



ISPE®

New Jersey Chapter

Celebrating 30 Years

VOLUME 23 ISSUE 3 | 30th Anniversary Edition

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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.



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PRESIDENT'S MESSAGE

By Harry Segner

It is my great pleasure to address you for the first time as the president of the New Jersey Chapter of ISPE for 2016-2017. Thank you very much for the confidence you have placed with me and all of the members of the recently elected Board of Directors, as we seek to lead the NJ Chapter through the upcoming year.

What a way to start a term in office, but with our outstanding 30th Anniversary Celebration event, held on October 6th at Beneduce Vineyards in Pittstown, NJ!! We have heard nothing but very positive comments from all who attended and participated in this memorable evening. Many thanks to the team, led by Mike Kelliher and Debra Bahr, for facilitating an outstanding event, which included interesting comments from Mike Arnold, newly installed International Chairman of ISPE, and John Bournas, President/CEO of ISPE. If you were not able to make it to the Vineyards on October 6th, a review of the event, along with a photo montage, can be found elsewhere in this Newsletter.

Our Programs Committee, led by Alok Bhatt and Ray Roggero with the support of a variety of other members, has developed a framework for an exciting and informative roster of programs, both educational and social, for 2016-2017 and we hope you will be able to attend and participate in these varied events. One of the primary goals of the Chapter is to provide our membership and friends with a variety of educational and enjoyable professional development and networking events during the year. Please make any of the Chapter leadership aware of areas of interest to you or if you would like to participate in the planning and execution of an event; this is your Chapter and we will respond to your needs and desires for the future.

We are very pleased to welcome to the Board of Directors three new members this year—James Canterbury (Ernst and Young), Donna Petro (Xyntek) and Monique Sprueill (Novartis- East Hanover). We are certain that these professionals will bring many new ideas and enthusiastic participation to the Chapter moving ahead. We also wish to acknowledge our departing Board members for their years of service to the Chapter and its membership; it is much appreciated by us all. Debra Bahr (OCVD Engineers), Frank DeMarinis (Purdue Pharma), Tony Hutchinson (Merck) and Phil Sumner (Pfizer) have elected not to stand for reelection and our Immediate Past President, Paul Malinowski (BD), will remain on the Board as a non-voting member. We thank you all for your service and dedication!!!

Looking forward to a GREAT year and I look forward to seeing each of you very soon.....

Harry



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COMING EVENTS 2016-2017

November 3, 2016	Think & Drink Student & YP Event Wyndham Hamilton Park Hotel 175 Park Ave. Florham Park, NJ
November 16, 2016:	Site Master Planning Pfizer Peapack 100 Route 206 North Peapack, NJ 07977
December 14, 2016	ISPENJ Holiday Party Nassau Inn, Princeton, NJ
February 9, 2017	Facility of the Year Sanofi, Bridgewater, NJ
March 2017	Professional Development Day Rutgers New Brunswick
May 15, 2017	Golf Outing & Winery Tours Neshanic Valley, NJ

Register for Think & Drink

<https://www.eventbrite.com/e/think-drink-student-and-young-professional-event-tickets-28507972112>

Register for Site Master Planning

<https://www.eventbrite.com/e/site-master-planning-tickets-28509023256>

Register for Holiday Party

<https://www.eventbrite.com/e/ispe-njc-holiday-party-2016-tickets-28580359625>



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ANNOUNCEMENTS

2016-2017 Board of Directors

Officers (one-year term):

President Harry Segner, Genesis

Vice President Jim Brinkman, Pfizer

Treasurer Mike Kelliher, Sanofi

Secretary Rich Smith, HDR

Directors (first year of a two-year term):

Monique Sprueill, Novartis
Donna Petro, Xyntek
James Canterbury, Ernst & Young

Directors (second year of a two-year term):

Christine Farner, Sanofi
Ray A. Roggero, CP Professionals
Tom Flachmeyer, Prolong Pharmaceuticals
Alok Bhatt, Bristol Myers-Squibb

Paul Malinowski will remain on the Board of Directors as Immediate Past President.



