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**New Jersey
Chapter**



Volume 19, No. 4

Winter 2013

Pharma Bulletin

IN THIS ISSUE

- Letter from the Editors **Page 2**
- President's Message **Page 3**
- Professional Development Day **Page 5**
- NJC Dinner at ISPE Annual Meeting
Page 6
- Annual Student Poster Awards **Page 7**
- Rutgers Student Chapter Event **Page 8**
- ISPE News Bulletins **Pages 10-11**
- Brain Puzzler #6 **Page 12**
- 2013 Programs **Page 13**
- NJ Chapter Committee Chairs **Page 14**
- Career Dr. Don Answers Questions
Page 15
- New Members List **Page 16**
- Officers/Board Members **Page 17**

ISPE NJC Gala & Student Scholarship Fundraising Event

When:

March 1, 2013

Time:

7:00pm—12:00am

Where:

Stone House, 50 Stirling Road, Warren, NJ

Evening Timeline:

7:00—8:00 Cocktail Hour/Casino/Music

8:00—10:00 Dinner/Casino/Dancing

10:00—11:00 Raffle Hour

11:00—12:00 Dancing/Bar

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Letter from the Editors

Welcome to the 4th Quarter 2012 edition of Pharma Bulletin, the newsletter of the NJ Chapter of ISPE. As 2012 came to a close we reflected back on a successful year of transition for the new Board and thank the membership for your support and participation. Much activity has occurred within the Chapter over the past 12 months, including several Professional Development Day events, an extremely successful Supplier Showcase event at the new MetLife Stadium and a host of successful and enjoyable social events. We plan on continuing with this positive trend and have revamped the 2013 event calendar with some new and exciting programs and venues.

Beginning with this edition of the Pharma Bulletin I have turned over the responsibility of publishing the quarterly newsletter to Rich Smith with CRB Builders. In this issue, we will review the Professional Development Day event held at The Tech Center at Mercer in West Windsor, the ISPE Annual Meeting in San Francisco and the Grand Pharmaceutical Networking Dinner meeting held at Rutgers University. Of course, we will also continue with the balance of our regular columns and features and reiterate that as NJ Chapter Members, this is YOUR publication. If you have suggestions for new or different features or articles, see areas for improvement or change, or wish to make a contribution, please contact us with your thoughts or ideas at any time.

As you are probably aware, the NJ Chapter's next event is the Gala & Student Scholarship / Fund Raising Event scheduled for March 1. This first major event of the year promises to be a fun and memorable experience that you won't want to miss. This will be followed by the Student Poster Competition in mid-April and then another exciting event that you won't want to miss — the annual golf outing on May 13. We have moved the location of the outing to Neshanic Valley Golf Course. If you haven't played this course yet you are in for a great day of golf. In 2012 Neshanic Valley was named as the 30th best public course in the nation and second best in New Jersey. Watch for invitations in the coming months and start lining up your foursomes!

We look forward to seeing you at an upcoming Chapter event and continue to encourage your active participation in ISPE.

Harry Segner
Secretary – Board of Directors
New Jersey Chapter of ISPE

Rich Smith
Chair-Communications Committee
New Jersey Chapter of ISPE

President's Message

The ISPE New Jersey Chapter continues to plan outstanding events for its membership. Our next program is the Gala & Student Scholarship / Fund Raising Event. This event is scheduled for March 1 from 7:00p.m. to 12:00a.m. A Casino Night with raffles, appetizers followed by dinner and dancing to music by the Infernos will be offered.

For those who attended last year's Gala, this year's event has built on the good times enjoyed by all and promises to surpass last year's venue. This will be an outstanding event and surely enjoyed by all who attend. Don't forget to register as proceeds will go towards the ISPE New Jersey Scholarship fund.

This year's programs calendar has changed from previous years. Rather than scheduling monthly sessions, our plan is to offer quality programs that will attract all sectors of our membership. Our scheduled programs include:

- a. Student Poster Competition and Professional Development in April
- b. Chapter Golf Outing in May
- c. Technical Showcase in September
- d. Professional Development Day in November/December

Of course, the summer baseball outing and an occasional plant tour will be considered / and perhaps scheduled.

