



Connecting a World of  
Pharmaceutical Knowledge

## New Jersey Chapter



ISPE Affiliates and Chapters Around The World

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Spring 2015

# PHARMA BULLETIN

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### New Jersey Chapter Statement of Value

New Jersey ISPE is an organization of, and for, professionals in the ever changing Life Sciences Community. As such, we strive to provide value to our various constituencies – owners, consultants, designers, contractors, vendors, students and the un- and under-employed – in a number of critical areas:

Wide range of multi-level **Education and Training** whether you are a newly graduated student or a multi-decade veteran, to enable you to be more successful at your current or yet-achieved "ideal" responsibilities within the Life Sciences community;

Sharing of **Industry Trends** to enable you to provide greater value to your employer, colleagues and the Life Sciences community in general, as we all strive to succeed in a "do more with less" environment;

Providing a forum in which you can **share** your expertise, experiences, innovations and thoughts/dreams with your colleagues via seminars, articles, roundtables, task forces and so on, where you can positively contribute to the future of the Life Sciences community

Encouraging "work hard, play hard" opportunities where **socializing and networking** provide forums to informally expand your professional and personal network, resulting in friendships that last for decade.

## Upcoming Events

### Latest Trends in Product Development, Young Professional Interactive Session & Annual NJ ISPE Student Poster Competition

April 28, 2015 – Johnson & Johnson, New Brunswick, NJ

### Golf Outing

May 18, 2015 – Neshanic Valley Golf Course, Neshanic Station, NJ

### Open Board Meeting

May 18, 2015 – 10:00am – Neshanic Valley Golf Course, Neshanic Station, NJ

## The President's Message



### Newsletter Brief from the President ISPE New Jersey Chapter

This weekend I saw the first crocus punching out of my garden! A reminder that the record cold and snowfall we experienced in the northeast this past winter is finally over. The NJ chapter continued to deliver solid programs in spite of the weather. A special thanks to Phil Sumner who leads the programs committee this year and who has brought fresh ideas and enthusiasm.

In January, Sanofi Bridgewater hosted an overview of the 2014 ISPE FOYA (Facility of the Year Award) annual program that recognizes state-of-the-art projects utilizing new, innovative technologies to improve the quality of products, to reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery. We were fortunate to have one of the seven award winning project teams share presentations about their project, providing details on why they were considered state-of-the-art, what is unique about their approach, and what the impact the project has had on business. Harold Bowman (Fluor) presented Category Winner for Project Execution: Grifols Therapeutics, North Fractionation Facility. Many thanks to Christine Farnor of Sanofi for hosting this standing room only event!

In February, Genzyme hosted a student tour of their Ridgefield, NJ manufacturing plant with a question and answer session, over 50 students and faculty from Manhattan College, NJIT, Rutgers, Stevens, and Kingsborough Community College attended. A special thanks to Shilan Motamedvaziri for coordinating, and Mike Kelliher and the entire Genzyme organization for hosting an "awesome" (as the students phrased it!!!) event.

This March, we once again delivered professional development training at Rutgers University, Biomedical Engineering Campus in Piscataway, NJ. Training was delivered on Biosafety and Containment Facility Design as well as Technology Transfer. Rutgers provided certification to recipients who received CEUs to renew their PE Licenses. Popularity of this event has grown significantly over the years we have offered it. Many thanks to Norman Goldschmidt and Stella Lamphear for all their efforts in preparing and delivering training.

March also hosted the annual Executive Advisory Committee dinner at Dinosaur BBQ in Newark, where we met current and new engineering leaders of BioPharma owners for their perspective on their organization needs. Many thanks to Frank DeMarinis for organizing and stuffing us full of pork!

Still ahead .....in April, we continue our commitment and support to university students with the annual Student Poster Contest to be hosted this year by J&J New Brunswick. It will include a presentation by Nancy Barber of BMS on the latest Trends in Product Development in the Pharmaceutical Industry, and a Young Professional interactive discussion by Tunde Babalola, also of BMS. Also, in May, our annual Golf Outing that will be held again at the Neshanic Valley Golf Course. We will be looking for opportunities to continuing our partnership with DelVal chapter and other organizations this year to help bring cost effective training, information and other networking opportunities to our membership sometime in June.

