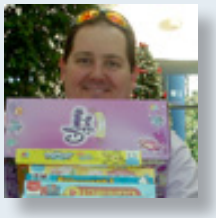
ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

Volume 19 • Number 1 FEBRUARY 2012

INSIDE THIS ISSUE



Don't miss it!

2012 CaSA Leadership Forum

McKimmon Center, Raleigh, NC

Register online at:

http://CaSAleadershipsymposium.eventbrite.com/

February 17, 2012

President's Message

David Brande

Wow and just like that, it's 2012! I hope your year is off to a fast and furious start and work is going well for you. So far (knock on wood), we have benefitted from a mild and somewhat dry beginning to winter and I am very pleased that we are not dealing with ice and snow. Just imagine, in a few short weeks we will see trees blooming and flowers emerging from the ground. It just reminds us of how quickly time goes by and how important it is that we keep up with the things going on around us.

Case in point, if you have not been keeping up with your CaSA calendar, you have already missed a couple of important events. Our first social event of the year was a Young Professionals get together at the FullSteam Brewery on Thursday, January 26. This event was held in conjunction with our "traditional" monthly Therapeutic Thursday outing.

Next, one of our biggest social events of the year, the 4th Annual Casino Night, was held Saturday, February 11, at The Capital City Club in downtown Raleigh. What a great opportunity to get dressed up for a "night on the town" and head "uptown" to an exclusive facility for some great food, friendly conversation and an opportunity to try your luck at a game of chance. I understand that Lady Luck was as fickle as ever!

Don't miss the CaSA Leadership Forum on Friday, February 17, another annual event that CaSA produces each winter, at the McKimmon Center off of Western Boulevard in Raleigh. The meeting will begin at 8:30 am and conclude at 4:00 pm that afternoon. All new folks to our industry are welcome to attend to learn more about how ISPE can assist you in attaining your professional goals. If you are well established in our industry this is an excellent opportunity for you to assist in mentoring our Young Professionals as they navigate through this unique and somewhat challenging time. The event is free, but we do need to know how many are coming in order to make sure we have enough food, so do not delay, register now!

Don't put the calendar away just yet. February is also the beginning of yet another CPIP Study Group that will hold regular meetings near Cameron Village. So if the CPIP exam is on your list of to-do-items, these are the folks you need to meet. Call the CaSA phone number to get the schedule and contact information of the organizers.

March will be fairly quiet, but on April 10, the biggest event of the year for CaSA is the 19th Annual ISPE CaSA Life Sciences and Technology Show, which will kick off mid-morning at the RBC Center. There will be a new member breakfast, important lectures, a myriad of who's who in the industry, great food and lots of free parking available to all who attend.

Finally, May will usher in the largest outdoor event that CaSA sponsors each year as the 18th Annual ISPE CaSA Golf Tournament tees off Monday morning, May 7, at Prestonwood Country Club. Be sure to sign up early! Prestonwood has offered us all three courses if we can fill them, so no more waiting lists! Remember, your Board of Directors is only a phone call away, so be sure to let us know your needs and how the Chapter can help you in your professional development. I look forward to seeing you at these upcoming events!

David Brande
Chapter President

ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

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- Amy Lineberry, CPIP, Programs
- LeAnna Pearson, Students
- Bruce Craven, Technology Show
- Blake Derrick, Young Professionals

Chapter Event Highlights

Spotlight on the 19th Annual ISPE-CaSA Technology Show

By Bruce Craven, Technology Show Committee Chair

It seems that 2012 is off to a quick start and that means we are getting closer to this year's technology and vendor show. Over the past several months, your CaSA Technology Show Committee has been preparing and organizing events, venues and speakers to make our 19th Annual Event one for the record books. So what's different about this year's event?

For starters, when you arrive for the event on April 10th, we will be at the RBC Center, but it will have a new name. We won't know what that will be until March, but the old signs are coming down now, so keep checking the newsletter for updates. What about the temperature? Will it finally be a balmy 76°F? Unfortunately, that is one change we can't make happen, so come prepared for a little cooler indoor weather.

