Letter from the Editors

As we begin the year with the release of the 1st Quarter 2012 edition of Pharma Bulletin, we also begin the second 25 years (and beyond!) of the history of the NJ Chapter of ISPE. We can all look forward with great anticipation to the future growth and development of the international organization as a whole, and to our continuing role as ISPE’s first Chapter in that growth and development.

In addition to the magnificent 25th Anniversary Gala event held on January 14, the Chapter has been very busy with a number of other activities reported within this edition. These activities included the Annual Holiday Party in December, a Student Affairs Committee event with a featured FDA NJ District speaker, and a regional reprise of the very successful “Build-a-Lab” educational program first presented during the 2010 ISPE Annual Meeting in Orlando, Florida.

We are pleased to report that Bill Schmeelcke of Commissioning Agents, Inc. was the first successful respondent to the Brain Puzzler in the last edition of Pharma Bulletin, which entitles Bill to a complimentary admission to our next regular Chapter event. Please take advantage of the opportunity to be the first to successfully respond to the Brain Puzzler in this issue … perhaps you can join with Bill and receive the economic incentive and bragging rights that accompany this accomplishment!

In the 4th Quarter 2011 edition of Pharma Bulletin, the Chapter rolled out the 2012 Advertising/Sponsorship Program. After careful consideration of the continuing economic situation within the industry and with a desire to have as many organizations as are interested support the Chapter in 2012, the Board has reevaluated the program and revised it significantly. We encourage you to take a look at the revised program, which is included in this issue, and determine whether your organization will be able to support the Chapter’s activities by participating in this important initiative.

The balance of this edition of our newsletter is rounded out with committee input as well as our regular features. We welcome your input on this, OUR newsletter, and would welcome any comments, suggestions or other ideas you might have to make Pharma Bulletin more useful to you in your day to day activities.

We look forward to seeing you at a future Chapter event and to the next 25+ years of success!

Paul Malinowski  
Secretary – Board of Directors  
New Jersey Chapter of ISPE

Harry Segner  
Chair- Communications Committee  
New Jersey Chapter of ISPE
President’s Message

... I Need to Wear Shades

Hello again, this is your president speaking. So, last time I gave a bit of a speech about volunteerism and all the good stuff about how the ISPE is all about you. Well, it was encouraging to get some feedback as well as a few people stepping up to help out. That is what our society is all about.

For those who embrace what we are about there are many rewards from camaraderie, networking, education and the down right reward of being part of something that helps make the quality of life for others better. As I sit and compose this message my feelings about the direction and promise of this organization are nothing but encouraging.

When I run into colleagues at events or project sites, either people I have know for many years or ones that I only met recently, it is a good feeling to know that the ISPE unites us. When I run into members that have found new opportunities through the networking, I feel even better about the value of the society. When I see CIPP study groups in Boston and now with our chapter and DelVal I think what other organization does something like this to further professional development in our industry? Finally, when Nancy Berg, our new CEO, tells me that the leaders of industry she has spoken with told her that the ISPE is significant and important, and that they whole heartedly support what we do I kvell.*

So, you can see where I am going with this. I think the future is bright for our industry and the ISPE, as well as for our slice of the pie in the NJ Chapter. Project spending is up, unemployment is going down. We are seeing more people looking to get involved, we are seeing better and more exciting events develop. The volunteers of the NJ Chapter work hard and are diligent about bringing the best to our

Chapter. We had an awesome 25th Anniversary party in January. For a bunch of stodgy engineers, it rocked! The "Build-a-Lab" program at BMS in February was sold out and exemplified the new direction for interactive events. We have exciting programs planned for the rest of the year, with most of them being held at owner sites. We will be pumping up our educational programs to offer more classroom training and CEUs locally, as well as more cost effectively. Our summer outing has grown and will top last year; and finally we are looking to knock it out of the park with our Technology Showcase in September.

Yes, thanks to you and all you do for the ISPE, internationally and locally; I must the future looks so bright … I need to wear shades!