Programs provide the financial independence we require in order to operate freely as a Chapter. Each event offers an opportunity to exchange information and network with your local peers. We are always looking for dedicated individuals who would like to assist with the planning and operations of Chapter activities. I encourage anyone who has ever thought of joining a Chapter committee to reach out to a New Jersey Board Member and learn how your involvement can make a difference.

Members are the strength of our Chapter. Without your continuous support, our Chapter would be a hollow organization without an ability to provide meaningful programs or services. Your participation is greatly appreciated, as it represents a strong sign of support for your Chapter.

Scott Hickok, President
ISPE New Jersey Chapter



2013 Chapter Sponsorship and Advertising Program

Advertising and sponsorship represents an excellent opportunity to be identified as an industry participant and a supporter of 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 2013. These include:

Chapter Sponsorship:

Chapter Sponsorship has many benefits, including:

Recognition as a Chapter Sponsor at all ISPE NJC events in 2013

Name and Logo on announcements for all ISPE NJC events in 2013

Advertising space in the ISPE NJC newsletter for 2013 (*A \$700 value!*)

Advertising space on the ISPE NJC website in 2013 (*A \$500 value!*)

10% Discount on all Special ISPE NJC event sponsorship opportunities in 2013

ISPE NJC Chapter Sponsorship is available for the low price of \$1650!

Advertising

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

Newsletter Advertising - The Chapter publishes a newsletter 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.

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 - \$250

12 months - \$500

Event Sponsorship

Look for more sponsorship opportunities to be announced for individual ISPE NJC events. Planned events for 2013:

Chapter Gala - March 2013

Student Poster Competition - April 2013

ISPE NJC Chapter Golf Outing - May 2013

Technology Showcase - September 2013

Professional Development Day - December 2013

Event Sponsorship opportunities will be released closer to the event.

Sign up now for your 2013 Advertising and Sponsorship opportunities!

For additional information please contact:

David Rochow

ISPE NJC Marketing Chair

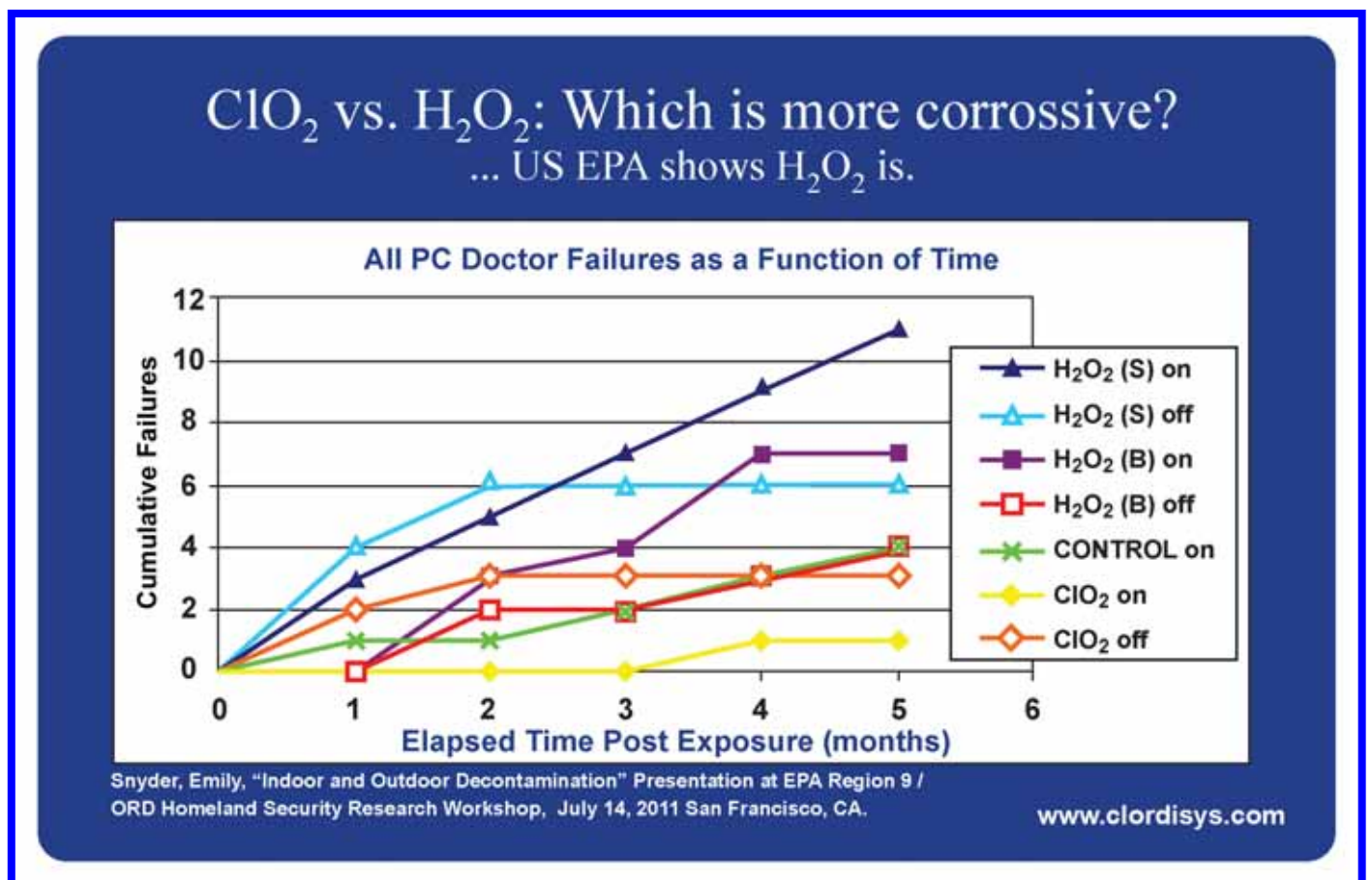
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Professional Development Day

