



Connecting a World of  
Pharmaceutical Knowledge

## New Jersey Chapter



ISPE Affiliates and Chapters Around The World

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Winter 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

**Professional Development Day**  
March 19, 2015 – Rutgers University

**Student Poster Competition**  
April 28, 2015 – Johnson & Johnson, New Brunswick, NJ

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

## The President's Message



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

Welcome to a new and exciting year for both the ISPE NJ Chapter and the industry! Trends in product development, biologics, novel devices, new/changes to regulation and insurance promise make this a very challenging year. Chapter leaders have continued to listen to our membership and provide meaningful events that keep us informed in a constantly changing industry. Our board has changed and committees have grown with new, talented and committed membership and guidance from a stronger Executive Advisory Committee. The ISPE International has changed as well with new leadership. We were introduced to John Bournas the new President and CEO, who promises to bring a fresh approach, greater integration with the chapters and affiliates and a closer relationship with regulatory officials.

2014 ended with a strong series of presentations and development programs in “Capital Cost Benchmarking”, “Serialization”, “ISPE Baseline® Guide: Biopharmaceutical Manufacturing Facilities”, “Product Robustness and Validation” and “Reliability Maintenance”. We continued our commitment and support to the University students with the annual Student Poster Competition. It included an executive presentation by Roberta McKee of BMS on Strategic Changes Facing the Pharmaceutical Industry. Our social events have improved as well. This year, driving to make events more inclusive, the annual Golf Outing also included a brewery tour, and we closed the year with a great holiday party at the Nassau Inn in Princeton.

This year, ISPE NJ Chapter will again partner with Rutgers University, to host a Professional Development Day event at their Biomedical Engineering Building in Piscataway. For all of those looking for CEUs to renew their PE License, Rutgers provides certification as an added bonus to a great day of education and learning. We have also revamped our University student program from the ground up. Other upcoming events include a FOYA (Facility of the Year Award) Presentation at Sanofi, the annual Student Poster Competition which will be hosted by J&J in April, and our annual Golf Outing that will be held again at the Neshanic Valley Golf Course in May. We will be continuing our partnership with DeVal Chapter and other organizations this year to help bring cost effective training, information and other networking opportunities to our membership.

We are always looking for your feedback for improvements to these and other events, promoting our value proposition, and always welcome your contribution of support. Opportunities this year include developing our young professional population, seeking potential committee and board members from the ISPE community.

Wishing you all a healthy, successful and prosperous new year!!!

Tony Crincoli  
President, ISPE NJ Chapter

## Chapter Sponsor



## Newsletter Sponsor

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## Upcoming Events

### Spring 2015 Plant Tour for Student's

February 5, 2015

8:30 – 2:00pm

#### Genzyme – A Sanofi Company

Ridgefield, NJ

Genzyme Ridgefield is a vertically integrated manufacturing site specializing in biological extraction, bulk formulation, aseptic processing, automated syringe/vial filling, terminal sterilization, inspection, global labeling/packaging, and distribution. Synvisc® and Hectorol® are the facility's major products. Synvisc® is the market leader in the visco-supplementation treatment for osteoarthritis. Bulk Hyaluronic Acid is produced for Synvisc® by extraction using a proprietary technology to yield high molecular weight HA. Hectorol® is a vitamin D analog for renal patients administered at dialysis centers. The environmentally controlled facility has the capacity to produce over 70MM syringes and 50MM vials annually.

#### **You MUST register soon to attend this event**

To register contact your **School** ISPE Student Representatives or ISPE Faculty Advisor for details.

The number of seats for each school is limited and will be offered on the first come, first served basis

You must be an ISPE Member <https://www.ispe.org/students/membership>

### Professional Development Day

March 19, 2015

Rutgers University

CEU's awarded!

This one day program will focus on two important topics pharmaceutical and biotechnology professionals deal with on a regular basis.