*Yiddish folk word for standing tall with pride like a peacock (thumbs under arms optional) – ref – my mama, again

Gordon Leichter, Ph.D.
President
NJ ISPE
Gordon.leichter@belimed.us
New Jersey Chapter Celebrates the Holidays!

On December 8, 2011 forty-three Chapter members and friends gathered at the Harvest Moon Brewery in New Brunswick to celebrate the Holiday Season and to look forward to a strong 2012! An always enjoyable event, the Holiday Party features great networking, good food and drink and an opportunity to socialize without a very formal agenda or educational mission.

The attendees were asked to consider bringing an unwrapped toy for the benefit of the United Way Gifts of the Season program, and many members very generously complied with that request. Irene Netal of United Way was very pleased and appreciative of our group effort and is shown in one of the accompanying photographs with our own Caroline Shelly when the toys were delivered for distribution to the needy kids.
Upcoming Chapter Events

May 17, 2012 — Annual Golf Outing
Farmstead Golf and Country Club, Lafayette, NJ

June 7, 2012 — Pfizer Facility Tour (Vial and Syringe Filling Lines) - Pearl River, NY

Stay tuned for updates on the details of these exciting future events !!

June 2012 — Joint NJC and DVC Event
Guest Speaker—Lou Schmulker (President of Global Manufacturing and Supply) Bristol—Myers Squibb — Site — TBD

August 3, 2012 — Baseball Outing to see the NY Yankees
Bronx, NY

September 12, 2012 — Supplier Showcase & Tabletop Show
MetLife Stadium, East Rutherford, NJ

We Wish to Thank Our Annual Platinum Sponsor
New Jersey Chapter Celebrates 25th Anniversary in Style!

On the very cold but clear evening of Saturday January 14 one hundred and ten members, spouses, guests and friends of the New Jersey Chapter of ISPE were treated to a magnificent celebration of the Chapter’s Silver Anniversary at The Manor in West Orange, NJ.

The event, very ably conceived and planned by Bob Lechich, CPIP, and Joe Manfredi, both Past Presidents of the Chapter, was a wonderful opportunity to network with old (and new) friends and associates within the industry while paying tribute to ISPE’s first Chapter and it’s rich legacy within the history of the organization. A very interesting and moving visual presentation including many video clips from former leaders of the Chapter, who reminded us of where we came from and how we got here, in addition to revealing (or confirming) some of the rumored events over the past 25 years! The evening was topped off by a delicious five course meal with entertainment and dancing provided by an outstanding North Jersey band, The Infernos.

We were all pleased to meet the new ISPE President, Nancy Berg and to have with us the current ISPE Chairman (and NJ Chapter Member) Randy Perez, as well as some of our predecessors who may be retired or no longer as active with the Society. We also honored those leaders of the Chapter who are no longer with us and thanked them all for what they did to lead the Chapter to become what it is today.

The Special Grand Sponsors of the event were INTERPHEX 2012 and Pfizer, and we thank them, along with the many Silver and Anniversary Sponsors, for making the evening possible. A complete list of all of our Sponsors for this event is provided later in the newsletter.

If you were not able to attend the evening’s festivities, please enjoy the photo montage we have provided herein and if you did attend, perhaps this montage will just remind you of the success of this fine event. The Gala Planning Committee intends to have all of the photography shot that evening available for download. When that process is finalized, we will forward a communication throughout the Chapter.

Now we can all get started planning for the next 25 years and beyond!

See Photo Montage on next page.
A Toast to ISPE New Jersey Chapter.

And . . . Let the party begin!!!
Current Board of Directors

Past Presidents of ISPE NJC

Photo Montage continues on next page.
The outstanding 25th Anniversary Gala Event would not have been possible without the generous support of the many sponsors listed below. All of us at the Chapter thank them for stepping up to enable us to enjoy such a memorable evening of camaraderie and fun and for their ongoing support of the chapter and its activities.