So what's really different about the event? There are many noticeable and subtle changes, but the one you will notice first is our speaker line up. Based on feedback from many of our attendees last year, we have elected to fill the time slot formerly reserved for a Keynote Speaker with more training classes and panel discussion opportunities. So instead of having one speaker spotlighted, we will have several. Over the next few weeks, the committee will be sending emails to signal the opening of attendee registration. Be sure to not only register, but take a look at the details. Included with registration information, you will find the course schedules, speaker bios, vendor representation, local HR representatives and other useful information to help you plan your day with us.

Need a little more information? Who is speaking? Who are they representing? Since I have a few of these to write over the coming weeks, I will try to save something new for each one; but to give you a taste, there are multiple speakers representing local and international operating companies, engineering and service providers, ISPE International, and two representatives from our state funded programs (NC Bio and BTEC). Just to create a little more intrigue, one of our speakers is the current president of a well-known international drug company and resides here at its RTP site. He has been a member of ISPE since 1994 and became the founder of the ISPE Spain Affiliate and its first Chair in 2006. Can you guess who? Check your future emails for the answer and more details.

I hope this teaser has intrigued you enough to sign-up for the 19th Annual ISPE CaSA Technology Show, on April 10, 2012, at the venue formerly known as the RBC Center. (Remember to keep checking future articles for the new name and more inside details.) Mark your calendar — advanced registration began February 9th, and there is no charge to attend, so bring a colleague.

Upcoming Chapter Events

Upcoming CaSA Leadership Symposium

By Jennifer Lauria Clark, CPIP

The CaSA Leadership Symposium's intended audience is Young Professionals and Professionals in the pharmaceutical and biotech industries. Student ISPE members are also welcome to attend the event.

When is the CLS?
Friday February 17, 2012 8:30 am—4:00 pm

Where is the CLS?
NC State McKimmon Center, 1101 Gorman Street, Raleigh, NC

What is the cost of the CLS?
The cost of this event is FREE. Breakfast and lunch are included.

Can I come for just part of the day?
Yes. However, registration is required.

Who is going to be speaking at the event?
CAI, Biogen Idec, Biomerieux, Novartis, Novozymes, Kelly Scientific Resources, McDonald York, Merck, INC Research, Inc, NC Biotechnology Center, Pfizer, Metrics.

Please pass this information and the link along to your colleagues, family and friends. It is the seventh year we have hosted this great event! Hope to see you Friday, February 17th at the NCSU McKimmon Center.

Register at:
http://CaSAleadershipsymposium.eventbrite.com

See additional information on the following pages.

International Young Professionals Committee Meeting at the 2011 Annual Meeting

Featured CaSA Event

ISPE Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

2012 CaSA LEADERSHIP SYMPOSIUM

Friday, Feb. 17, 2012
8:30 AM—4:00 PM
McKimmon Center
1101 Gorman St.
Raleigh, NC 27606

CaSAleadershipsymposium@gmail.com

UNDERSTANDING THE FORMAT OF THE CLS:

The format of the 2012 CLS is geared towards face to face discussions with panels and the audience. The environment is non-formal but professional.

If you are interested in speaking on one of the below topics, please contact:
Jennifer Lauria Clark

CaSAleadershipsymposium@gmail.com

Agenda

- Overview of industry in our geographical area
- Panels include:
  - How to Get Hired
  - Career Path to Leadership
  - In House vs. Consulting
  - Young Professionals Career
- Resume submission to sponsors
- Benefits of ISPE
- Networking & MORE

Featured CaSA Event

Sponsorships Available

Platinum Sponsor **$1000**
- Table at event for recruiting and marketing.
- Signs placed in prime locations at event
- Logo placed on all promotional material before, during, and after event
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- Sign placed at event

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- Inclusion in all website announcements and emails
- Verbal recognition at event
- Sign placed at event

Bronze Sponsor **$100**
- Verbal recognition at event
- Sign placed at event

Don't miss this opportunity for top talent to learn about your organization! Spaces are limited. For more information about sponsorships email Jennifer Lauria Clark at:

CaSAleadershipsymposium@gmail.com

ISPE Membership Information

"What do I get?"
- As a Member-based Society, ISPE provides you with
  - **Knowledge** to excel at your job
  - **Global Community** of experts in the industry and regulatory practices to coach and mentor you through challenges
  - **Professional Tools** to develop yourself professionally
  - **Continuing Education** opportunities

