



ISPE NJ Newsletter

Volume I, Issue I

February 2018

Coming Events

February 22, 2018

Facility of the Year Award to BMS
for Facility Integration
Sanofi, Bridgewater

March 13, 2018

Professional Development Day
Rutgers Busch Campus
Piscataway, NJ

April 4, 2018

Student Poster Competition
BMS New Brunswick

May 14, 2018

ISPE NJ Annual Golf Outing
Neshanic Valley Golf Course

June 14, 2018

Top 10 Inspection Trends in the
Pharmaceutical Industry

July 27, 2018

Member Appreciation Event
Somerset Stadium

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by Donna Petro

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President's Message by Jim Brinkman



As we ring in the New Year it's an appropriate time to both look back over the past and contemplate the future. We have had a very successful program over the fourth quarter that started with a "Welcome Back From Summer" social event at Beneduce Vineyard on September 28th. The event was organized by Dina Manfredi and Mike Kelliher and sought to engage our Young Professional and Industry membership groups. The event attracted 50 attendees to the event and, as usual Beneduce did not disappoint, as a nice time was had by all. On October 19th, an educational event was held at Pfizer that focused on applying quality risk management (QRM) principles to HVAC in classified spaces to enable air change reductions, with their

associated reductions in energy use, cost, and improved sustainability. We were fortunate to have both our own Norm Goldschmidt (Genesis Engineers) and Randy Hansen (Pfizer), who authored an article in *Pharmaceutical Engineering*, as speakers on this topic. The event was well attended, with significant technical dialog, during the technical program. Many thanks to both Norm and Randy for volunteering their time to prepare and present this well-received presentation.

We did not schedule an event in November, as many of us attended the ISPE Annual Meeting in San Diego that was held at the beginning of the month. We did have our annual holiday party at the Nassau Inn in Princeton on Dec. 13th. We were fortunate to have a record number of attendees at this event with over 80 registered! Every year this event seems to attract more and more participants. There may be several reasons for this- perhaps it's the wonderfully decorated venue, or the amazing and abundant food, or the festive atmosphere, or most likely it's the annual gift raffle led by Rich Smith. This year was even more exciting as those popular gifts were "stolen" back and forth among the winners. Many thanks to Rich for organizing the event and to Bettyjane Watkins, our chapter manager, who did the shopping (and wrapping).

The Programs committee, led by Ray Roggero and co-chaired by Neeraj, has been hard at work preparing the spring program for the Chapter. We are fortunate to have Bristol-Myers-Squibb present their Facility of the Year (FOYA) project during our Feb. 22nd at the Sanofi Bridgewater site. It's always beneficial to stay current and have a look at the "latest and greatest" projects that have been completed- especially as presented by the project managers themselves. While it's now officially winter and weather can be iffy, I am hopeful that the event will occur as planned as I know it won't disappoint!

There will be another educational opportunity offered as part of the Chapter Professional Development Day on March 13th at Rutgers University. This year we are planning two full-day tracks- Operational Excellence and Strategies for Managing Aging Facilities- more to come on this event in the upcoming weeks. We have tentatively planned the Student Poster Competition and Technical Presentation for April 4th at BMS New Brunswick, so mark your calendars. Anyone wishing to join us for the afternoon as a poster judge should contact Monique Sprueill or Matt Mowatt, our Student Activities Co-Chairs. We have tentatively scheduled the Annual Golf event for May 14th, so mark your calendars and pray for favorable skies (and low winds). Finally, there are two more events planned in the spring/summer timeframe- an educational event in June (a venue is needed if anyone wishes to volunteer their facility) and a "Member Give Back Event" at TD Bank Ballpark in Bridgewater, NJ set for July 27th. There's more to come on both of these events. I am very fortunate to have such a strong Board that is highly engaged in the operation of the Chapter and in the strategic direction of the Chapter for the future. Please note the roster of Board members in this newsletter. If any member has interest in becoming a committee member, I'd encourage him/her to contact that committee chair. In addition, anyone that has interest in becoming part of Chapter leadership should contact Harry Segner, who leads the nominations committee. The Communications, Membership, and Marketing (CM&M Committee) recently distributed a survey to the membership to get a pulse on what's going well and where we can improve. We are in the midst of analyzing this feedback, which will assist us in setting the strategic direction for the future. Many thanks to everyone who took the time to complete and return the survey. As I close, I'd like to wish the entire Chapter membership a happy and healthy New Year. - Best, Jim

Young Professional Fall Events 2017

By Dina Manfredi, YP Chair
“Welcome Back from Summer” Event, September 2017

This Fall’s “Welcome Back from Summer” event was held at the beautiful and popular Beneduce Vineyards, in Pitts- town, NJ, the site of previous ISPE-NJC events. The more than 40 attendees enjoyed an evening of networking and great food as part of the win- ery atmosphere while celebrat- ing the kick-off the 2017-2018

Chapter program and event schedule. Participants for the “Welcome Back from Summer” event included, numerous Chapter “regulars” and many new members, as well as multi- ple interested prospective new members. A significant group of Young Professionals and stu- dents were also in attendance. We look forward to continuing the momentum of this event into the holidays and through- out the entire program year. We hope to see you and your colleagues at upcoming events

and that you’ll consider volun- teering to support the Chap- ter’s programs and initiatives.