**Program 1: Bio Containment Facility Design** will give detailed explanations and practical advice to help engineers, hygienists, quality professionals, researchers, development scientists and operations personnel address bio hazards related to research and product manufacture. The course will explore the latest updates to industry standards and guidance (BMBL and DRM) from the NIH as well as current safety, operations and facility design tools / concepts to help you meet the challenges of bio-containment and bio-security without compromising cGMP compliance. Presenters will include subject matter experts from the National Institute of Health (NIH) as well leaders in the engineering and Industrial Hygiene community. (full day)

**Program 2; Technology Transfer** will cover project management, differing concerns depending upon product transfer type (e.g. site to site transfer vs new product) , regulatory issues, process and facility design. Presenters will include SME consultants and owners. Bring your tech transfer challenges and develop solutions at the workshop. (full day)

Each program will review the latest trends and tools including ISPE guidance documents available.

This conference will be of value to professionals from the pharmaceutical and biopharmaceutical industry, suppliers and regulators, process development scientists, technology transfer managers, manufacturing managers, engineers, quality assurance professionals, quality control professionals, risk assessment professionals and academia.

There are a limited number of Table top vendor displays available. Those interested may contact Phil Sumner: [philip.e.sumner@pfizer.com](mailto:philip.e.sumner@pfizer.com)

## Past Events

### Maintenance and Reliability Excellence – Bristol-Myers Squibb

#### New Jersey Chapter November 2014 Meeting

On November 18, 2014 ISPE NJ Chapter held a meeting on Maintenance and Reliability Excellence at Bristol-Myers Squibb in New Brunswick, NJ. The meeting was well attended, with 40 participants. Among the meeting participants were 8 new members, or first meeting attendees. BMS facilities and meeting support were excellent and well appreciated by all. The meeting focused on Reliability and included three speakers with diverse perspectives on this topic.

Presentations included:

**ISO 55000: What is it and how can Pharma benefit?** – Speaker, George Williams of Bristol-Myers Squibb

**Designing reliability into projects: The maintenance and reliability team provide immense value as stakeholders to capital projects.** – Speaker, Richard Tree of Commissioning Agents Inc.

**TPM, it's more than just reliability and maintenance, it's a partnership.** – Greg Walker of Pfizer

Presentations from this meeting can be found at: <http://www.ispe.org/new-jersey/past-events-presentations>

We were fortunate to have Bancroft Constructions as our meeting sponsor. Sponsoring an event is very helpful to the Chapter in defraying operating costs, while providing member firms with added visibility.



## Past Events

### Holiday Party – Nassau Inn, Princeton, NJ

Our Holiday Party was held on December 9, 2014 at the Nassau Inn in Princeton, NJ. As with last year's event, the Nassau Inn provided an ideal and memorable venue for the Holiday party. The fire alarm that occurred during the cocktail hour was a bit more excitement that we bargained for. Thankfully, the evacuation was expeditiously completed and the festivities continued. Rich Smith led the holiday raffle, which did not disappoint, as fun was had by all. There were 73 people in attendance. Our thanks to the generous members who brought many toys to donate to Toys for Tots.

Our thanks to the event sponsors, which included: ProPharma Group, Friends of ISPE NJ, Vantage Consulting Group, MGM Integrated Solutions, HDR, Moonstone Group, CAI, PS&S and Currie and Brown.



## 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

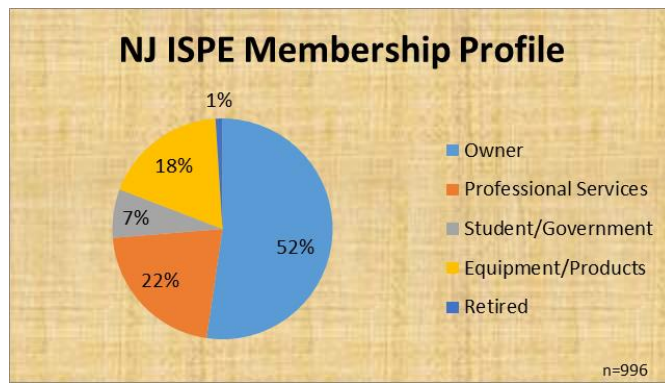
### Event/Program Sponsorship - (Opportunities start at \$125 depending on Event)