Now it's your turn: Nominations request for the 2015-2016 NJ Board of Directors will be issued shortly. We are looking for committed industry professionals to volunteer their efforts on behalf of their industry colleagues and students. There are several committees already in place to provide our membership with all that ISPE has to offer, including Programs, Professional Development and Education, Communications and Membership, Young Professionals and Student Activities. Over my 30+ year history with ISPE, I have been fortunate to contribute to each of these committees and have truly enjoyed the mentoring, networking opportunities and knowledge gained from this unique community. If you would like to volunteer, suggest new ideas or discuss any of the upcoming events, please feel free to get in touch with me or any board or committee member.

Springing ahead!!!

Tony Crincoli  
President, ISPE NJ Chapter

## Chapter Sponsors

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## Upcoming Events

### Latest Trends in Product Development, Young Professional Interactive Session & Annual NJ ISPE Student Poster Competition

**April 28, 2015**

**5:00 – 9:00 pm**

**Johnson & Johnson World Headquarters**

ISPE New Jersey Chapter will also be judging the Student Poster Competition and announcing the winner at the meeting.

Speaker - **Nancy Barbour**, Senior Vice President, Drug Product & Technology, Bristol-Myers Squibb  
Nancy Barbour is currently the Vice President of Drug Product Science & Technology at Bristol-Myers Squibb Co. She joined BMS in 1991 after receiving her B.S. in Pharmacy from Albany College of Pharmacy and Ph.D. in Pharmaceutical Chemistry from the University of Kansas. In her role at BMS she is responsible for global product and process development for the entire pipeline of small molecules, biological compounds, and devices.

**Young Professional Tunde Babalola**, Manager - Bristol-Myers Squibb Quality Operations/External Manufacturing and Alliance Management

**Topic:** A young professional will speak to the students about their experience and journey.

Tunde Babalola is a Quality Operations Manager for External Manufacturing Americas at Bristol-Myers Squibb, New Brunswick, NJ. Her role includes quality oversight of contracted third party manufacturers for Bristol-Myers Squibb and involves numerous other projects within her team and the company. Prior to joining the External Manufacturing team in New Jersey, Tunde was a Global Manufacturing and Supply Associate with BMS, where this role took her through 6 to 12 month rotations and projects in devices operation, manufacturing operations, supply chain and quality assurance, both in New Brunswick, NJ and Manati, Puerto Rico. Tunde received her B.Sc. in Biomedical Engineering with a concentration in Mechanical Engineering from the University of Rochester at Rochester, NY and her Ph.D. in Biomedical Engineering from Cornell University at Ithaca, NY. Introduced to ISPE through the ISPE NJ Young Professionals Chapter in early 2013, Tunde has been an active member in the ISPE NJ Chapter since then.

#### **Schedule of Events:**

3:00 - 5:00 pm - Poster Presentations & Student Poster Competition

5:00 - 6:00 pm - Networking, Open Bar, Hors d'oeuvres

6:00 - 7:00 pm - Dinner Buffet Served

7:00 - 7:20 pm - Young Professional Presentation, Tunde Babalola

7:20 - 8:10 pm - Speaker Nancy Barbour

8:10 - 8:30 pm - Awards Ceremony

9:00 pm - Meeting Adjourns

**Registration** - <https://www.eventbrite.com/e/2015-ispe-njc-latest-trends-in-product-development-young-professional-interactive-session-annual-nj-tickets-15930832549>

*Please support the students of ISPE NJC at the annual Poster Competition. Student Members in Student Chapters sponsored by the NJC are doing research relevant to the health sciences and pharmaceutical industries.*

