



Connecting a World of  
Pharmaceutical Knowledge

## New Jersey Chapter



ISPE Affiliates and Chapters Around The World

VOLUME 22, ISSUE 4

Fall 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

### Holiday Party

December 16, 2015 – Nassau Inn, Princeton, NJ

## The President's Message



Welcome to a new year of ISPE. On behalf of the NJ Chapter Board of Directors, I would like to introduce our 1015 Chapter members to the new Board. The Board is comprised of (13) members from a cross-section of companies that are part of this varied and dynamic industry. It gives me great pleasure to introduce you to:

**Harry Segner**, Genesis Engineers - **Vice President**  
**Jim Brinkman**, Pfizer - **Treasurer**  
**Debra Bahr**, Propharma - **Secretary**  
**Raymond A. Roggero**, CP Professional Services - **Vendor Representative**  
**Christine Farnor**, Sanofi Pasteur - **Engineering Representative**  
**Thomas Flachmeyer**, Prolong Pharma - **QC Representative**  
**Alok Bhatt**, Bristol-Myers Squibb - **YP Representative**  
**Anthony Hutchinson**, Merck - **Representative at Large**  
**Frank DeMarinis**, Purdue Pharma - **Representative at Large**  
**Rich Smith**, HDR - **Representative at Large**  
**Philip Sumner**, Pfizer - **Representative at Large**  
**Michael Kelliher**, Genzyme - **Representative at Large**

Tony Crincoli, Immediate Past-President – BMS, was recently elected to the ISPE International Board of Directors. Tony joins fellow NJC member, and Past-President, Jim Breen – JNJ, to the International Board.

The NJC Board is working very hard to ensure that the Chapter's programs are aligned with the needs of our members. Last month there was sold-out attendance at the International Leadership Forum event, which was hosted by BMS. This type of attendance encourages us to do more events like this.

We are all volunteers who share a common goal of enriching both our industry and professions – and having a little fun along the way. We encourage you to join us. To paraphrase former US President John F Kennedy: “ask not what ISPE can do for you, but what you can do for ISPE”. An easy way to do this is become involved with a committee and/or volunteer to help organize a program.

On Behalf of the NJC Board of Directors, we wish you a very successful year and look forward to working with you.

Paul Malinowski, President - BD

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## Past Events

### Vaccines and Biologics Double Header – Pfizer, Peapack, NJ

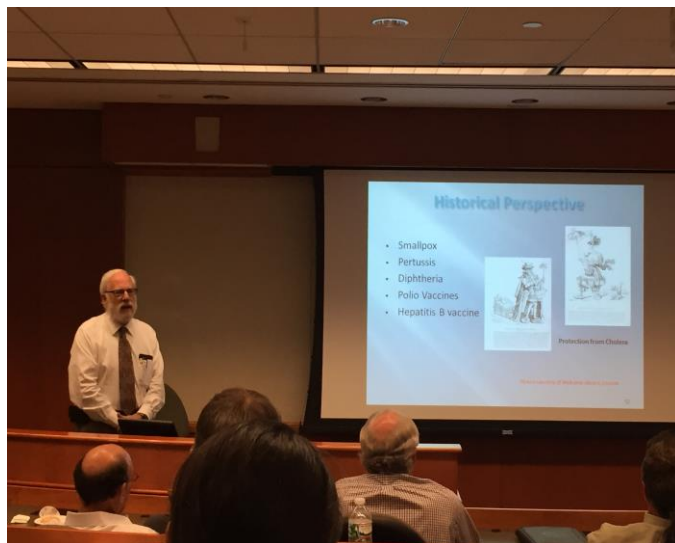
June 2015

What a game! The fans went wild! The June event, focusing on Vaccines and Biologics, had two energy packed presentations. The first, Vaccines and Biologics Development, by Dr. Dennis Gross, was packed with case studies and real time examples that provided an in depth overview of vaccines and biologics. The physical differences between small molecule drugs and large molecule biologics, processes, clinical requirements and varying facility needs were discussed. What was particularly eye opening was the challenge everyone faces with respect to quality control, regulatory approval and supervision regarding the commercialization of bio-similars.

