffic, many braved the obstacles and it was a pleasure to see a true family event with both kids and spouses in attendance. Finally, talk about starting out the chapter year on a high note, our Women in Pharma event hosted by Johnson and Johnson this past September was one of the liveliest events I can recall! The biggest challenge of the night was wrapping up the event on time (and gently encouraging everyone to move the enthusiastic networking session into the primary room) as time flew by thanks to the inspirational and valuable experiences shared by the panelists and moderator. Brief descriptions of these events and photos are included within this newsletter.

The remaining slate for 2018 entails the Annual Meeting in Philadelphia November 4-7 and our Holiday Party in Princeton on December 12<sup>th</sup> at the Nassau Inn. Our programs committee is leading the way for Q1/Q2 2019, diligently working on topics, speakers, and venues for our upcoming educational and networking sessions. Thank you to our Chapter and event sponsors who continue to make our endeavors viable. I look forward to seeing everyone at a future Chapter event soon.

## Welcome Our New Board



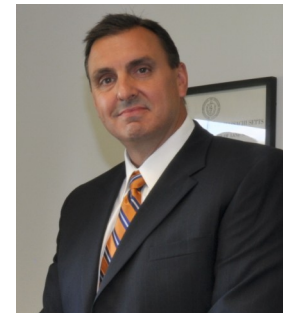
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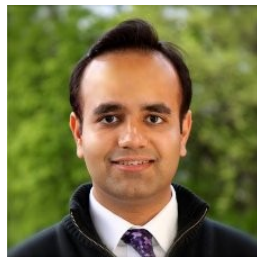
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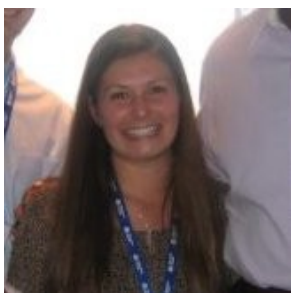
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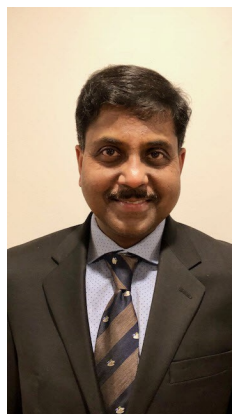
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## Top Trends in Pharmaceutical Regulatory Inspection Prolong Pharmaceuticals, South Brunswick, NJ June 14, 2018

On June 14<sup>th</sup> John Geissler, the Global Head of Compliance, Incident Management and Audit at Novartis presented on his recent global health authority inspection experiences and emerging trends. A broad range of topics was covered and several valuable insights were shared that can help manufacturers prepare for inspections from health authorities, in particular the US FDA, European authorities, and the Russian Ministry of Industry and Trade (MoIT). The discussions ended with a description of CAR-T therapy and the compliance challenges that this new innovation in cancer care presents.

The FDA is in the midst of a multi-year program to update and maximize the efficiency and effectiveness of its inspection program. John explained that these changes are designed to provide a more holistic, data driven assessment of a company's quality system and culture. The ISPE quality culture program is aligned with the new approach, and can be leveraged as a way to help prepare for future FDA inspections. There was also a discussion around the EU-US Mutual Recognition agreement that now is in operation. As this program matures, it will reduce the number of inspections that companies in the US and EU experience. John also discussed some specific examples of observations that are being commonly issued by the MoIT, as well as issues commonly seen when combination products, such as pre-filled syringes or dry powder inhalers, are inspected. Finally, as CAR-T and similar therapies move from research into an approved commercial production program there are some compliance challenges that are being noticed. This will be an exciting period as industry and regulators adopt to the new technologies, which will bridge into global Good Tissue Practice (GTP) regulations and guidelines.

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## Membership Appreciation Night Somerset Patriots July 27, 2018

A special thank you to all of our members who took advantage, and braved the rain and thunderstorms, to attend our first annual free Member Appreciation event on July 27<sup>th</sup>, at the Somerset Patriots Stadium in Bridgewater NJ. The stormy weather didn't dampen the enthusiasm of those who attended from taking part in enjoying the food buffet, drinks and member networking opportunities. The ballpark management was nice enough to offer us use of an additional room off the covered party deck to ensure that it was an enjoyable evening for all! We value our chapter membership and hope those who could not attend this year will be able to make next year's event.



## Women In Pharma Johnson & Johnson, New Brunswick, NJ September 18, 2018



New Jersey is respected globally for its strength in the biopharmaceutical and medical device industry. The state is home to 14 of the world's 20 largest pharmaceutical companies. Women have proven their capabilities throughout the biopharma market and continue to bring technical knowledge and insight to the industry.

This event allowed women and men participants time to network among their peers and panelist then engage in a lively, candid panel discussion. The community of Women in Parma includes mentors, resources across all levels, and education sessions that will be an enabler for career success and work life balance.

ISPE's Women in Pharma networking community aims to provide women in the pharmaceutical industry a forum for connecting and cloaborating on technical and career advancement topics.

The panelists shared their personal experiences regarding their career advancement, challenges they faced, finding mentors and sponsors, and family life. We appreciate the time and effort of our esteemed panelists:

Shannah Falcone, CRB; Donna Gulbinski VP Lachman Consultants; Nidhi Shah, Assoc. Dir. Sanofi; Nandita Kamdar Dir. J&J; Ilse Blementals, Exec. Dir. Celgene; Ediuska Laurens, Stryker; Liz Blackwood VP J&J; Robin Kumoluyi, VP J&J

### Thank you to our Chapter Sponsor



## YP Member Spotlight—Roya Amami

Where did you grow up?  
Parsippany, NJ

Tell us something unique or interesting about yourself.