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: 4TH Quarter 2014

**Welcome all 43 of our new Members!**

Sree Aravapalli, Aurex Laboratories  
Shehzad Asim, Pricewaterhouse Coopers LLP  
Suresh Bagaria, Bagaria Bio Pharm Solutions  
Bianca Beltran, Manhattan College  
Peter Blok, Sigmapharm Laboratories, LLC  
Nicholas Boccio, Manhattan College  
Kanyaphat Bunchongprasert, Stevens Institute of Technology  
Maureen Castiglione, Novartis  
Marilia Cavaco, J & J Pharma R&D LLC  
Luis Dasta, US Food and Drug Administration  
David Enck, Janssen  
Martha Folmsbee, Pall Corporation  
Sebastian Garcia, Manhattan College  
Gerard Geiger  
Tian-lin Han, Manhattan College  
James Hathcock, Pall  
Kellee Herbert, Johnson & Johnson  
Robert Hersh, Bristol-Myers Squibb Co., Inc.  
Alex Kakad, Gore PharmaBIO Products  
David Kim  
Claudius Maranhao, AECOM  
Stefan Marrecau, Merck & Company, Inc.

Scott Messenger, McNeil Consumer Healthcare  
Margaret Miller, Corning Incorporated  
Edward Morris, The Morris Group, LLC.  
Owen Murray, Recordati Rare Disease  
Regina Noh, SK Life Science  
Cory Notaro, Thermo Systems, LLC  
Patrick Nwaoko, Stevens Institute of Technology  
Thomas O'Leary  
Robert Otten  
Greg Parker, Mace North America Limited  
Hardik Patel, Stevens Institute of Technology  
Randall Pinto, Magnetrol  
Sagar Shah, Mylan Pharmaceuticals  
Daniel Sherer, Ferring International Pharmascience Center, US  
Kshamip Soni  
Ann Standard, Kyowa Hakko Kirin Pharma Inc  
Einar Ulfsson, Hitachi  
Xi Wang, Stevens Institute of Technology  
Hayes Williams, Knowledgent  
Rob Worsham, Insmmed  
Lawrence Yu, FDA



## ISPE NJ Member Anniversaries

### 35 Years

Mr. James M. O'Brien  
Mr. James P. Agalloco  
Mr. Victor CF DiChiara  
Mr. Richard S. Overton

### 30 Years

Mr. Claudio Pincus  
Mr. Clifford L. Satterfield, Jr.

### 25 Years

Mr. William N. Hons  
Mr. Scott Friedland  
Mr. Claudio M. Radossi  
Mr. Michael J. Varrone, AIA  
Mr. Charles J. Buckle  
Mr. Orlando Perez, PE  
Mr. Marc Steinman

### 20 Years

Mr. Maik W. Jornitz  
Mr. Stanley O. Berg  
Mr. Thomas A. Powers, PE  
Dr. Peter D. Bernardo  
Mr. Charles Tiranno  
Mr. Eyal Mares  
Mr. Jeffrey S. Maynard  
Mr. Robert G. Groff

### 15 Years

Mr. Matthew P. Bestercy  
Mr. Michael B. Gershman  
Mr. George J. Serafin  
Mr. Richard E. Lemire  
Mr. Vinay Shah  
Dr. Erwin J. Wenning  
Mr. Darren J. McCurry  
Mr. Michel D. Renard  
Mr. Paul N. Schank  
Mr. Dennis Thomas  
Mr. Allen L. Foust  
Mr. Tarik M. Abdala  
Mr. Matthew J. Bosco, P.E.  
Dr. Prafulla Agrawala  
Mr. James A. Breen, Jr.