The **NSI Capacity Expansion Project** at Grange Castle, Ireland, presented by George Skillin, highlighted a variety of planning and execution activities that enabled the team to resolve issues real time and achieve a high quality product, meeting the complicated manufacturing requirements for the conjugation of 13 vaccines into one dosage form. The presentation was packed with example tools and techniques used. The time frame in which this project was accomplished, including meeting with the necessary regulatory agencies involved was impressive.

Everyone very much enjoyed both presentations as the speakers were very engaging. There were others in the room that also participated in the NSI project, from Pfizer and other companies, which highlighted what a small community it is in which we all operate. Copies of each presentation are available on the ISPE NJ website. <http://www.ispe.org/new-jersey/past-events-presentations>

We would like to thank our sponsors: Jacobs and Pall Life Science.



## Past Events

### Facility of the Future – Bristol-Myers Squibb – Plainsboro, NJ

#### September 2015

The future was here and it rocked! The ISPE International Leadership Forum developed this program in an ongoing effort to address the question “What are the current trends and how will manufacturing be different in the future?”. The topic was timely given the host of changes going on in the industry.

We would like to extend a special thank you to Jim Breen VP JNJ, who is a member of the ILF and especially to Mark Butler who assembled this team of illustrious speakers. Each presentation was packed with case studies and real time examples that provided an in depth overview of current and future developments impacting pharmaceutical manufacturing and facility design. The presentation topics are listed below. We had tremendous feedback from the attendees. Everyone very much enjoyed the discussion and felt you were each very engaging.

We would also like to thank Henrik Pedersen and Rutgers University for processing the Continuing Education Competency Credits which are required for many of us to continue with our professional registrations. The BMS facility and delicious food was coordinated by Tony Crincoli, Janet Diaz-Pinto and Team.

#### Facility of the Future Program Presentations

- Jim Breen Jr, PE Vice President, Worldwide Engineering and Technical Operations for Johnson & Johnson “*ISPE International Leadership Forum - Facility of the Future Update*”
- Mark Butler, Sr. Vice President with IPS “*Industry Survey Factory of the Future*”
- Rafi Maslaton, Founder and President of cResults “*Big Data / FDAAware*”
- Bruce Snyder, Senior Automation Engineer with IPS “*Continuous Processing for Bio manufacturing Down Stream Processing*”
- Matt Kennedy, Biotechnology Process Engineer with CRB “*Industry Case Study*”
- Rick Mitzner, Senior Director, Engineering Technology for Pfizer Global Engineering “*Small Molecule Continuous Manufacturing Case Study*”
- Eric Staib, Executive Director in Corporate Quality Assurance at PRA Health Sciences “*Mobile Apps and New Technologies*”

We would like to thank our sponsors: CRB, DME Alliance, PendoTECH, Hargrove Life Science, Pall Life Science, IPS, Horizon Controls Group.



## 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

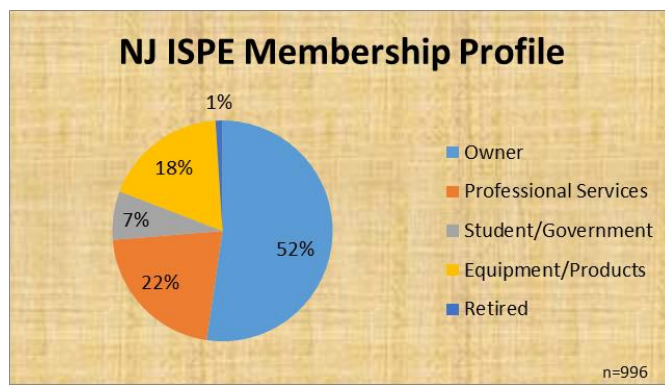
### Event/Program Sponsorship - (Opportunities start at \$125 depending on Event)