Finding balance in life is a struggle we all face on a day-to-day basis therefore I spend my down time meditating and practicing yoga. Music is soothing to my soul so I enjoy attending concerts of various different genres. I recently incorporated a very healthy lifestyle by eliminating my bad eating habits and incorporating fitness in my daily regimen. I am also a High Brown Belt in Mixed Martial Arts.

Where did you attend college?  
County College of Morris, CCM  
New Jersey Institute of Technology, NJIT

What degree(s) did you earn?  
A.S. Biology, Pre-Med  
B.A. Biology  
M.S. Pharmaceutical Engineering, Expected Graduation: May 2019

What is your current position?

Certified Pharmacy Technician, CPhT at Morristown Medical Center, Morristown NJ.

What do you like most about your job?

Morristown Medical Center is the number one hospital in New Jersey and to be an employee for a prestigious and innovative company makes me feel proud. The healthcare industry is where my passion lies and I always dreamt of bringing positive changes to patients' lives. As a CPhT, I play a crucial role in the day-to-day tasks that take place in the pharmacy and I love working side by side with some of the most influential and intelligent individuals I have ever met. It is very inspiring to be able to make a difference as a CPhT in the hospital setting.

Why did you join ISPE?

ISPE is an organization that brings awareness and togetherness of employees in the pharmaceutical industry. They provide opportunities, services, and resources to improve the quality of medicine for patients, which inspired me to join. I am currently pursuing my M.S. in Pharmaceutical Engineering and I wanted to join ISPE to meet other individuals in the pharmaceutical industry. I would like to expand my networking circle and to gain knowledge by attending events and meeting those who work in the different fields within the pharmaceutical industry. I was attracted to the Women in Pharma group within ISPE which encourage young professionals to step outside their comfort zone and to follow their dreams.

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

Bristol-Myer Squib, BMS- Poster Contest

I volunteered to assist in the coordination of the event. I met several members who work for various pharmaceutical companies and students who were Chemical Engineering and Pharmaceutical Engineering majors. This was the first ISPE event that I attended and I had a great experience. The event was very informative because I got to look at each poster and speak to the students about the research they conducted.

Johnson & Johnson, J&J- Women in Pharma

This event was one of the most influential, inspiring and invigorating events I have ever attended. I am a huge advocate for empowering women and for standing up for our rights and I saw a panel of women who were very intelligent. I was able to relate to each and every one of them and many of my questions and concerns were answered. Being a young professional and a woman in the pharmaceutical industry is intimidating but after attending this event I was introduced to many women who went thru what I am going thru right now and it was very comforting!

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

The best advice I can give students who are considering a career in my field is to get involved, it's who you know not what you know. One thing they don't teach us in school is how to brand ourselves and how to network. Get out of your comfort zone and "take a chance"; the greatest leadership phrase I learned was to be uncomfortable. Reach out and tell your story, someone is listening.





## Industry Member Spotlight—Monique L. Sprueill, ISPE NJ Director

What is your full name?

Monique L. Sprueill

Where did you grow up?

Irvington, NJ

Tell us something unique or interesting about yourself.

I am passionate about the importance of exposing children to Science, Technology, Engineering and Mathematics (STEM) programs. I believe that it strengthens their critical thinking skills and helps them focus.

Where did you attend college?

I attended New Jersey Institute of Technology in Newark, NJ.

What degree(s) did you earn?

B.S. Chemical Engineering and M.S. Engineering Management

What is your current position?

Life Sciences Advisory Manager at Ernst and Young

What do you like most about your job?

As a person with a background in Validation, Process Engineering, Quality Assurance and External Supply Management for major pharma/biotech companies, I now have an opportunity to utilize all my skillsets to help clients determine the best strategies to accomplish their goals.

Why did you join ISPE?

I joined ISPE because I wanted to learn more about the Pharmaceutical Industry, gain exposure to people who could mentor me and network with professionals who share common interests.

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

I was on the Boston ISPE Board of Directors (2003-2004, 2009-2012), Delaware Valley Board of Directors (2012-2015), New Jersey Board of Directors (2016-present) and the Membership Development Committee Chair (International) in 2014. I've led the Communications, Membership and most recently Student Activities Committees for various chapters. I also participate in Biotechnology, C&Q, Critical Utilities, Process/Product Development, Project Management and Sterile Products Processing Communities of Practice.

I enjoy interacting with the membership and strive to increase the quality of the membership experience. I believe that active participation is important and that members should feel valued. Each position has its challenges and rewards, but I have learned a lot and continue to grow with each new experience.

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

My advice is join professional organizations such as ISPE and network with people who can help you navigate your career. You can define your own path and you should use every avenue available. Life promises one thing and that is constant change. Be prepared to move and grow when the right opportunity is presented to you.



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

## Member Message by Donna Petro, Membership 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 Summer and are looking forward to the Fall season.

A special thank you to all of our members who took advantage, and braved the rain and thunderstorms, to attend our first annual free Member Appreciation event on July 27<sup>th</sup>, at the Somerset Patriots Stadium in Bridgewater NJ. The stormy weather didn't dampen the enthusiasm of those who attended from taking part in enjoying the food buffet, drinks and member networking opportunities. The ballpark management was nice enough to offer us use of an additional room off the covered party deck to ensure that it was an enjoyable evening for all! We value our chapter membership and hope those who could not attend this year will be able to make next year's event.

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!

Donna V. Petro

Outgoing Board Member/Membership Chair

## Thank you to our Chapter Sponsor



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- 1/2 page Advertising space in the ISPE NJC newsletter for 2018 (A \$800 value!)
- 12 month Advertising space on the ISPE NJC website in 2018 (A \$500 value!)
- Two complimentary tickets for all 2018 NJC Events<sup>1</sup>
- A vendor/display table at one event per year – excluding Holiday Party

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