The ISPE New Jersey Chapter held its annual Professional Development Day at the Tech Center at Mercer in West Windsor, New Jersey on November 30, 2012. The three educational offerings included: Sterile Manufacturing Facilities; Pharmaceutical Water Generation; and Product Lifecycle Project Management.

The speakers featured W. Bruce Eckman, PhD., Joe Manfredi, David Kristjanson, PMP, Steven Moccio, PMP, Dr. Gary Forrest of Pfizer, and Michiel E. Ultee, PhD. Chief Scientific Officer - Laureate Biopharmaceutical Services, Inc. The event was organized as an all-day, multi-track educational series that allowed the attendees to attend multiple sessions while enjoying the features of a state-of-the-art facility serving food and refreshments all day. The event was capped off with a holiday cocktail and networking hour.



ISPE Annual Meeting – NJ Chapter Dinner

On Sunday night before the start of the 2012 Annual meeting about 25 members and guests of the NJ Chapter gathered for dinner in San Francisco at a fantastic Italian restaurant called North Beach Restaurant. The restaurant features Tuscan-style ambiance surrounded by original works of art, exquisite Florentine floor tiles, Carrara marble, Venetian granite, hand-crafted cherry wood paneling, and vaulted ceilings created by Italian craftsmen.

Nancy Tomoney graciously arranged a prefix menu with the Owner that included appetizers, dinner and dessert in the wine cellar. Immediately adjacent to the dining area in the cellar is the Prosciutto Room where the owner proudly cures Prosciutto.



ISPE Annual Meeting – NJ Chapter Dinner.



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International Student Poster Competition Awards

The International Student Poster Competition Awards honor the top undergraduate and graduate student posters among finalists who won competitions earlier in the year and as selected by judges at the Annual Meeting.

The Student Poster Competition is held during the ISPE Annual Meeting. The international winners (undergraduate and graduate) were announced at the Membership Luncheon. Both the undergraduate and graduate student winners receive cash awards and the opportunity to publish research in ISPE's magazine, *Pharmaceutical Engineering*, as well as other Affiliate/Chapter publications.

Before and after the completion of judging, the posters of all competitors were displayed for the attendees of the Annual Meeting to view. **We are proud to announce that both winners are from the New Jersey Chapter!**



Shyamala Pillai from NJIT receiving her award in the Graduate Student category from Randy Perez and Charlotte Enghave Fruergaard representing ISPE.



Kerri Killen from Stevens Institute of Technology receiving her award in the Undergraduate Student category, from Randy Perez and Charlotte Enghave Fruergaard representing ISPE.