30th Anniversary Celebration at Beneduce Vineyards Pittstown, NJ

ISPE New Jersey Chapter members and friends gathered on October 6, 2016 to celebrate the 30th anniversary of the chapter.

The event took place in a greenhouse on the grounds of the winery. Everyone enjoyed sampling the vineyard's

wines, delicious hor d'oeuvres followed by a buffet dinner. Guests were entertained by a live band and enjoyed relaxing around the outdoor fire pit and even took hayrides around the vineyard. There were some notable "dignitaries" of ISPE present including John Bournas, President and CEO of ISPE and some ISPE NJC past presidents; Tony Crincoli, Bruce Eckman, Jerry Guillorn, Robert Lechich, Joe Manfredi, Chris Martinson, Jim O'Brien, and Dragutin Stoicovici. Also in attendance were Mike Arnold, Chairman of ISPE and Tracey Ryan, Manager, Affiliate/Chapter Relations.

Many thanks to all the people who made this event possible including our current board members, and Elaine Gaeta of PS&S and former board secretary Debra Bahr.



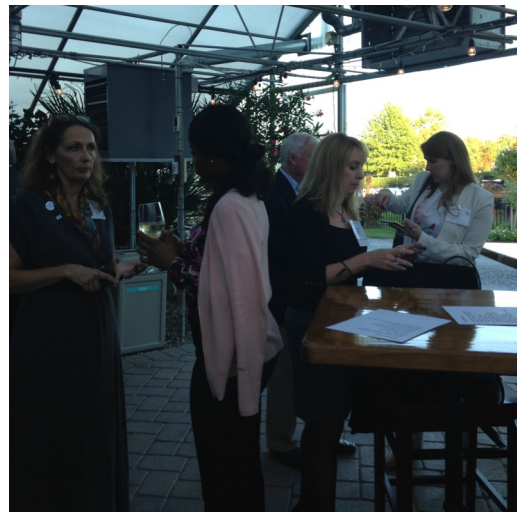


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Memories of the event





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Thanks for the Memories

By Harry Segner and Paul Malinowski

Paul Malinowski (President 2015-2016)

It has been (30) years since the New Jersey Chapter, the very first ISPE Chapter, was established. A lot of very dedicated people contributed to the Chapter's development and many others helped guide it through recently challenging times. Many of us have established lifelong professional relationships with other members and have served in leadership positions on the Board and/or Committees. Being a member of the Board is a special and sometimes deeply personal way of connecting to the industry and supporting the Chapter. I am happy to have served the members, during the past 7 years, as a Committee member and elected Board member - most recently as President.

For the 25th anniversary (already 5 years ago!), we approached a variety of individuals, that played a key role in making the Chapter what it is today, and asked them to share some of their thoughts and memories. For the 30th anniversary, we've repeated this request, and we are delighted to share their responses with you. We hope that you enjoy the trip down memory lane.

Tony Crincoli, (Chapter President 2014-2015)

I had been contributing to ISPE since I started as an engineer at BD in 1980's. Greg Butler had asked me to help him write an article, and I came to appreciate the collective repository of knowledge the membership brought. If there was ever a question or problem, someone in the membership had either lived it or solved it, and always someone to go to for advice.

It wasn't until 2007 that I was approached by Gordon Leichter, that I became an active committee member. Little did I know what I would get myself into! Meetings, committees, soliciting experts, fund raising....all the elements of back office activities that it takes to run a non-profit organization.

All the hard work was worth it however, as I received more than I gave. I also came to appreciate ISPE as much more than a technical society. I met some brilliant, giving and charitable people, found a few mentors, and made genuine lifelong friendships along the way.



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Emad Youssef 2001-2002

It's been 20 years or so since my days as President of the New Jersey ISPE chapter, and I am so grateful for the opportunities my association has afforded me. Everybody has a story regarding how and why they first got involved, and mine goes back to a pivotal decision I had to make between two opportunities.

I joined PS&S back in the mid 1970's as an engineer-in-training where I served in progressive engineering roles for about 15 years. I then decided I had gained enough knowledge of engineering, design and construction and wanted to embark on a new career adventure. After all, I always had wanderlust that began right after I finished engineering school and spent more than a year on non-stop travel through many countries.