**Special Grand Sponsors**

*INTERPHEX 2012*

*Pfizer*

**Silver Sponsors**

*Aquafine*

*Commissioning Agents, Inc.*

*DPR Construction*

*Global Automation Partners*

*PSCBiotech*

*Rotronic*

*Scott Process Equipment Corp*

*Turner Construction*

**Anniversary Sponsors**

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*Yula*
As we reported in the Letter from the Editors, Bill Schmeelcke of Commissioning Agents, Inc. was the first successful respondent to Brian Puzzler #2 in the 4\textsuperscript{th} Quarter 2012 Pharma Bulletin, which entitles Bill to a complimentary admission to our next regular Chapter event. His successful response was……

“The young professional was dressed as a football player or fan. The numbers 45-8 and 42+15 refer to yardage lost and gained as the ball crosses mid-field (the 50 yard line).”

We congratulate Bill on his logic (and his sports acumen!) and look forward to seeing him at a future Chapter event to congratulate him in person.

The Brain Puzzler for this quarter will bring a variety of your intellectual skills into play and comes again courtesy of Paul Malinowski, NJ Chapter Board Secretary. Give it a try and remember to send your responses to hsegner@ewingcole.com to have the opportunity to have the first successful response and be rewarded with a complimentary admission to our next regular Chapter event. (Please also remember to place the phrase “Brain Puzzler” in the subject line to prevent your response from being blocked by our security system).

One day, a YP is sitting at his desk working away, reading a very technical process validation manual...

Suddenly he’s awakened, or rather startled, by the sound of his stomach growling. He turns in his seat and looks at the electric clock on the wall behind him. This is one of those clocks that plugs into the wall – a big round analog clock. He looks at the clock, and as he turns back to his work, he says, “Well, it’s obviously too early to eat lunch. He goes back to work.

A short time later, he’s again startled, by the growling of his stomach. This time, he turns to look at the clock and notices that it says a time later than what it did the first time he looked at it. The second hand is sweeping. The hour hand has moved from where it was the last time he looked at it, and the minute hand is in a different position. And as he turns back to his desk, again thinking he doesn’t know how he’s going to make it to lunchtime, his stomach growls a third time, and he says, “The clock is broken.” And yet, everything seemed to be working.

The question is: How did he know the clock was broken? Hint: The two hands are exactly 180 degrees apart, like they would be at 6:00.
The ISPE-NJ Young Professionals Committee is still recruiting new members, so please encourage any young professional or graduating senior to join the group! Young professionals receive discounted membership and event rates, and we will be planning specific YP social events. Any YP would is interested in getting more involved in the chapter can contact ispe.nj.yp@gmail.com. Several NJ Chapter committees have requested young professionals to help serve on their committees. This is a great way to get involved in the chapter and help give direction to the Chapter! Any questions please contact ispe.nj.yp@gmail.com or keworden29@gmail.com!

Young Professionals Update

Rutgers Student Chapter

Hosts FDA Presentation

Captain Joseph McGinnis, Director of Inspection Compliance for New Jersey District of the Food & Drug Administration, spoke at the Rutgers Busch Campus Center on February 2, 2012. Captain McGinnis is an alumnus of Rutgers Pharmacy School and was invited by the NJ ISPE Rutgers Student Chapter to talk about the pharmaceutical and medical device industry and career potential for graduating student with the FDA.

The audience included students and faculty advisors from the Rutgers, NJIT, Stevens, and Kingsborough ISPE Student Chapters, as well as other students from the Rutgers Pharmacy School, Rutgers School of Engineering and the New Brunswick College of Arts & Sciences who are not members of ISPE.

Captain McGinnis’ talk was well received by the students and after the event had concluded, there was an extensive question and answer period between the students and Captain McGinnis. We thank Captain McGinnis and the FDA for their continuing cooperation with ISPE and our Student Chapters and encourage all of our student members to avail themselves of opportunities to learn more about our industry.