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Rutgers Student Chapter Meeting

Representatives from a few of the country's largest pharmaceutical corporations dined with Rutgers University students on November 27 to network at the Grand Pharmaceutical Networking Dinner. Johnson & Johnson, Merck, Bristol-Myers Squibb and Pfizer are just a few of the 17 companies present in the Life Sciences Building on Busch campus in New Brunswick, NJ. The dinner, hosted by the University's ISPE chapter featured two hours of networking and presentation of graduate student's research and ended with an address from Remo Colarusso, Vice President of Pharmaceutical Development and Manufacturing Sciences at Johnson & Johnson.



He spoke to 170 students from organizations including the American Institute of Chemical Engineers and the Omega Chi Epsilon National Honor Society for Chemical Engineers. Colarusso, a 1983 Rutgers University alumnus, said there was little progress in the technological landscape and development processes, so he encourages students to take up careers in these fields.

Jumana Dakka, president of the ISPE Student Chapter, said the recognition of graduate students' research was a main feature of the event, as well as a method to promote the pharmacy department to the industry giants. "I think our School of Engineering really needs more events like this," said Dakka, a School of Engineering senior. "We have the SHE SWE MEET Career Fair every year, but we don't have anything that's really student-led, student-organized."



FOR IMMEDIATE RELEASE



2013 Facility of the Year Awards (FOYA) Winners Announced

(TAMPA, FLA. USA, 29 January 2013) – The Facility of the Year Awards Judging Panel has named six Category Award Winners in the 2013 Facility of the Year Awards (FOYA) program. The winning projects for 2013 were selected from 27 well-qualified entries and are located in Ireland, Switzerland, the United Kingdom and the United States.

"The FOYA program is about recognizing the pharmaceutical industry's innovation and technical advances in facility manufacturing, which ultimately is about helping patients who need and depend upon us for a reliable supply of quality medications," said Chaz Calitri, Vice President of Network Performance at Pfizer and chair of the 2013 FOYA Judging Panel. "The six facilities honored by this year's awards program embody innovation, exemplified by advances in areas including flu vaccine manufacturing, which is very relevant in parts of the world right now where outbreaks have occurred, threatening public health. All of this year's honorees are to be commended for their important contributions to our industry and, most importantly, to improving people's lives."

The winning companies and respective award categories are:

- **Biogen Idec**, winner of the Facility of the Year Award for Facility Integration for its Flexible Volume Manufacturing (FVM) Project in Research Triangle Park, North Carolina USA.
- **F. Hoffmann – La Roche**, winner of the Facility of the Year Award for Project Execution for its TR&D – Building 98 Facility in Basel Switzerland.
- **MedImmune**, winner of the Facility of the Year Award for Equipment Innovation for its UK Automation Upgrade Project in Speke, Liverpool UK
- **Merck & Co., Inc.**, winner of the Facility of the Year Award for Operational Excellence for its Vaccine and Biologics Sterile Facility (VBSF) Project in Carlow Ireland
- **Morphotek, Inc.**, winner of the Facility of the Year Award for Sustainability for its Morphotek Pilot Plant in Exton, Pennsylvania USA
- **Novartis Vaccines and Diagnostics**, winner of the Facility of the Year Award for Process Innovation for its U.S. Flu Cell Culture Facility in Holly Springs, North Carolina USA

More information about the 2013 Category Winners and their projects can be found at www.FacilityoftheYear.org/FOYAWinners2013.

About the Facility of the Year Awards Program

Sponsored by ISPE, INTERPHEX, and *Pharmaceutical Processing* magazine, the [Facility of the Year Awards \(FOYA\)](http://www.FacilityoftheYear.org) is an annual program recognizing state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a superior project, as well as reduce the cost of producing high-quality medicines. Now in its ninth year, the awards program effectively demonstrates the accomplishments, shared commitment, and dedication of individuals in companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of all global consumers.

For more information, contact:

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ISPE Releases New Guidance for Definition and Use of Non-Investigational Medicinal Products in Clinical Trials

(TAMPA, FLORIDA, USA, 06 February 2013) – [ISPE](#), a leading authority on publishing best practices documents for the pharmaceutical industry, announced today that it has issued [groundbreaking guidance](#) to help companies involved in clinical trials determine which medications qualify as non-investigational medicinal products (or NIMPs). The document also contains practical strategies for risk management as it relates to classifying, sourcing and packaging NIMPs.