### Golf Outing

**May 18, 2015**

**Neshanic Valley Golf Course, Neshanic Valley**

The New Jersey Chapter annual Golf Outing will once again be held at Neshanic Valley Golf Course on Monday, May 18<sup>th</sup>. Last year almost 90 golfers enjoyed a magnificent day at one of the top courses in NJ. If you're not a golfer we will again be offering an alternative networking event before dinner at a vineyard near the Delaware River. The afternoon will include; a tour of the vineyard, wine tasting, an opportunity to learn about growing grapes and making wine, more tasting and appetizers at a venue that is sure to create a memorable experience and meet some new friends. Please mark the date on your calendars, start thinking about organizing your foursomes and watch for registration emails soon. Sponsorship opportunities will be available. If you have any questions or would like to help with the event please contact Rich Smith at 609-619-9618.

**Registration** <https://www.eventbrite.com/e/2015-ispe-njc-golf-outing-tickets-16355414485>

# Past Events

## Facilities of the Year Award – Sanofi

### January 2015

In spite of another furious snow storm by Mother Nature, ISPE NJ was able to hold its January 28, 2015 meeting. Mr. Harold Boman, Senior Vice President of Operations, Fluor presented the Grifols' North Fractionation Facility Project. This project was the ISPE Facility of the Year Award Winner (FOYA) for the Project Execution Category. Included in the discussion was a plasma fractionation process overview, the project design and an innovative project execution plan.

This ISPE NJ Chapter event was held at Sanofi in Bridgewater, NJ. The meeting was well attended, with over 50 participants. The Sanofi facilities and meeting support were excellent and well appreciated by all.

We were fortunate to have Fluor, Sweetwater Construction and Friends of ISPE NJ as our meeting sponsors. Sponsoring an event is very helpful to the Chapter in defraying operating costs, while providing member firms with added visibility

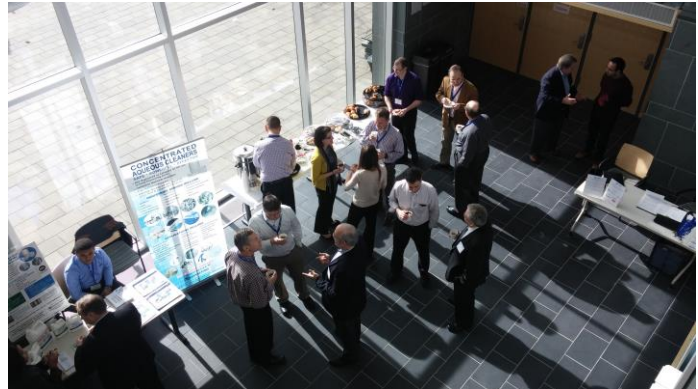


## Past Events

### Professional Development Day – Rutgers University

March 2014

Spring and CEU credits were in the air at our March 19, 2015 Professional Development Day meeting. This dual track training event had something for everyone. The first topic “BioSafety and Containment Facility Design”, explored the latest updates to industry standards and guidance (BMBL and DRM) from the NIH as well as current safety, operations and facility design tools. Presenters included subject matter experts from the National Institute of Health (NIH) as well leaders in the engineering and Industrial Hygiene communities. Chaired by Norman Goldschmidt, Genesis Engineers.



The second topic “Technology Transfer” focused on differing concerns depending upon product transfer type (e.g. site to site transfer vs new product), regulatory issues, process and facility design as well as project management techniques. Presenters included SME consultants and owners and was co-chaired by Stella Lanphear CAI.



We had an excellent turn out for the meeting with approximately 60 member, sponsor and attendee signups.

Thank you to Dr. Henrik Pedersen and Rutgers University for hosting our meeting.