Captain Joseph McGinnis, FDA
On February 23 2012, the New Jersey and Delaware Valley Chapters of ISPE jointly offered a highly interactive workshop program focused on planning, designing and constructing a biopharmaceutical research facility. The event, held at the Bristol-Myers Squibb Campus in Plainsboro, NJ, offered participants detailed exposure to core elements of a capital project including current industry trends, corporate business and project design drivers, design concepts and their cost implications, engineering system planning and design impacts, sustainability, constructability, and value management techniques and the impact of Value Management (VM) on project outcomes. Participants acted as stakeholders and were given the opportunity to select the design concepts and engineering schemes driving the project scope, schedule and cost. The group participated in a detailed VM evaluation of their project design and benefitted from a review of lessons learned and best practices from actual projects in the region.

The afternoon session was followed by a networking reception, dinner and roundtable discussion featuring three senior executives from the biopharmaceutical industry who focused their comments on “Value Management in Today’s Capital Environment”.

We thank Jim Breen of Johnson & Johnson, Jim Kimmel of TEVA, and Marty Tyrie of Bristol-Myers Squibb for their participation representing the biopharma industry and Donna DeFreitas of R.G. Vanderweil Engineers and Jerry Guillorn of M+W Group for organizing and facilitating this interesting and valuable program.
ISPE NJC Welcomes 87 New Members
(October 2011 through March 2012)

David Anderson, Covance
Fred Angioli, Merck & Co Inc
Christopher Bailey, Lend Lease (US) PM&C
John Barrett, Duke University
Paul Barsa, Industrial Controls
Patricia Bernal, Landsteiner Scientific S.A. DE C.V.
Connor Bilchak, Manhattan College
Courtney Billington, Johnson & Johnson - Janssen Supply Group, LLC
Ernest Bogner, Dendreon Corp
Dileep Kumar Boinipally, New Jersey Institute of Technology
Lawrence Boothroyd, Manhattan College
Joseph Carney, Manhattan College
Taimour Chaudhary, Rutgers University
Michele Christian, International Products Corp
Saadat Chuhan, Kingsborough Community College
Matthew Coleman, Colgate-Palmolive Co
Christopher Critelli, Manhattan College
Peter Cruz, Manhattan College
Abidemi D’Ada, Rutgers University
Michael David, QC Laboratories
Jim Davis, Core Power Inc
Danielle DeAngelis, Amicus Therapeutics
Anna Deleón, University of Rhode Island
Thomas Docherty, Avarent, L.L.C.
Danielle Dorris, Merck & Co Inc
Travis Downey, Raritan Valley Community College
Phil Duncanson, MedImmune
Meenakshi Dutt, Rutgers University
Kimberly Ezdebski, Chartwell Pharmaceuticals
Pablo Figueroa, Kingsborough Community College CUNY
Ron Filler, Drug Development Consultants Inc
Drew Finley, Rutgers University
Kevin Fitzsimmons, M & W Group
Molly Geoghegan, Widener University
Lizzette Gomez Ramos, Merck & Co Inc
Vladislav Gudesblat, Siemens Industry, Inc
Michael Hange, G. C. Hanford MFG. Company
Darren Hanway, Coviden
Joseph Interrante, Fougera Pharmaceuticals Inc
Han Jia, New Jersey Institute of Technology
Jingwen Jia, New Jersey Institute of Technology
Mark Johnson, Dendreon Corporation
Neena Joseph, Manhattan College
Kevin Kelly, Celgene Corp
Brian Kim, Merck & Co.
Robin Knopf, Vitaquest International
Manda Koss, Avanceon
Karthikeyan Kumarasamy, SUN Pharmaceutical Industries, Inc.
Larry LeGrand, Glatt Air Techniques
Jennifer Leopold, J&J
Antoinette Liggians, Astra Zeneca
Jenna Lo, Rutgers University
David Lorah, Bristol-Myers Squibb
Karthikeyan Kumarasamy, SUN Pharmaceutical Industries, Inc.
Bridget Loughran, Manhattan College
Catherine McGuinness, Pfizer Inc.
William Mendoza, Novartis Pharma
Sandeep Modi, Bristol-Myers Squibb
Robert Murphy, Vision Point Systems Inc.
Anthony Occhino, Siemens
Lucas Onder, Raritan Valley Community College
Michael Osenni, Franklin and Marshall College
David Padula, Regeneron Pharmaceuticals
Kushalkumar Patel, New Jersey Institute of Technology
Parth Patel, New Jersey Institute of Technology
Andrew Reef, CSL Behring
Jeff Reingold, Stony Brook University
Mark Richards, ImClone Systems
Craig Ritter
Mojisola Rotibi, Kingsborough Community College
Michael Ruberto, Material Needs Consulting
Maribel Santos, Raritan Valley Community College
Javeed Shaik, New Jersey Institute Of Technology
Ying Shi, Merck & Co Inc
Snehanjani Shivakumar, Manhattan College
Annie Shulamite, Fairleigh Dickinson University
Andy Soliman, Rees Scientific
John Stark, University of Massachusetts Amherst
Kevin Swenson, Manhattan College
Sai Siva Prasad Tadiboina, New Jersey Institute of Technology
Eric Thostesen, Janssen Pharmaceutical Company Inc.
Brian Turbitt, University of Rhode Island
Kimberly Ulaky, Rutgers University
Henry Waldron, Merck & Co Inc
Peter Wisniewski, Colgate Palmolive Co
Jae Deok Yoo, Aprecia Pharmaceuticals