"Until now, there has been no clear guidance to help define NIMPs and their use. As a result, many pharmaceutical companies take a cautious approach and treat all study medications as investigational medicinal products. Since the regulatory requirements for IMPs are so much more stringent than for NIMPs, these companies are subjecting themselves to unnecessary complications and expense," said Esther Sadler-Williams of Catalent Pharma Solutions, one of the Guide's lead authors. "This guidance answers many of the questions surrounding what constitutes a NIMP versus an IMP, and gives practical advice for simplifying the use of NIMPs."

The *ISPE Good Practice Guide: Harmonizing the Definition and Use of Non-Investigational Medicinal Products* helps companies who operate studies in multiple countries devise strategies for risk management that take into account country-specific rules and regulatory requirements. It clarifies issues related to NIMP supply chains and outlines how the sourcing strategy employed for NIMPs can impact a number of the manufacturing and clinical site aspects for the complete clinical trial.

The [ISPE Good Practice Guide: Harmonizing the Definition and Use of Non-Investigational Medicinal Products](#) is available for purchase on the [ISPE website](#).

About ISPE

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit association serving its Members through leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. The 20,000 Members of ISPE are building solutions in the development and manufacture of safe and effective pharmaceutical and biologic medicines and medical delivery devices in more than 90 countries around the world. Founded in 1980, ISPE has its worldwide headquarters in Tampa, Florida, USA and offices in Brussels, Belgium, Singapore and Shanghai, China. Visit www.ISPE.org for more information.

For more information contact:

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BRAIN PUZZLER #6

The Brain Puzzler for this issue again comes courtesy of Paul Malinowski of BD and the rules remain the same. Please forward your responses to Rich.smith@crbusa.com (the new Communications Chairman and Editor of Pharma Bulletin) and include a reference to Brain Puzzler #6 in the subject line to ensure your e-mail is not blocked as spam or some other mischievous item.

The first person to send the correct response will be rewarded with a \$75.00 credit to be applied to any of the upcoming events they may wish to attend. Good luck!

Brain Puzzler #6 Question:

During her formative years as an undergraduate student, an adventurous Young Professional (YP) spent a summer abroad, as a member of an archaeology team. The team came upon some ancient Roman ruins. The ruins included a stone quarry, a fortress, an aqueduct, some houses and a series of roads.

The roads were stone-paved. The Romans were famous for having constructed thousands of miles of these paved roads throughout their Empire. The archeology team theorized that the Romans probably obtained the stones, for the roads, from the local quarry. After careful observation, the clever YP determined that the Romans drove their carts and wagons on the left side of the road, same as the British do today.

How did the YP know this?

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ISPE NJC 2013 PROGRAMS

The ISPE New Jersey Chapter has set the stage for an exciting year of Program events. This year's programs calendar has changed from previous years. Rather than scheduling monthly sessions, our plan is to offer 5 quality programs throughout the year that will attract all sectors of our membership. Please watch for emails and notices about the events throughout the coming year.

Annual Gala & Student Scholarship Fundraising Event – March 1, 2013 at The Stone House in Warren, NJ featuring a Casino Night theme with raffles and dancing.

Student Poster Competition – April 18, 2013

Golf Outing – May 13, 2013 at Neshanic Valley Golf Course in Neshanic Station, NJ. This is a new venue for the golf outing and it promises to be a memorable golfing experience. In 2012 Neshanic Valley was named as the 30th best public course in the nation and 2nd best in New Jersey.

Technology Showcase – September 12, 2013

Chapter Professional Development Day – scheduled for December 2013

2013 Classroom Training

ISPE's in-depth courses cover the entire product lifecycle and are led by instructors who are active in the industry.



Newton, Massachusetts USA (Boston Area)

8 – 11 April

- Biopharmaceutical Facilities (T31)
- HVAC for Pharmaceutical Facilities (T14)
- Overview of Biomanufacturing Processes (T24)
- Pharmaceutical Water Generation (T04)
- Q7A: Implementing Good Manufacturing Practices (T30)
- Sterile Drug Manufacturing Facility (T12)
- Storage, Delivery and Qualification of Pharmaceutical Waters (T23)

San Francisco, California USA

10 – 11 April

- Risk-MaPP (T41)
- Process Validation in Biotechnology Manufacturing (T32)