I was approached by an Asian EPCM firm to join their office in Hawaii to work on a large project in Honolulu. I figured this was the change I needed and proceeded to give notice and pack my bags. Well, PS&S's Chairman Tony Sartor had another idea for me.

"New Jersey is the medicine chest of the country," he said. "Why don't you think about increasing our presence in the pharmaceutical sector? With so many companies headquartered here, most within an hour of our headquarters, it makes a lot of sense." I thought and thought for a couple of days and decided to accept Tony's challenge. And I have never looked back.

Since I first joined ISPE, I have learned a lot from the programs and also from the members, many of whom continue to be current clients, friends and colleagues. I worked my way up the ladder, volunteered for various chapter committees and ended up presiding over the NJ chapter in 2000/2001. When I first got the assignment as President, it was customary for the current president to include a "president's message." The membership at the time was large and included many industry veterans. I thought, what can I possibly write that they don't already know?

Then I had an idea. I decided to interview top leaders in the industry who are local to NJ and members of the chapter, in lieu of writing a monthly and perhaps uninspiring president's post. That series of interviews was well received by the membership, and included interviews with leaders from J&J, Pfizer, Sanofi and others.

As I stated at the outset, ISPE has provided many terrific opportunities for me, and I continue to encourage colleagues at PS&S to join the chapter to learn and keep updated on this ever changing and exciting pharmaceutical industry.

Jon Tomson

A long time ago when I was first elected to the Board, Joe Manfredi talked to me about getting students involved in the chapter as he was actively involved with NJIT at the time. He enticed me to reach out to the Rutgers Chem E program to see if I could muster some interest. With some prodding, some progress was made. Joe and I went to our next Board meeting to report our progress and were stunned to have the then Chapter President inform us that there was no interest in pulling students into ISPE as "business" was its focus. Well, we listened, sat down for a beer after that meeting, and, like true children of the Sixties, decided the heck with him (his term was soon to be up). We continued forward and luckily incoming leadership embraced the idea of student chapters. Here's to you Joe!



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Jerry Guillorn (Chapter President 2003-2004)

I remember how I became involved with ISPE: it was early fall of 1993 and the "infamous" Jim O'Brien approached me about helping him out on preparing a newsletter for an organization to which he belonged, since he had been receiving newsletters for a year or so that I was responsible for while at El Associates. I naively told him I'd meet with him and a couple of his colleagues, Joe Manfredi and Bob Lechich, to figure out what could be done to help out. I told them how I was handling ours, with whom, costs, layout and content thoughts, etc . . . BAM!! The next thing I knew I was "volunteered" to develop the next newsletter for ISPE, then joined in September 1993, and have been involved ever since.

Then, as if that wasn't enough, I guess in about '97 or so, I was again "volunteered" to "help" with a golf tournament as a fund-raiser, during a time when the Chapter's financial outlook was a bit dim. To keep the costs down, I was able to negotiate a great deal with Farmstead Golf Club (as I had run a couple of outings there for some local organizations in my home town, which is only a mile or so away from Farmstead, which explains why it has been "way up there" for all of these years!!). We had a great turnout, made some money for the Chapter that got us back on a positive financial track, and the rest is history- I've been involved with the golf outing and it has been "way up there" ever since!!

So, my takeaways on my involvement with ISPE are: be careful when you talk to Jim O'Brien; run if he says anything that sounds like "volunteer"; but, once you join, get involved!!! I have developed some truly *tremendous* friendships, personal and professional, within ISPE, and looking back on it, I wouldn't change those decisions for anything.

I can't believe I'm saying this, but Thanks, Jim for "volunteering" me! It's been a great 18+ years and I look forward to more great times in the future!!

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THE HISTORY OF THE ISPE NJ CHAPTER

By Bruce Eckman

The International Society of Pharmaceutical Engineers, was founded in 1980 by a group of individuals, a number of whom were from New Jersey. One of the Charter Members, Jim O'Brien is still active in the Society and New Jersey Chapter today. During the formative period, participation in ISPE required travel to locations often remote from the heart of the pharmaceutical industry here in New Jersey.