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: 2nd Quarter 2015

**Welcome all 64 of our new Members!**

Lou Ambrogio – **Ambro Consulting Services**  
Heather Armbruster – **Johnson & Johnson**  
Gary Ball  
Michael Banua – **ProMetic BioSciences**  
Adam Bloom  
Ravi Kumar Boggavarapu  
Adam Brown – **Stantec Consulting Services**  
Jacqueline Bruey  
Alan Carver – **Novartis Pharmaceuticals**  
Ki Chan – **Bracco Diagnostics**  
Nityanand Choubey  
Alexander Debets – **Merck**  
Ashav Desai – **Rutgers University**  
Marina Dheri – **Daiichi Sankyo Pharma**  
Gilbert DiMaio  
Michael DosSantos – **CP Professional Services**  
David Dube – **Kedrion Biopharma**  
Avijit Dutta – **Infosys Technologies**  
Marius Edu – **Datwyler Pharma Packaging**  
Robert Falana – **Bristol-Myers Squibb**  
Philip Gallaro – **Core Reliance**  
Marci Goldfinger – **Johnson & Johnson**  
Nicholas Griffin  
Anitha Gunasekaran – **Celgene Corp**  
Sermin Guvenc  
Matthew Hariegel – **Integra Life Sciences**  
Caren Harris – **Acelity**  
Steven Heller – **Seiden Krieger Associates**  
Ziwei Huang – **Stevens**  
Melvin Kaufman  
Karl Kressley – **M. Davis & Sons**  
Paul Lefebvre – **Johnson & Johnson**

Nathan Lubansky – **Ortho Clinical Diagnostics**  
Michael Lui – **Johnson & Johnson**  
Georgina Anderson Maines  
Joseph McGinnis – **Johnson & Johnson**  
Sravan Kumar Nadipalli – **NJIT**  
Nazem Obidat  
Travis Ormandy  
Anusha Pantula – **NJIT**  
Rakesh Patel  
Jeff Peragallo  
Donna Petro  
Tuam Pham – **Stevens**  
Mark Philhower  
Gina Pierre – **Johnson & Johnson**  
Spencer Pontell – **West-Ward Pharmaceutical**  
Christopher Renzi  
Donald Rodrick – **Janssen Diagnostics**  
Allen Salerno – **Regeneron Pharmaceuticals**  
Aami Shaghala – **West-Ward Pharmaceutical**  
Chadakarn Sirasitthichoke – **NJIT**  
Kevin Soltis – **Bristol-Myers Squibb**  
Carl Sprang – **Oncobiologics**  
Jeffrey Steward – **DPT Laboratories**  
Steven Tackach – **Sandoz**  
Vanya Telpis – **McKinsey & Company**  
Allison Tirrell – **Hargrove Life Sciences**  
Stephen Todderud  
Balaaji Valapadi-Bhaskar – **Hyde Engineering**  
Mary Van Horn – **Johnson & Johnson**  
Rick Vohden  
Raoul Watson  
Eric Wesoloski - **Apicore**  
Qian Zhuge



## 2015-2016 – ISPE New Jersey Board of Directors

Paul Malinowski, BD (Becton Dickinson) – **President**

Harry Segner, Genesis Engineers – **Vice President**

Jim Brinkman, Pfizer – **Treasurer**

Debra Bahr, ProPharma Group – **Secretary**

Christine Farner, Sanofi Pasteur – **Engineering Representative**

Ray Roggero, CP Professional Services – **Vendor Representative**

Tom Flachmeyer, Prolong Pharmaceuticals – **QC Representative**

Alok Bhatt, Bristol-Myers Squibb – **Young Professional Representative**

Anthony Hutchinson, Merck – **Representative at Large**

Frank DeMarinis, Purdue Pharma – **Representative at Large**

Rich Smith, HDR – **Representative at Large**

Mike Kelliher, Genzyme – **Representative at Large**

Philip Sumner, Pfizer – **Representative at Large**

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Annual Meeting 2015  
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Philadelphia, PA, USA

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[www.ISPE.org/2015-Annual-Meeting](http://www.ISPE.org/2015-Annual-Meeting)