Ms. Marie E. Carpenter  
Mr. Mark B. Garber  
Mr. Michael A. Greenholtz  
Mr. Robert M. Forlenza, PE

### 10 Years

Mr. Pankaj A. Shah, PhD  
Mr. Joseph A. Szmul  
Mr. Michael Hanssens  
Mr. Srinivas Moramchetty  
Mr. Michael Hausmann  
Mr. Nejat Babur  
Mr. Jonathan Myjak  
Mr. Minesh N. Desai  
Mr. Arabindakshya Mishra  
Mr. David J. Armistead  
Ms. Christine C. Harty  
Mr. Jared Koscinski  
Mr. George M. Lancos  
Mr. Anthony Consolo  
Mr. Joseph S. Krizan, PE  
Ms. Paula R. Mastrangelo  
Mr. Michael J. Prahl  
Mr. Anthony J. Esposito  
Mr. Frank J. Urbanski  
Mr. Jeffrey W. Lorenz  
Mr. Samuel Maya  
Mr. Eric D. Nickerson  
Mr. Harry M. Segner  
Mr. Gerald J. Brown  
Ms. Christine J. Farner  
Mr. Jeffrey J. Blumenstein, PhD  
Mr. Joseph F. Masiello  
Mr. Angel Montanez, Jr.  
Mr. Michael J. Moussourakis  
Mr. William G. Randolph, III, PhD

### 5 Years

Mr. Shawn R. Haynes  
Mr. Gino P. Nassi  
Ms. Kavita P. Shah  
Mr. Anthony J. DiSanti  
Mr. Gary V. Faigle  
Mr. Nicholas Mandala  
Ms. Kavitha Bolla  
Mr. Vincent D'Agostino  
Mr. Paul G. Doherty  
Dr. Glenn W. Howard, Jr., Ph.D.  
Mr. Jeffrey C. Lane  
Mr. Robert K. Orgera, AIA, LEED AP  
Mr. Robert J. Corso  
Mr. Michael ODonoghue  
Mr. Christopher Pastorello  
Mr. Michael Bocchini  
Mr. Ed Bunge  
Mr. Richard E. Urban, PE  
Mr. Eric M. Cochran  
Mr. Jason H. Hartman  
Mr. Randy A. Dwiggin, PE, CPIP  
Ms. Theresa Lane  
Mr. Ronald P. Torlini  
Mr. Robert Kowal, MS, RPh  
Mr. Douglas F. Wright  
Ms. Toni J. Fernandez  
Ms. Nancy A. Jay  
Dr. Yadagiri R. Pendri  
Mr. Roy Sandry  
Ms. Gayle Heffernan  
Mr. Marcus Terneus  
Mr. Thomas Vella

## ISPE NJ 2014-2015 Board of Directors

### PRESIDENT



Tony (Antonio) Crincoli is currently Executive Director of Global Engineering Services, at Bristol-Myers Squibb with oversight over all major capital projects, strategic project planning, project execution and Technical Services. He has 30 years of experience in the pharmaceutical, biotech, and device industries with Pfizer, Hoffman LaRoche and Becton Dickinson. In various roles as design engineer, project manager and team leader, he has completed a wide variety of projects from design through commissioning in pharmaceutical manufacturing, R&D, laboratories, facilities and infrastructure. He holds a BSME from New Jersey Institute of Technology and an MBA in Management from Seton Hall University. Tony is a registered Professional Engineer in New Jersey and 14 other states. He has long been an active ISPE member, most recently as NJ Board Vice President, has contributed to articles, standards, local committees, mentoring and development programs.

### VICE PRESEDENT



Paul Malinowski is the Director of Global Real Estate and Construction at Becton, Dickinson and Company (BD) in Franklin Lakes, NJ. He is currently responsible for the company's worldwide real estate portfolio and facility construction delivery program. He joined BD in 1992 and has lived and worked in Asia. Paul is a member of several professional organizations, which include: ISPE, where he is currently VP of the NJ Chapter; the Project Management Institute, and is a certified Project Management Professional (PMP); and is a registered Professional Engineer. He holds an MBA from Seton Hall University, and a Bachelor of Engineering from Stevens Institute of Technology.