As 1986 arrived, a member from Merck, John Stefanowicz recognized that ISPE meetings should be more accessible to members near their places of business. Thus the concept of ISPE Chapters was born. New Jersey members created the first ISPE Chapter in 1986 with John as the first president. We had only about 25 Chapter Members that first year. Our total membership has steadily grown over the ensuing 20 years until we now number nearly 2000 Chapter members including 72 student members.

The Chapter's first meetings occurred at the Tower Steak House on Route 22 in Mountainside, New Jersey. The first Chapter meeting took place on September 23, 1986. Early steering committee/board members included Mike Sisti, Wayne Sadowski, John Lee and Jean O'Connor in addition to John Stefanowicz. Others who were involved included Elliott Goldberg and Karen McCullough. This author joined the Chapter at the end of the first year of existence (spring 1987).

In January of 1987, we had our most famous guest lecturer, Lawrence Peter "Yogi" Berra who autographed pictures, answered questions and put in a good word for his son's flooring business. Another meeting that year featured 20 of us having polite dinner conversation as the scheduled speaker did not appear.

Our Chapter, as the first, is proud of the many "firsts" we count among our accomplishments. Based on previous successful table-top shows and seminar programs held by ISPE in New Jersey, the Chapter initiated an annual Vendors Night in 1989 with thirteen tables in the basement of the Tower Steakhouse. Our membership had grown to almost 400 at this point. A few years later, on February 24, 1992, Bob Lechich and Joe Manfredi kicked off ISPE's Student Chapter program with the original Student Chapter at the New Jersey Institute of Technology in Newark.

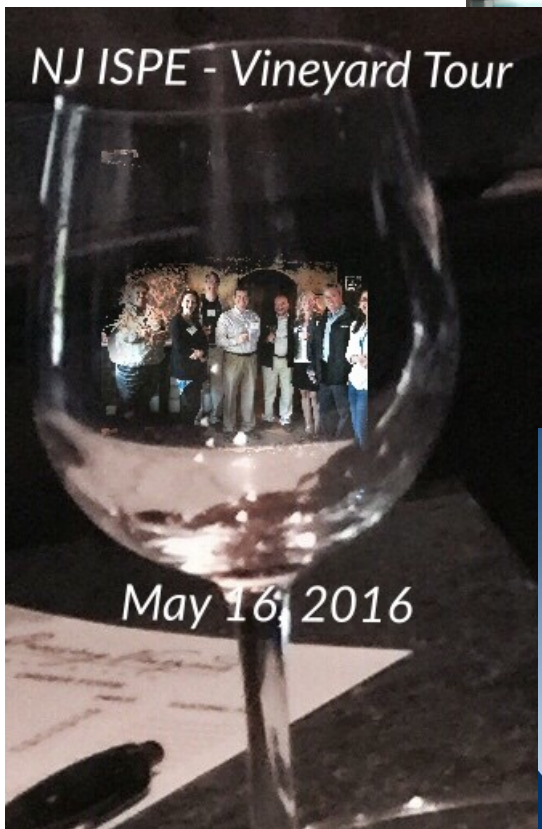


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Photos from past events



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ISPE NJ Chapter Past Presidents	Year	Company
Paul Malinowski	2015-2016	Becton Dickinson
Antonio Crincoli	2014-2015	Bristol-Myers Squibb
Nandita Kamdar	2013-2014	Johnson & Johnson
Scott Hickok	2012-2013	EMCOR
Gordon Leichter	2011-2012	Belimed
Jim Breen	2009-2011	Johnson & Johnson
Dragutin Stoicovici	2008-2009	Quality21
John Postiglione	2007-2008	Spirax Ultra Pure
James Livolsi	2006-2007	Wyeth
Janit Buccella	2005-2006	Omnival
Bob Ranard	2004-2005	TCPI
Jerry Guillorn	2003-2004	Skanska USA
Jenny Wong	2002-2003	Astra Zeneca
Emad Youssef	2001-2002	PS & S
Chris Martinson	2000-2001	Whiting Turner
Dominick Smith	1999-2000	Regeneron
Tom Creaven	1998-1999	Schering Plough
Bruce Eckman	1997-1998	Torcon
Jim O'Brien	1996-1997	Merck
Joe Manfredi	1995-1996	GMP Systems
Mark Milano	1994-1995	Lockwood Greene
Bob Lechich	1993-1994	Hoffmann-LaRoche