We would also like to thank our speakers:

Alamelu Ramesh – NIH  
Raj Chainani – NIH  
Steve Breslin – NIH  
Scott Taylor – NIH  
Barbara Owen – Merck  
Norman Goldschmidt – Genesis Engineers  
Bob Beall – ProPharma Group  
Patti Parekh – CAI Consulting  
Bill Deckert – CAI Consulting  
Stephanie Gaulding – CAI Consulting  
Luke Gong – PS&S  
Brian Petuch - Merck



We were fortunate to have the following sponsors:

**AAF International**

**ProPharma Group**

**Wilco**

**Genesis Engineers**

**International Products Corp**



## Sponsorship and Advertising Opportunities

Advertising and sponsorship represent an excellent opportunity to be identified as an industry participant and a supporter of the ISPE New Jersey Chapter's Professional Programming. It is a particularly cost effective means of increasing your firm's visibility to the Chapter membership and beyond. ISPE NJC has many exciting sponsorship and advertising opportunities in 2015. These include:

### Chapter Sponsorship: \$1,650

Chapter Sponsorship has many benefits, including:

- Recognition as a Chapter Sponsor at all ISPE NJC events in 2015 (see fact sheet for details)
- Name and Logo on announcements for all ISPE NJC events in 2015 (see fact sheet for details)
- 1/2 page Advertising space in the ISPE NJC newsletter for 2015 (\$800 value!)
- 12 month Advertising space on the ISPE NJC website in 2015 (\$500 value!)
- Two complimentary tickets for all 2015 NJC Events<sup>1</sup> and additional attendees from your organization receive 10% off any event ticket cost.

### Advertising

Advertising opportunities are available for the Newsletter and Website "a la carte":

**Newsletter Advertising (2015-2016)** – The Chapter publishes a newsletter 4 times a year, highlighting recent and upcoming events, educational programs, technical articles and general interest of interest to the Members. The newsletter is published electronically to all current ISPE NJC Members and others on our circulation list. (5000+ recipients). Advertise for 1 issue or 4 consecutive issues:

Business Card size -	\$100 per issue or \$350 for 4 issues	(a \$400 value!)
1/4 page-	\$150 per issue or \$525 for 4 issues	(a \$600 value!)
1/2 page -	\$200 per issue or \$700 for 4 issues	(an \$800 value!)

**Website Advertising** – Your ad is visible to everyone who visits the ISPE NJC website.

6 months - \$275      12 months - \$500

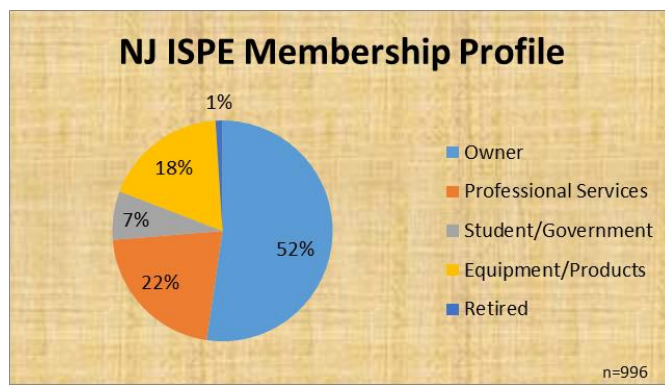
### Event/Program Sponsorship - (Opportunities start at \$125 depending on Event)

Event Sponsorship has many benefits, including:

- Name and Logo on all Announcements for designated event
- Recognition at Event during session
- Complimentary Tickets for Two Attendees<sup>1</sup>
- Select Event(s)- Vendor Table/Display (Professional Development Day and Golf Outing)

**Note 1- Golf outing complimentary tickets are limited to Clubhouse Outing activities only.**

To become a sponsor please visit - <http://www.eventbrite.com/e/2015-ispe-njc-chapter-sponsorship-advertising-program-tickets-14267028065> or contact [manager@ispenj.org](mailto:manager@ispenj.org)



### Did You Know???

Newsletter Distribution-

996 Members

5,387 Non Members

*Total Distribution to Owners, Professional Services, Equipment/Products Providers and Students located in:* Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Indiana, Iowa, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin

## ISPE NJ New Members: 1ST Quarter 2015

**Welcome all 84 of our new Members!**

Arianna Adams, Kingsborough Community College  
Hassaan Ahmad, Suneris, Inc.  
Miguel Anderson, Kingsborough Community College  
Andrew Aychouh, NJIT  
Bekhruz Bazarov, Kingsborough Community College  
Prakash Bhojani, Stevens Institute of Technology  
Amna Bhutta, Rutgers University  
Alice Bianco, Stevens Institute of Technology  
Cody Bishop, Rutgers University  
Rambabu Bodda, Rutgers University  
Wesley Bonafe, Advance TEC  
Alexander Brown, Kingsborough Community College  
Agnessia Cabrel, Kingsborough Community College  
Abraham Chong, Colgate-Palmolive  
Nick D'Ottavio, Lundbeck Research USA  
Janet Diaz-Pinto, Bristol-Myers Squibb Co., Inc.  
Tayyeb Din, Kingsborough Community College  
Maria Cristina Ferreira Da Cunha, Stevens Institute of Technology  
Emma Fleisher, Rutgers University  
Thomas Garvey, Garvey Corp  
John Gossard, Catalent Pharma Solutions  
Brian Haight, NJIT  
Kristie Henrici, Faith & Royale Consultants  
George Hollerbach, JR, Quantum Management Group, Inc.  
Michael Ibrahim, Balchem Corp  
Veeraj Jadeja, Actavis  
Sayeli Jayade  
Saket Kashettiwar, Rutgers University  
Brian Kavanagh, Performance Contraction, Inc.  
Muhammad Ashraf Uzzaman, Radiant Pharmaceuticals Limited  
Andrew Konop, NJIT  
Yuanfu Kuang  
Jason LaRoche, TransCelerate Biopharma  
Richard Li, Actavis  
Kexin Lin, Stevens Institute of Technology  
Dongxin Liu  
Luis Llubes, Regeneron Pharmaceuticals Inc.  
Brain Lorcheim, Johnson & Johnson  
John Maiero, Luitpold Pharmaceuticals  
Paul Martinez, CurTec USA  
Richardo Mendes, Lighthouse Worldwide Solutions  
Lynda Messiheddine, Kingsborough Community College  
Kasam Mohammad  
Christian Monchinski, Automated Control Concepts, Inc.

Raksha Nadubeedi Ramesh, Stevens Institute of Technology  
John Nordberg, Novartis  
E. Kwame Obeng, Valeant Pharmaceuticals  
Jeffery Palmer  
Girish Patel, Daiichi Sankyo  
Mitul Patel, KeRi Engineering  
Niyati Patel, Stevens Institute of Technology  
Punit Patel, PL Developments  
Ronak Patel, Prolong Pharmaceuticals  
Ruchi Rajendrabhai Patel, Stevens Institute of Technology  
Jehan Poco  
Jeannie Robertson, World Courier, Inc.  
Brian Roscoe, Calvary Automation  
Diana Russo, Eli Lilly and Company  
Silene Aracely Salazar Huarita, Rutgers University  
Olivia Schultz, Stevens Institute of Technology  
Dhara Dhaval Shah, Stevens Institute of Technology  
Hitarthi Devendrakumar Shah, Stevens Institute of Technology  
Priya Shah, Rutgers University  
Vearesh Sharma  
Piyushkumar Sheladiya, Amneal Pharmaceuticals of NY LLC  
John Silva, Johnson & Johnson  
Elizabeth Smith, NJIT  
Alyssa Smith-Sennon, Kingsborough Community College  
Lin Song, Stevens Institute of Technology  
Yufeng Song, NJIT  
Pooja Talsania, West-Ward Pharmaceutical Corp  
Ashutosh Tamrakar, Rutgers University  
Jatinkumar Umedlal Tanna, Stevens Institute of Technology  
Daniel Tummillo, Par Pharmaceutical Inc.  
Jason Urban, Celgene  
Khrystyna Vasylyshyn, Kingsborough Community College  
George Waidell, Formpipe GXP  
Hongji Wang, Stevens Institute of Technology  
Eric Wolf, Preferred Freezer Services  
Sze-Hoong Wong, Merck  
Janice Wortham, Mettler-Toledo PCE  
Oksoun Yee, Bristol-Myers Squibb  
Jing Zhang, Stevens Institute of Technology  
Wanhe Zhu, Stevens Institute of Technology