Young Professional Fall Social, November 2017

The NJ Chapter of ISPE has long supported the Young Professional (YP) initiative of ISPE International having sponsored a multitude of programs over the past 10 years, the most recent of which was our Fall Social held at The Famished Frog in Morristown, NJ. Attendance was excellent with more than 20 participants that included a number of NJC Board members and other long-time senior members and friends.

Excitingly, we had many new prospective Young Professional members join us, along with a number of current YP members. This was a great networking event, at a pleasant, comfortable and relaxed venue providing help- ful industry and career insight to the young professionals attending. Networking was the theme and many of the YP’s left with a pocket full of business cards. The next YP event is scheduled for March 2018, watch for email announcements or check the Chapter website for details.

We’re looking forward to another successful year in 2018 and hope to see you at future YP programs and events.



Applying QRM to HVAC To Improve Environmental Sustainability

By Jim Brinkman, ISPE NJ President

On October 19, approximately 50 industry professionals and students gathered at the Pfizer Peapack campus for an evening of net- working and education. The subject matter for this event was utilizing Quality Risk Management (QRM) principles for reducing air change rates in qualified spaces for the purposes of energy/cost reduction and environmental sustainability. The session was led by Norm Goldschmidt, president of Genesis Engineers and Randy Hansen, Sr. Manager, Pfizer Global Engineering, based on an article published in the July-August 2017 issue of *Pharmaceutical Engineering*. This was a topic near and dear to many ME’s and HVAC engi- neers in the room who recalled using rules of thumb to assign air change rates to classified areas in the past without regard for actual particulate and energy loads in the space. There was a lot of keen interest in the room for this technical topic as evidenced by significant Q&A throughout the entire presentation. Feedback received following the meeting was superlative. In fact many re- quested more presentations in the future having deeper technical topics such as this one. Additional feedback on this program or suggestions on technical content for future educational sessions would be welcomed by Ray Roggero, the Chapter Programs Com- mittee Chair.

ISPE Annual Meeting 2017 San Diego, CA



From left to right: Tom Flachmeyer, Jim Breen, Alok Bhatt, Jim Brinkman, Maria Pineda, Harry Segner, James Canterbury, Mike Kelliher

The ISPE Student Poster Contest provides a stage for our brightest students. They share their research in areas that will lead to advancements in patient care and quality of life. We are proud that Maria de Abreu Pineda was recognized for her outstanding work on “CerebroSense: A Brain Pulsatility Measurement Device”. She is a member of our student chapter at Stevens Institute.

*ISPE Annual
Meeting
Student Poster
Winner
Maria de Abreu
Pineda!*

ISPE NJ Annual Holiday Party December 13, 2017



Academic Member Spotlight —Mark E. Byrne, Ph.D., Rowan University

Where did you grow up?

I grew up in the suburbs of Pittsburgh, Pennsylvania.

Tell us something unique or interesting about yourself.

My wife and I had 4 children in 4 years (one set of twins). This probably has something to do with why I am a competitive runner, and why I enjoy coaching soccer.



Where did you attend college? What degree(s) did you earn?

I received a BS in Chemical Engineering/Biomedical Engineering from Carnegie Mellon University, and MS and PhD degrees in Chemical Engineering from Purdue University.

What is your current position?

I recently joined Rowan University as Founding Department Head and Professor within the Department of Biomedical Engineering. The Department is growing rapidly with both undergraduate and doctoral programs, with excellent opportunities for both new students and faculty. I direct my research labs - Biomimetic & Biohybrid Materials, Biomedical Devices, & Drug Delivery Laboratories, in which I have advised over 17 PhD students and over 80 undergraduate students in research. I am also Founder/CTO of OcuMedic, Inc., a drug delivery company commercializing the first drug releasing contact lens through human clinical trials. Previously, I held the title of Daniel F. & Josephine Breeden Distinguished Professor at Auburn University. I am a leader in the field of biomaterials engineering, controlled therapeutic delivery, polymer engineering, and biomedical devices. My work has been funded by numerous government agencies including NIH and NSF as well as industry, and I have taught both graduate and undergraduate courses as well as directed a US Department of Education Doctoral Program in Biological & Pharmaceutical Engineering and an NSF REU Site in Micro/Nano-Structured Materials, Therapeutics, & Devices.

What do you like most about your job?

I enjoy impacting people's lives. Discovering and describing new phenomena, moving existing science forward, building a new academic and research department, running my own research lab, commercializing and translating technologies that can make it to patients, as well as educating and training new leaders in the field. We create people and discover new things.

Why did you join ISPE?