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Past Presidents continued

Ed Blejwas	1992-1993	Blejwas Associates
Bruce Eckman	1991-1992	Sverdrup
Dick Rooney	1990-1991	Getinge
Elliott Goldberg	1989-1990	Jacobs Engineering
Ernie Rottman	1988-1989	Squibb
Mike Sisti	1987-1988	Syska & Hennessey
John Stefanowicz	1986-1987	Merck

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NJ CHAPTER STUDENTS & YOUNG PROFESSIONALS

The Young Professionals and Student specialized group was started within ISPE in 2011; as ISPE recognized the need to elevate this important area of focus. In 2016 the importance of this group was further recognized; now reporting directly into the national ISPE board with regular committee updates. The focus is on the future of Pharmaceutical Engineering; more experienced professionals are dedicated to ensure that the group of young professionals and students are guided to their highest ability and possibilities within the Pharmaceutical Business! The Young Professional groups themselves also guide the more experienced professionals on the 'how to' of getting them involved and often lead in many areas!

The NJ Chapter of ISPE is focusing on a couple of key events that form the core activities for this group:

- The annual Student Poster Competition allows each of the schools supported by the ISPE NJ Chapter (Stevens Institute of Technology, Rutgers, New Jersey Institute of Technology, Manhattan College and Kingsborough Community College) to provide pharmaceutical related project posters from as many students as are willing to enter into the competition. This contest provides for a winner(s) in the undergraduate area and graduate area. The annual winners are then taken to the ISPE annual meeting to further enjoy the ISPE focus, learning and experiences.
- Young Professional "Think and Drink" nights out are restarting where all interested meet in a restaurant's open area to discuss the prominent issues in the industry and collaborate with experienced professionals in a casual setting. These are being started this season; 'first event in a while' on 03Nov2016.

•
Watch for more great things from this group of talented individuals as we survey the group for likes and dislikes and move forward with additional events focused on their specific needs and desires.

Thank you,

Christine Farnar and Mike Kelliher

Chair and Co-chair of the NJ ISPE Students and Young Professional Committee

ISPE NJ Chapter 2015-2016 Photo Recap





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ISPE NJ SPONSORSHIP OPPORTUNITIES

Chapter Sponsorship: \$1,650

- Recognition as a Chapter Sponsor at all ISPE NJC events in 2016
- Name and Logo on announcements for all ISPE NJC events in 2016
- 1/2 page Advertising space in the ISPE NJC newsletter for 2016 (An \$800 value!)
- 12 month Advertising space on the ISPE NJC website in 2016 (A \$500 value!)
- Includes 2 complimentary tickets to all NJC events (*Golf Outing Limited to Clubhouse activities only-excluding 30th Anniversary Celebration Event).
- All additional attendees from you organization receive 10% off event ticket cost

Advertising:

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

Newsletter Advertising (2016-2017): The chapter publishes a newsletter four (4) times a year, highlighting recent and upcoming events, educational programs, technical articles and general interest to the members. The newsletter is published electronically to all current ISPE NJC members and others on our circulation list. (5,000+ recipients). Advertise for one (1) issue or for all four (4) issues:

- Business Card Size: \$100 per issue or \$350 for four (4) issues
- 1/4 Page Size: \$150 per issue or \$525 for four (4) issues
- 1/2 Page Size: \$200 per issue or \$700 for four (4) issues

Website Advertising: Your ad is visible to everyone who visits the ISPE NJC website

- Six (6) Months—\$275
- Twelve (12) Months—\$500

Event/ Program Sponsorship: (Opportunities starting at \$125 depending upon Event*)

- Name and Logo on all Announcements for designated event
- Recognition at Event during session
- Complimentary Tickets for Two Attendees
- Select Event(s) - Vendor Table Display (Professional Dev’t Day and Golf Outing)

*Contact ISPE NJ Chapter Manager for more information—manager@ispenj.org

To become a sponsor click on the link below.