### TREASURER



Harry Segner holds the position of Director of Business Development for Genesis and has responsibility for the business development and marketing of this architectural, engineering, CQV and construction management firm. Genesis focuses on high technology projects and has a significant presence in the pharmaceutical, biotechnology, medical device and other life sciences related industries and institutional environments. Harry has spent the majority of his 30-plus year career with design, engineering and CM firms which focus on life sciences and healthcare areas of specialization. A lifelong resident of the State of NJ, Harry is a graduate of the Wharton School of the University of Pennsylvania, where he received a Bachelor of Science with a concentration in marketing and marketing research in 1979. He has been actively involved with the NJ Chapter for the past several years, previously served as the ISPE NJ Chapter Secretary and now serves as Treasurer of the NJ Chapter. Harry is looking forward to continuing to support the Chapter through service on the Executive Committee of the Board.

### SECRETARY



Jim Brinkman is Senior Director within Pfizer Global Engineering, supporting BioPharma Operations. He joined Pfizer in 2003 and has provided both engineering operations leadership and site support through various roles. Prior to joining Pfizer, Jim held a variety of roles at Schering-Plough and Wyeth. At Pfizer, Jim's team provides engineering services for the Pfizer Bio-Pharma network of sites. Jim's background includes project management, drug product manufacturing, API processing, biotechnology, and maintenance/facility operations. Mr. Brinkman is a degree mechanical engineer and holds professional engineering license within the State of New Jersey. Jim completed his undergraduate studies at Stevens Institute of Technology and received an MBA from Monmouth University.

# 2014-2015 Board of Directors

## **DIRECTORS**

### **ENGINEERING REPRESENTATIVE**



Norman Goldschmidt is Vice President and Principal at Genesis Engineers Inc. He has over 25 years of experience in engineering management, planning, design and construction in the pharmaceutical and biotech industry. Prior to joining Genesis, Norman served in multiple roles during 20 years with Bristol-Myers Squibb, culminating as Executive Director - Global Engineering. His industry experience spans many types of facilities and processes from R&D through API and Dosage Form Manufacturing. Mr. Goldschmidt holds 4 patents for innovations in Pharmaceutical Processing and HVAC, is an International Standards Organization (ISO) delegate, Adjunct Professor in Pharmaceutical Engineering at NJIT, Lead Author of the ISPE Good Practice Guide for HVAC as well as being an author, contributor and instructor for ISPE, ASHRAE, NSF/DBA and others. Norman studied Engineering Management at the State University of New York and Mechanical Engineering at the University of Buffalo. He has served the NJ Chapter as Education and Professional Development Chair.

### **VENDOR REPRESENTATIVE**



Stephen Fowler is the founder and principal partner of Process Equipment Resources and Consulting Services, a firm specializing in process engineering design, equipment analysis, and system review for hydraulic and fluid mechanic operations in the pharmaceutical and process industries. With over 30 years of experience in engineering, sales and marketing functions, he started his career with the Nowland Organization [for industrial marketing research and analysis] and continued for over sixteen years with Mixing Equipment Company {LIGHTNIN Mixers} in a variety of marketing, engineering and operations executive roles. He previously co-founded and led Process Equipment Sales & Service Inc, an equipment engineering and sales organization. He is a graduate of Hamilton College and University of Rochester with BA, MA, and MBA degrees. He is a member of ISPE, AIChE, AWWA and WEFTEC. He has been active for several years with ISPE, and is currently Chairperson of Community Affairs, and member of the Programs Committee of the ISPE NJ Chapter. Active in community organizations, he is a Board member with civic and non-profit organizations in Somerset County NJ.

### **QC REPRESENTATIVE**



Debra Bahr has an extensive background in providing client relationship and account management to support firms in the science and technology industry. Debra's career spans work with clients to design and build laboratory and manufacturing facilities to helping clients return to or maintain compliance. With the regulatory environment constantly changing, Debra currently works to provide her clients an array of comprehensive compliance consultancy services. Debra feels her experience has given her a well- rounded view of the rapidly evolving challenges in the industry.

As a mother of a daughter who was diagnosed with psoriatic arthritis at age 19, she is first-hand witness to the positive outcomes for patients with access biologic therapeutics.

Her education includes Liberal Arts at Hope College and New York Institute of Finance.