"How much does it cost?"
- ISPE Membership is affordable with options from which to choose. Membership is "portable;" it follows you if you change jobs, so you never lose your benefits.
  - Industry Professional—$239 first year
  - Young Professional—$75 per year
  - Student Member—$20 per year & 1 year post grad

For Member Information and Benefits:

http://www.ispe.org/cs/members_section/membership

February 2012

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12	13	14	15	16	17	18
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26	27	28				

Register Online at:

http://CaSAleadershipsymposium.eventbrite.com/

ISPE Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

Featured CaSA Event

2012 CASA LEADERSHIP SYMPOSIUM

FREQUENTLY ASKED QUESTIONS

Who is the intended audience of the CaSA Leadership Symposium (CLS)?
The intended audience is Young Professionals and Professionals in the pharmaceutical and biotech industries. ISPE Student Members are welcome to attend the event.

Why do you include Professionals and Young Professionals?
ISPE is committed to the growth and development of tomorrow's leaders.

When is the CLS?
Friday, 17 Feb 2012; 8:30 am—4:00 pm

Where is the CLS?
NC State McKimmon Center, 1101 Gorman Street, Raleigh, NC 27606

What is the cost of the CLS?
This event is FREE. Breakfast, lunch, and parking are included.

Can I come for just part of the day?
Yes. However; registration is required.

What is the dress code for the event?
Business casual/business professional are recommended.

Come network with like-minded professionals while learning important soft skills for your own professional development.

Please

Please share this information with your friends, family and colleagues. In today's job market, this is a great place to come and learn about the pharmaceutical and bio-tech industries and network with some top companies in the area.

2012 CASA LEADERSHIP SYMPOSIUM

ISPE: PROVIDING YOUNG PROFESSIONALS A PLATFORM FOR GROWTH AND MENTORSHIP TO DEVELOP AS THE FUTURE LEADERS WITHIN THE INDUSTRY.

Chapter Event Highlights

University Spin-Off to Acquisition by a Pharmaceutical Company: One Company's Voyage

By Yong Zhang, UNC-CH ISPE Student President

ISPE University of North Carolina (UNC) Student Chapter invited Dr. Anil Goyal to present a seminar on his experiences and stories from the journey of Serenex as a University spin-off to its ultimate acquisition by Pfizer on Nov. 30th, 2011. Dr. Goyal received his PhD degree jointly from Rutgers, The State University and University of Medicine and Dentistry of New Jersey. He has over 20 years of experience at venture-backed and public biotechnology companies. He led business development, marketing, licensing, mergers/acquisitions and technology development for drugs and diagnostics across multiple therapeutic areas. In 2010, he co-founded Qualiber, Inc. with Professor Leaf Huang at UNC Eshelman School of Pharmacy. In addition to leading Qualiber, he is head of business development for Ascletis, Inc., a Hangzhou, China & RTP, NC based biotech/specialty pharmaceutical company. He is also a founding member of Certifier Licensing Professionals (CLP) organization.

Dr. Goyal's talk attracted a large crowd ranging from faculty, graduate students, and industry professionals. The intellectual property protection of the startup, how to obtain funding from venture capital, and effective deal negotiation with big pharmaceutical companies were some of the questions raised during the Q & A session after the presentation. The audience was impressed by Dr. Goyal presentation and broad experience and knowledge. The ISPE UNC Student Chapter cordially thanks Dr. Goyal for his presentation. This event was co-sponsored with AAPS (American Association of Pharmaceutical Scientists) UNC Student Chapter.

Chapter Event Highlights

Another Successful Toys for Tots Drive!

By Jane Brown, Membership Committee Member and Nancy Padgett, Membership Committee Chair

On December 1, 2011, members of ISPE CaSA opened their hearts and wallets to help make our annual Toys for Tots drive a huge success. Members came together at GSK in RTP, and enjoyed a continental breakfast, sharing good conversation with each other, and agree it was a great way to kick off the holiday season. They also enjoyed displaying (and in some cases playing with!) the toys as they were delivered. Stuffed animals, dolls, games, building blocks, footballs, baseballs, basketballs, and lots of other toys were collected by member companies, student chapters, and at various drop locations throughout the Triangle. In spite of the challenging economic times, our members helped to ensure that many children found something special from Santa under the tree on Christmas morning.