<https://www.eventbrite.com/e/2016-ispe-njc-chapter-sponsorship-advertising-program-tickets-19824345150>



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Benefits of Membership:

Networking Opportunities - Whether networking at face-to-face events or collaborating online, the value of ISPE is in the links forged between industry professionals with common work challenges, connecting professionals and companies to practical guidance and dialogue between industry and global regulators.

- Membership Directory-
- Affiliates and Chapters -
- CoP Online Discussion Forums -
- Networking Events -

Technical Resources - ISPE Guidance Documents, industry-leading publications and on-demand training courses and webinars provide practical information and solutions to real-world problems.

- ISPE Guidance Documents
- Review and Comment on Regulatory Guidance
- Pharmaceutical Engineering Magazine

Professional Development - Industry-leading education and training, global volunteer opportunities and industry-focused career solutions allow ISPE Members to grow their professional knowledge and skills.

- Education and Training
- ISPE Career Solutions
- Volunteer Opportunities

Who We Serve -

Traditional Pharmaceuticals/Biotechnology/Generics/CMOs/Global Regulators/Suppliers and Service Providers/

To become a member, click the link below.

<http://www.ispe.org/new-jersey-chapter>



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Welcome New Members



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Nitin Kumar
Mr. Kuriakose Thomas Kunnath
Mr. Kazuhiko Kurosaka
Paul Labas
Mr. Allan Y. Lin
Satish Maddula
Amrita Mandapati
Ms. Samantha Masri
Mr. Frank Mastromonica
Nick Matarese
Mr. Josh Mathew
Erin McCaffery
Randal McCarthy
Amelia McCracken, Bach Mech Eng
Ms. Elizabeth A. McLellan
Dr. Hamidreza Mehdizadeh, PhD
Bassem Mosise
Natalia Muzychishin, MS
Manikandan Namasivayam
Bob Naugler
Leonard Nowak
Bhargava Ramudu Nutakki
Mr. Daniel Palermo
Mr. RJ Palermo
Jatin Patel
Randy Persico
Brandon Pollack
Sheila Rector
Miss Keyaara M. Robinson
Mr. Mark Salerno
Robert Savage
Brian J. Schendt
Lori Semeraro
Mr. Chintan Mukesh Shah
Mr. David Shannon
Mr. Robert Siefert
Mr. Sanjay Singh

Robert L. Amariti, BSME, MBA
Michael Ambrosio
Tristan Bacha
John Ballard
Parimal Barot
Frank Berardocco
Rohan Kush Bhaumik
Mrs. Glenna C. Bishop
Chris W. Bliziotis
Mr. Robert James Bolden
Robert Bondi
Paul Brodbeck
Dr. Mark Byrne
Tiffany Cheng
Mr. Maclean Dan-Jumbo
Joseph Delloiacovo, BSCHE
Tyler C. Diorio
Kevin Dsouza
Dr. Srinivas Duggirala
Mr. David Eherts, PhD, CIH
Dr. Rama Joga V. Eranki, Ph.D, ASQ-CQA
Dr. Robert Fasciano, II, BA, MS, PhD
Kristen Gaylord
Dr. Angela Goodenough, PhD
Devora Grieco
Miss Margaret Guntner
Ms. Angela Haqq
Janell Hetro
William Thad Holden, BA, MS
He Huang
Daniel Iampietro
Kimberly Iuele
Ilhyun Joung
Mr. Aditya Anant Kamat
Dr. Jagannadha Rao Kandula, Ph.D.
Stefani Kocevaska, B.S.ChE



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New Members continued

Ms. Jana Spes

Ms. Annie Tannhauser

Erik Terry

Michael E. Thomas, MS, MBA, BA

Ronald P. Torlini

Rostislav Udod, B.S. in ChemE

Jacqueline Vega, BS, MS

William Wenrich

Mr. George Edward Wittmann, Jr.

Hong Zhao