ISPE is a leading organization in the pharma space. My research areas include pharmaceutical engineering, and my background in chemical engineering with emphasis in biology and biomedicine are a perfect fit. To me, pharmaceutical engineering is a very broad field that encompasses discovery to manufacturing to regulatory pathways to reaching patients.

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

I have participated in a few meet and greets and attended the annual meeting. ISPE is an excellent organization that really supports the global pharmaceutical and biopharmaceutical industries.

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

Work hard, spend time focusing on and learning the technical fundamentals, and gain practical experience at numerous places. It is also never too soon to start networking.

Also, challenge yourself in all aspects of your life and strive to achieve excellence. Doing what you think you can't, makes all the difference.

Member Message by Donna Petro, Membership Chair

**To become a
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 \$20
gift card!**

As we move into 2018, the chapter has many exciting events planned for the year which will be of interest to all of our members, including experienced Professionals, Young Professionals and Students alike.

We are happy to let you know that this summer we are planning a Member Appreciation event to be held July 27th at the Somerset Patriots Ballpark. This will be an excellent opportunity for all members to interact and get to know other members in a relaxed environment, and we are expecting a big turnout. Details concerning the event will be coming in the near future. We remind you to check out our Chapter website often to take advantage of any newly announced membership benefits. <http://www.ispe.org/new-jersey-chapter>

For 2018, new member benefits include access to the Guidance Document library of Good Practice Guides (GPGs) through an online Guidance Documents Portal which provides web-based access to 24 titles outlining best practices and technical details with specific solutions.

We are also offering a "Refer a Friend" program - members who refer another member receive a month's free membership upon their annual membership renewal.

Additionally, bring along a guest to a scheduled ISPE event and receive a \$20 gift card!

While you may find yourself only occasionally attending programs, there are many opportunities to get even more involved in the chapter. Volunteer by joining a committee, think about mentoring a Young Professional ISPE member, or consider becoming a member of our board to help shape the organization and give back to the industry. Feel free to reach out to myself or another board member directly for details.

For overall information, visit the International ISPE website: www.ispe.org

To view the ISPE Global Calendar: <https://www.ispe.org/calendar>

With approximately 20,000 members worldwide, ISPE is an organization that offers opportunities to build your brand, your business, and your network. We look forward to seeing you at the next event!

Donna V. Petro
Board Member/Membership Chair

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Pharma Headlines

New research paper shows that AstraZeneca has achieved greater than four-fold improvement in R&D productivity

In a research paper published today by Nature Reviews Drug Discovery(1), AstraZeneca's IMED Biotech Unit documents a more than four-fold improvement in R&D productivity following significant revision of its approach and adoption of a '5R framework' - right target, right pa-

tient, right tissue, right safety, right commercial potential.

Sandoz announces exclusive global collaboration with Biocon on next-generation biosimilars

Sandoz, a Novartis division and the global leader in biosimilars, today announced a global partnership with Asia's premier biopharmaceuticals company, Biocon, to develop, manufacture and commercialize multiple biosimilars in immunology

and oncology for patients worldwide.

AI 'scientist' finds that toothpaste ingredient may help fight drug-resistant malaria

An ingredient commonly found in toothpaste could be employed as an anti-malarial drug against strains of malaria parasite that have grown resistant to one of the currently-used drugs. 'robot scientist'.

www.worldpharmanews.com/

Pharma News

AstraZeneca

Sandoz

University of Cambridge

Research

Amgen

Novartis/Biocon

Valeant

Amgen kicks off 2018 with double the good news for slow-growing Kyprolis

www.fiercepharma.com/pharma/amgen-kicks-off-2018-double-good-news-for-slow-growing-kyprolis

Novartis and Biocon partner on 'next wave' of biosimilars

www.fiercepharma.com/pharma/novartis-and-biocon-partner-next-wave-biosimilars

Judge signals early support for Valeant settlement, company says

<https://www.fiercepharma.com/legal/judge-signals-early-support-for-valeant-settlement-company-says>

Job Opportunities

Are you looking for your next career challenge? Did you know that the ISPE website contains a list of job opportunities? Visit www.ispe.org to find more information for the job postings below and more.

www.alvogenus.com/Joinus/Jobopenings/Read/director-project-management/

<https://jobs.sanofi.us/job/-/507/6364548/>

https://www.jobs.abbott/us/en/job/ABLAUS3341/Senior-Manufacturing-Process-Engineer?job-source=indeed&utm_source=indeed&utm_medium=indeed&utm_campaign=indeed-feed

<https://workforcenow.adp.com/jobs/apply/posting.html?client=quvapharma&jobId=101604&source=IN>

<https://sjobs.brassring.com/tgwebhost/jobdetails.aspx?jobId=2511640&PartnerId=13617&SiteId=5260>



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- Recognition as a Chapter Sponsor at all ISPE NJC events in 2018
- Name and Logo on announcements for all ISPE NJC events in 2018
- 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 Events¹
- A vendor/display table at one event per year – excluding Holiday Party

www.eventbrite.com/e/2018-ispe-njc-chapter-sponsorship-advertising-program-tickets-19824345150