The event was also attended by Sergeant Singleton, from the US Marine Corps, who came to pick up the toys. He expressed his appreciation for our donations. Because of the generosity of our members, we filled his van to almost over-flowing with the toys we collected.

A big thank you goes out to the companies and members that participated to make this year's event a success. Your demonstration of kindness and community spirit is something that CaSA prides itself in maintaining year after year.

Chapter Event Highlights

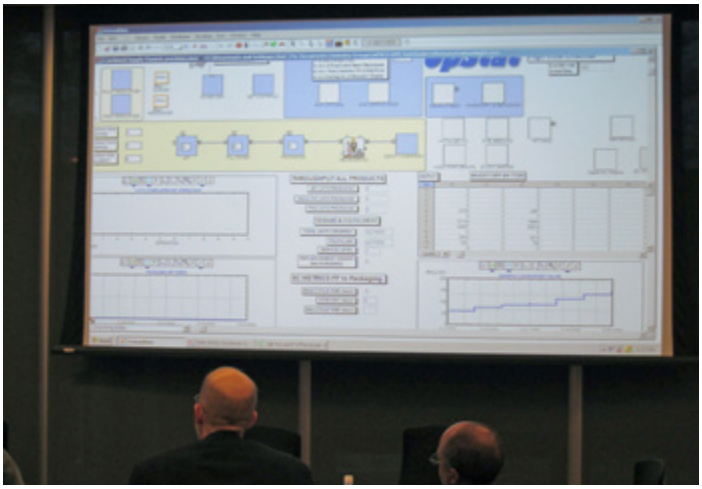
Operational Efficiency: A Joint Event with APICS

By Amy Lineberry, CPIP, Programs Chair

ISPE held a joint event with APICS (Advancing Productivity, Innovation, and Competitive Success) on January 17th, 2012 at the North Carolina Biotechnology Center. APICS is an organization which focuses on operations and supply chain management.

The speaker, Jim Curry, presented a case study on "Simulations for improved production cycles using a lean supply chain postponement strategy." The case study highlighted several issues that are important for several industries including the pharmaceutical industry. The three issues for the plant used in the case study were: demand variability; production campaigning and change-overs/cleaning; and quality testing and QA documentation.

These types of issues caused two main problems for the European Plant: high inventory and missed orders. He discussed the solutions for the three issues and the methodology used to reach the solutions. The company was presented with a solution to achieve a 98% service level. The demand variability was used to reduce lead time and inventory levels. Mr. Curry also demonstrated simulation software and showed how changing different variables produced different outcomes in inventory levels. The information that Mr. Curry shared was very informative for all skill levels within the manufacturing industries.



Chapter Event Highlights

Therapeutic Thursday at Full Steam Brewery

Almost sixty ISPE members and guests, including many Young Professionals and "Friends of ISPE", participated in the Full Steam Brewery tour and networking event. There were many introductions and connections made which is a pleasure to see as we're all eagerly hoping to see the economy begin to turn around. Attendees were from over 40 different companies and organizations and represented various operating departments inside local pharmaceutical and biopharmaceutical companies.

ISPE Young Professionals planned the event along with the help of our sponsor, Bray. The evening was filled with great networking and Fullsteam conducted a few in-depth and highly interactive tours in the production area of the brewery. We heard from our guests that the tour was top-notch and some said it was one of the best. Their brewmaster even taught us, a group of pharmaceutical engineering professionals, a number of things about engineering, aseptic technique, and materials handling! The brewmaster, Chris, was superb and very fun to talk to throughout the evening.

If you haven't made it out to one of these ISPE Young Professional events then you must plan to come to the **next "Therapeutic Thursday" scheduled for February 23rd at the Carolina Ale House in Cary, from 6-8 pm** (also sponsored by Bray). It's a great way to meet various industry professionals and spark new relationships with peers throughout industry. More details will be coming soon, so we hope to see you there!