Indianapolis, Indiana USA

13 – 15 May

- GAMP® 5 Process Control Systems (T21)
- Sterile Drug Manufacturing Facilities (T12)
- Auditing for GMP (G07)
- Oral Solid Dosage (T10)

- Process Validation in Biotechnology Manufacturing (T32)
- Q7A: Implementing Good Manufacturing Practices (T30)
- HVAC for Pharmaceutical Facilities (T14)



Register Early and Save!

www.ISPE.org/Training

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Career Doctor Don Answers Your Questions



*Don Sutaria is Founder and President of CareerQuest, located in New Jersey and New York. Don earned his MS degree in Management from Kansas State University, an IE (Professional) degree in International Management and Personnel Relations from Columbia University, and obtained New York University's postgraduate Certificate in Adult Career Planning and Development. A popular speaker and author, his latest book is titled, **Career and Life Counseling From the Heart (Your Career is a Pathway to Your Soul!)**.*

Question: Can you give me some tips as to how I can make my present job in the pharmaceutical industry recession-proof?
H. R. C. (PA)

Answer: Dear H. R. C.:

Without offending you, let me change the semantics of your question a little bit.

There is no such thing as a *recession-proof job*, as you have probably observed over the past 10 years. Job security is a figment of our imagination. Even the so-called recession-proof industries like Food and Pharmaceutical have suffered many layoffs in recent years. The only thing you can do is to try and make your job *recession-resistant* by following a strategy which I will outline below, in three segments.

Let me caution you. My tips may appear to be commonsense axioms or empty platitudes, but do you follow them? Knowing what to do is one thing but doing it is another. The \$64,000 question is: "*Are we doing it?*"

1. Hone Your Relationships

If I took a survey of readers of this column, I bet at least 50% of you may have been laid off or quit in disgust to get another job. I have been laid off too, not once but twice, in my long and chequered career. Once it was due to a personality conflict (which had nothing to do with the quality and work output), and another time due to lack of work / loss of major contracts (which is understandable).

Time and again, studies have shown that in 90% of the cases people are laid off because of relationships, and 10% because of incompetence! Does that surprise you?

Personal chemistry with the boss is very important, because your boss is the company to you! Repair your relationships, if necessary, during these economic times. Networking is very crucial. Join professional organizations and become active in them, if you are not already doing so.

2. Be Visible and Available

90% of success is just showing up!, a quote attributed to comedian Woody Allen. There is more than a kernel of truth in it. If you are out of sight, you are out of mind. Be available to pitch in as a part of your team. During recessionary times, come in at least 15-30 minutes early, and leave 15-30 minutes late. I don't mean in a phony way but in a sincere way, to shoulder a little greater share of your department's workload. Working harder and smarter does not make you a doormat!

(Continued on Next Page)

(Dr. Don continued from previous Page)

3. Be Easy Going and Show Your Usefulness

Don't complain or whine in front of peers, subordinates or supervisor. *Thoroughbreds don't whine!* Keep your temper under control, and if your flare-ups are frequent under pressure, consider taking an anger management course. Develop your reputation of being helpful and useful. Complete your projects on time, within budget, and simultaneously maintaining a high quality. *Under promise and over deliver*, because the other way around will be disastrous!

I want to wish you good luck during these turbulent times. Thank you for your stimulating question and keep me informed of your experiences, after following the suggestions given above.

[Special note: Please send your career-related questions to don@careerquestcentral.com and also visit our website at www.careerquestcentral.com. Questions will be selected based on their contemporary nature and general interest. We regret we will not be able to send individual replies as in the past, because of the large volume of domestic and international e-mails. Your patience and understanding are appreciated.]

ISPE NJC Welcomes 50 New Members (October 2012 through December 2012)

Robert Accardi, Tishman Construction Corporation
Joseph C. Aquilina, Manhattan College
Dr. Timothy A. Ayers, Sanofi
Kevin Belisle, Vaisala Inc
Iqbal Bhuiyan, Forest Research Institute
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Anqi Zhou, New Jersey Institute of Technology

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QC Rep	Nancy Tomoney, PSC BioTech, 732/640-1177, ntomoney@biotech.com
Young Professionals Rep.	Shilan Motamedvaziri, Bristol-Myers Squibb, 732-227-7898, shilan.motamedvaziri@bms.com

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