Pharma Bulletin
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:** My work-life balance is completely out of whack! Due to the present economy, management is using winning through intimidation. I am spending more and more time at work and less and less with the family, due to the fear of losing my job. Can you give me few hints which can help me cope?

Emma G. (New Brunswick, NJ)

**Answer:**
Dear Emma:

This new term, work-life balance, signifies the unhealthy choices that many of us are making in favor of the workplace, as we knowingly decided to neglect our physical and mental health, family members, friends and leisure activities in the pursuit of corporate goals and the almighty dollar. Many of us discovered that our ladder was leaning against the wrong tree and that we cannot take it with us, a rude awakening!

We can’t do everything, but neither can we retreat from the things that are important.

It is my firm belief that an integrated and balanced life is like a pizza with eight slices. If one of the slices is missing, it is not a complete pizza! The eight slices are: physical, mental, emotional, spiritual, financial, social, cultural, and educational.

There’s lip service about work-life balance, and then there is reality. We can’t do everything, but neither can we retreat from the things that are important. My opinion is that family obligations cannot be conveniently subordinated to those at work. Child rearing is a difficult proposition and cannot be rationed or given a lower priority because you get only one chance!

If we want time with our families, time to give back to our communities, time to stay slim, we’re going to have to accept a pay cut........a tough proposition! We are all guilty sometimes of the Superwoman/Superman trap. We want everything which is just not possible.

Have you ever seen a U-Haul truck following a hearse? I haven’t.

No one on their death bed has wished they had spent more time in the office! Check it out.

Time poverty is very tragic because while we are pursuing success, it simultaneously eats up our near and dear ones. Rob parsons, author of The Heart of Success, offers seven guidelines:

1. Don’t settle for being money rich - time poor.
2. Believe that the job you do makes a difference.
3. Play to your strengths.
4. Believe in the power of dreams.

(Continued on Page 16)
5. Put your family before your career.

6. Keep the common touch.

7. Don't settle for success; strive for significance.

One final personal note. Your dilemma is not a sexist issue. Juggling domestic duties is not just the domain of women. A Harvard study found that there is also a minority of men who actually work fewer hours to be with family. They also cover for each other. Their performance reviews and compensations were not affected.

Emma, I hope these pointers give you some great insights. However, you will have to make the decisions about work-life balance yourself and live by their consequences.

Good night and good luck!

[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.]
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.

In addition to our “a la carte” items, various packages are available, which offer numerous advantages and savings.

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**SAVINGS**

|          | $1,350 | $1,050 | $650  | $200   |

(Continued on next Page)
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 NJC members and others on our circulation list.