A volunteer for fund raising for Project FIRST, she is passionate about engaging youth and giving them the tools and support to discover their creativity. She has enjoyed her affiliations such as former board member for Rutgers Equine Advisory Board, National League for American Pen Women, Susan B. Koman Walk for the Cure, and CROP Hunger Walks.

At home she enjoys the family's horses, and raises sheep to spin wool, as well as hand paints silk and watercolor paintings.

As an ISPE member for over a decade, she understands the value of long term relationships and collaboration and is passionate about bringing people together to trigger creativity.

### **YOUNG PROFESSIONAL REPRESENTATIVE**



Shilan Motamedvaziri is a Global Manufacturing and Supply Associate at Bristol-Myers Squibb, New Brunswick, NJ. Currently she works in the Strategic Supply Chain Planning- Biologics group in New Brunswick, NJ. Previously she worked in Quality Organization at BMS-Mount Vernon, Indiana for 7 months and Manufacturing Technology group at BMS-New Brunswick, NJ for one year. She received her B.Sc. in Chemical Engineering from Isfahan University of Technology, Iran in 2001. Then she worked for four and half years as a Chemical /Process Engineer. After moving to the United State, she received her Master's and Ph.D. in Chemical Engineering from New Jersey Institute of Technology (NJIT) in 2012. At NJIT Shilan did her thesis research on studying Single and Multiphase Mixing in Partially Filled Stirred Vessels which are common processes used in pharmaceutical/ biological manufacturing. Moreover, she taught several core courses in chemical engineering while she was at NJIT. She was involved in ISPE at NJIT, serving as the ISPE-Vice President of NJIT Student Chapter (2009-2010) and also as ISPE-President at the end of academic year of 2009-2010. She has been a member of ISPE NJ Committee since March 2012 and she served as the Young Professional Representative in ISPE NJ Board of Directors (2012-2013) and led several ISPE NJ events such as ISPE NJ Yankee's game event (August 2012), NJ Science and Engineering Festival (October 2012) and ISPE NJ Student Poster Competition (April 2014).

## 2014-2015 Board of Directors

### REPRESENTATIVE-AT-LARGE



David Kristjanson is the Director of Business Development, at Sweetwater Construction Corp. with expertise in the life sciences and healthcare sectors. David is responsible for marketing, new business development and cultivating existing client relationships with Sweetwater. He has 18 years of experience in the pharmaceutical industry with Bovis (Merck), IPS (Cephalon), Valeant Pharmaceuticals and Alharma Pharmaceuticals. In various roles over his career, David has managed a wide variety of projects including product development, technology transfer, product launch, mergers and acquisition, rebranding, facility design, construction and validation. He is involved with several organizations including BioNJ where he is on the manufacturing committee. He holds a BS in Business Administration from The College of New Jersey and a Diploma in Building Construction Management from New York University. David is a certified Project Management Professional (PMP), and has received certificates in Lean Six Sigma Leadership, and Managing Contract Manufacturing Organizations (CMO). David is an active teacher and speaker of project management for various organizations and universities and has long been an active ISPE member, most recently as NJ Programs Chair.

### REPRESENTATIVE-AT-LARGE



Rich Smith - Upon graduating from Arizona State University with a degree in Construction Engineering Rich began his career with Del Webb Construction with roles in Estimating, Scheduling, Project Controls and Project Management on a variety of large projects in the Phoenix area. In 1985 he joined Turner Construction and helped build their Phoenix office. In 1990 he was promoted to Manager of Business Development for their Los Angeles office and was successful in helping them secure a portfolio of large complex life science and healthcare projects in Southern California. Rich moved his family back to the eastcoast in 1996 and opened and managed a regional office for ADP / Marshall Contractors (purchased by Fluor) in Princeton, NJ focusing on design build projects for the life science and microelectronics industries.

Rich rejoined Turner in NJ in 2000 as National Director of Business Development for their Pharmaceutical Division and was responsible for a \$750 million sales and marketing program for this market segment across all of Turner's US offices. Rich went on to hold VP, Business Development and Operations positions for Skanska and DPR Construction, again focusing on Science & Technology and Life Science clients and projects.