CaSA New Members and Events

Welcome New CaSA ISPE Members

New Members who joined December 15, 2011-January 31, 2012

Steve Bearden
Matthew Bray
Jason Brown
Ivan Cartagena
George Chase
John Groth
Christopher Janik
Ashley Johnson
Mark Johnson
Stephanie Johnston
Christina Le
Dongyun Liu
Frank Miller
Yelitza Ortega
Marita Plymel
Juan Quinones-Cobos
Jennifer Register
Joseph Rogalewicz
Laurie Scaggs
Rajesh Sharma
Jamie Sigmon
Michael Sink
Angela Stewart
Todd Taintor
James Tatone
Katherine Torrecillas
Katherine Whitley

MARK YOUR CALENDARS!

CaSA Chapter Events

February 17, 2012
CaSA Leadership Symposium

February 23, 2012
Therapeutic Thursday
6:00-8:00, Carolina Ale House, Cary, NC

April 10, 2012
Annual CaSA Technology Show and Student Poster Competition

May 7, 2012
Golf Tournament
Prestonwood, Cary, NC

ISPE NEWS
FOR IMMEDIATE RELEASE

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www.ISPE.org

ISPE Supports Pharmaceutical Industry with New Guide on Project Management

--Guide is industry's first to address unique aspects of Project Management within the pharmaceutical industry--

(TAMPA, FLORIDA, USA, 16 January 2012) – ISPE announced today that it has released a new industry Guidance Document, *Project Management for the Pharmaceutical Industry*. This ISPE Good Practice Guide is the first document of its type to discuss and compile best practices for project management concepts within the context of the pharmaceutical industry. The Guide serves as a toolkit to help pharmaceutical project managers deliver successful projects quickly. It also offers content that addresses managing risks common to pharmaceutical projects and develops a common language for the pharmaceutical Project Management community.

"The pharmaceutical industry presents unique regulatory and business aspects to the field of Project Management," said Dr. Trish Melton, one of the Guide's lead authors. "Increased speed to market for new drugs has meant that most projects are under pressure to deliver faster while maintaining compliance in a shifting regulatory environment and meeting cost and scope objectives in an increasingly competitive market. This welcomed Guide is the industry's first to offer user-friendly, specific tools and techniques to integrate regulatory compliance with the project lifecycle."

The *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* is a reference source of good practices for project management. The Guide covers a wide variety of project types within the pharmaceutical industry, including facility, improvement, product, IT, and automation projects.

The Guide covers the tools and techniques supporting project delivery, the lifecycle of a typical project in the pharmaceutical industry, and how compliance to pharmaceutical industry regulations should be integrated with the project lifecycle. Key concepts include Business Context, Regulatory Context, Value Management, Technology and Innovation, Collaborative Working, Integrated Validation Lifecycle, Integrated Risk Management, and the Stage Gate Approach.

To complement the Guide, ISPE will debut its Facility Project Management Training Course 19 – 20 March 2012 at its San Diego, California USA training event and 28 – 29 March at the ISPE Frankfurt Conference. The course will focus on the project management of facility projects. For more information on the course, visit www.ISPE.org/training.

For more information on the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry*, or to order an electronic copy or bound version, visit www.ISPE.org/ISPE-Good-Practice-Guides/Project-Management-Pharmaceutical-Industry.

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ISPE Announces Q4 2011 Certified Pharmaceutical Industry Professional™ (CPIP™) Recipients

(TAMPA, FLORIDA, USA, 23 January 2012) – ISPE announced today that five pharmaceutical professionals were awarded Certified Pharmaceutical Industry Professional™ (CPIP™) credentials during the fourth quarter of 2011. This credential is given to experienced pharmaceutical technical professionals who meet the program's eligibility requirements and pass a rigorous exam covering product development, facilities and equipment, information systems, and other pertinent areas of pharmaceutical industry knowledge.

The five individuals who earned their CPIP certification are:

- **Jeffery Odum, CPIP** – Operations Manager, Integrated Project Services (IPS), USA
- **Jennifer Lauria Clark, CPIP** – Southeast Manager of Technical Services, Commissioning Agents, Inc., USA
- **Amy Lineberry, CPIP** – Project Manager, SpecLine Consulting, Inc., USA
- **Steven Miller, CPIP** – Director of Process Engineering, MedImmune, Inc., USA
- **Jean-Claude Cusin, CPIP** – Quality Engineer, Merck Serono SA, Switzerland

The CPIP credential is administered by the ISPE Professional Certification Commission (PCC), an independent board within ISPE. In order to be eligible for CPIP certification, a candidate must have a bachelor's or higher (or globally equivalent university degree) from an educational institution accredited by a generally-recognized accrediting body (e.g., ABET, SACS, UK Science and Engineering Research Council) and three years of documented drug product development/manufacturing pharmaceutical/ biotechnology industry-related experience or five years of documented product development/ manufacturing experience in an industry other than the pharmaceutical or biotechnology industries.