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

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

- 6 months - $250
- 12 months - $500

Event Sponsor – The Chapter plans to hold approximately 4 on-site monthly events/meetings for 2012, featuring networking opportunities and education content of general interest to the membership. Sponsors are recognized during the program, on all “e-blast” announcements of the event, plus acknowledgement in next quarterly newsletter as part of the article on the event. Sponsors are furnished with a six to eight foot table in a highly visible location, where they can set up an unattended Table Top display of their literature (restrictions may apply to off-site venues). Admission to event is not included. Vendor Showcase, Holiday Event, Annual Golf Outing and Off-Site Facility Tours are excluded from this price offer.

- $300 per event

Education/Training/Webinar Sponsor - Conducted throughout the year, providing more in-depth education content with less focus on networking. Logo/Listing on event announcements, plus acknowledgement in next quarterly newsletter, as part of the article on the event.

- $100 per event

Sign-up now for your 2012 Advertising/Sponsorship opportunities:
http://ispenjc2011-12advertising.eventbrite.com

For additional information contact:
Lorraine Gallo
ISPE NJC Marketing Chair
lgallo@psands.com
732-584-0386
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Paul Malinowski, Becton Dickinson, 201/847-7041, paul_t_malinowski@bd.com
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Sustainability
Paul Malinowski, Becton Dickinson, 201/847-7041, paul_t_malinowski@bd.com
Sterile Process
Gordon Leichter, Belimed, Inc., 585/329-0497, gordon.leichter@belimed.us
ISPE NEWS
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For more information contact:
Danielle Hould
ISPE Communications Manager
Tel: +1-813-960-2105, ext. 277
e-mail: dhould@ispe.org
www.ISPE.org

ISPE Announces FDA to Co-Sponsor June CGMP Conference in Baltimore

(TAMPA, FLORIDA, USA, 14 March 2012) – ISPE announced today the Food and Drug Administration (FDA) will co-sponsor the upcoming “Redefining the ‘C’ in ‘CGMP’” Conference in Baltimore, Md. USA on 4 – 5 June 2012. The conference is the first joint ISPE-FDA conference focused on CGMP issues.

The conference will feature a new format with a number of audience-participation and interactive sessions. A Hot Topic Discussion Forum between attendees and regulators will feature discussion on critical industry issues, concerns and collaboration. A mixed panel of FDA and industry leaders will also answer the industry’s most pressing questions during a moderated “Meet the Press” session. Topical plenary and education sessions will be featured throughout the two-day event.

“This first annual co-sponsored conference reflects ISPE’s commitment to engaging its Members, companies and global regulatory agencies in dialog around critical problem-solving and learning,” said ISPE’s president and CEO Nancy Berg. “As the independent pharmaceutical manufacturing association, ISPE is dedicated to strengthening industry through relevant technical education, training and networking. This new conference hits the mark, assembling the entire supply chain to discuss industry’s commitment to identifying and adopting quality and manufacturing techniques that continue to deliver a safe, consistent and available drug supply.”

“FDA is very excited to be working on this joint conference,” said Steven Lynn, Acting Director, FDA/CDER/Office of Compliance/Office of Manufacturing and Product Quality (OMPQ). “Our goal is to make this a highly collaborative Agency and Industry conference, where we can come together to discuss the current and future state of CGMPs in the quest to ensure high-quality/fit-for-use drugs are continually available to the community that we serve.”

More information on the Redefining the “C” in “CGMP” Conference is available at www.ISPE.org/2012CGMPCompliance.

About ISPE
ISPE, the International Society for Pharmaceutical Engineering, is a not-for-profit Society of 22,000 pharmaceutical professionals in 90 countries who use expert knowledge to create high-quality, cost-effective GMP solutions. ISPE is “Connecting a World of Pharmaceutical Knowledge” by providing Members with opportunities to develop their technical knowledge, exchange practical experience within their community, enhance their professional skills, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE offers online learning opportunities for a global audience and has its worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; an Asia Pacific office in Singapore; and its newest office in Shanghai, China. Visit www.ISPE.org for additional Society news and information.
ISPE and FDA present
Redefining the “C” in CGMP
Creating, Implementing and a Sustaining Culture of Compliance
4 –5 June
Baltimore, Maryland USA

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See page 17 for further details