Rich is currently the Divisional Director for Currie & Brown responsible for the East Coast business unit in the United States.

### REPRESENTATIVE-AT-LARGE



Michael Kelliher is the Associate Director of Project Management at Genzyme, a Sanofi Company, where he manages site capital expenditures and justifies projects that represent business-critical endeavors, compliance initiatives, cost reductions, product transfers, process improvements, and facility expansions. Prior to this role, Michael headed Vial Manufacturing (Formulation, Fill, Finish) where he exceeded cost of production goals every year, delivered over 50 million units, and maintained sufficient field inventories at all times. Previously during Michael's 10 year Genzyme tenure, he served as Program Manager and transferred a drug product on time, within the capital budget, and at a swift payback of the entire investment. Michael successfully represented Manufacturing during audits, including FDA PAIs for a product/format new to the facility. Genzyme's Ridgefield, NJ site is an aseptic processing facility that produces both medical devices and liquid drug products.

Prior to Genzyme, Michael served as Director of Operations at Automated Systems, Inc (ASI), a Validation and Automation Controls consulting company. In this role, Michael sourced/oversaw teams and led validation efforts for 4 years that supported Bulk Chemical/OSD manufacturing at Schering-Plough, Elan Pharmaceuticals, and Novartis. Prior to ASI, Michael spent 5 years at Abbott Laboratories where he held various positions of increasing responsibility within the Quality Assurance realm, including F/U/E qualifications, process validation, and batch record audits. Michael joined ISPE in 1998 and recently hosted the Japan affiliate for a site tour prior to the 2013 annual meeting. He's also an active PDA member and presented at the "Innovations in Sterile Technology" conference in 2012. Michael holds a B.S. in Biomedical Engineering from Marquette University and an M.B.A. (anticipated August 2014) from New York University Stern School of Business.

### REPRESENTATIVE-AT-LARGE



Philip Sumner is Sr. Manager, Regulated Utilities Subject Matter Expert (SME) and Leader of the Pfizer Sustainability Water Program. He has 15 years with Pfizer and has 30 years experience overall in manufacturing, construction management and integrated equipment systems OEM supplier. With Pfizer he supports all phases of high purity water and related utility projects and operations on a global basis.

Philip served 3 years on the ISPE New England Chapter Board of Directors (1997-1999). In addition, he is a member of the International Society of Pharmaceutical Engineers (ISPE) utilities COP where he has contributed and co-authored numerous guidance documents, and most recently was team leader of the guide "Ozone Sanitization of Pharmaceutical Water Systems".

Philip holds a Bachelor of Science in Civil Engineering from Tufts University and a Master of Science in Environmental Engineering, also from Tufts University. He is a registered Professional Engineer (CT). He is married and has two college age daughters.

### REPRESENTATIVE-AT-LARGE



Frank DeMarinis, Senior Director of Engineering for Purdue Pharma L.P. currently directs the site operations at Purdue's two New Jersey facilities and leads the central engineering function responsible for the major projects within the organization. Frank has over 25 years of experience within the medical device and pharmaceutical industries having worked on numerous national and international assignments. He holds a Bachelor of Engineering degree from the Stevens Institute of Technology and has been a member of the ISPE since 1988. He was a contributed author for the ISPE Good Engineering Practices Guide and most recently chairmen of the NJ Chapter Executive Advisory Committee.

## 2015 Chapter Committees

### **Bylaws and Policy**

Chair: Paul Malinowski  
Becton Dickinson  
Tel: +1-201-847-7041  
[paul\\_t\\_malinowski@bd.com](mailto:paul_t_malinowski@bd.com)

### **EAC Executive Advisory Council**

Chair: Frank DeMarinis  
Purdue Pharma  
Tel: +1-973-837-5431  
[frank.demarinis@pharma.com](mailto:frank.demarinis@pharma.com)

### **Programs**

coChair: Phillip Sumner  
Pfizer  
Tel: +1-908-901-8419  
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coChair: David Kristjanson  
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