The PCC recently revised the eligibility and recertification requirements for the CPIP credential to shift focus to a career "lifecycle" management approach to technical competencies and the assessment and maintenance of those competencies as requirements for awarding the credential. CPIP seekers will now experience streamlined eligibility and recertification requirements, earlier access to the program for Young Professionals, and a greater focus on pharmaceutical industry-specific knowledge and skills

More information on the CPIP certification program, including detailed eligibility, examination, and re-certification requirements, is available at www.ISPE-PCC.org.

FOR IMMEDIATE RELEASE
For more information, visit www.FacilityoftheYear.org or contact:

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2012 Facility of the Year Awards (FOYA) Winners Announced

(TAMPA, FLORIDA USA, 24 January 2012) – The Facility of the Year Awards Judging Panel has named five Category Award Winners and selected one project for Special Recognition in the 2012 Facility of the Year Awards (FOYA) program. The winning projects for 2012 are located in Germany, India, Ireland, Italy, and the USA. The winning companies and respective award categories are:

- **Chiesi Farmaceutici S.p.A.,** winner of the Facility of the Year Award for Sustainability for its Chiesi Farmaceutici Research and Development Centre facility in Parma, Italy
- **Eisai Pharmatechnology & Manufacturing Pvt. Ltd.,** winner of the Facility of the Year Award for Project Execution for its Eisai Knowledge Centre facility in Visakhapatnam, Andhra Pradesh India
- **Merck & Co., Inc.,** winner of the Facility of the Year Award for Facility Integration for its Merck Vaccine Bulk Manufacturing Facility (VBF) Program of Projects in Durham, North Carolina USA
- **Rentschler Biotechnologie GmbH,** winner of the Facility of the Year Award for Equipment Innovation for its REX III manufacturing facility in Laupheim, Germany
- **Roche Diagnostics GmbH,** winner of the Facility of the Year Award for Operational Excellence for its TP Expand project in Penzberg, Germany
- **National Institute for Bioprocessing Research and Training (NIBRT),** winner of the Facility of the Year Award Special Recognition for Novel Collaboration for its New Greenfield facility in Dublin, Ireland

The FOYA program is the pharmaceutical industry's premier awards program dedicated to celebrating innovation and accomplishments in facility design, construction, and operation. The Facility of the Year Awards program recognizes state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a quality project, as well as reduce the cost of producing high-quality medicines. Now entering its ninth year, the awards program effectively spotlights the accomplishments, shared commitment, and dedication of individuals in companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of patients worldwide. The Facility of the Year Awards program is sponsored by ISPE, INTERPHEX, and *Pharmaceutical Processing* magazine.

"Our 2012 Category Winners reflect the true spirit of the Facility of the Year Awards program," said Judging Panel Chairperson and upcoming "Lessons from 483s" conference keynote speaker Chaz Calitri. "The winning projects exemplify innovation in pharmaceutical manufacturing for the benefit of patients all over the world, who depend upon us for medications that are high quality, available and

affordable. Our winners come from 5 different countries and include novel, low cost biologics facilities, creative and visionary industry-academia-government collaborations, and hyper-fast track investments made to ensure vaccine's get to patients in need. We are also proud this year to recognize facilities that seek to speed up drug development as well as facilities that greatly reduce the environmental "footprint" of manufacturing in the communities in which they reside"

The Facility of the Year Awards program is truly global, as submissions over the past eight years have been received from more than 25 different countries and territories. Each of the submissions was reviewed by an independent, blue-ribbon judging panel consisting of global senior-level executives from all aspects of the industry. The judging panel met personally in December to select the Category Awards Winners and select the 2012 overall winner, which will be announced to the world for the first time at ISPE's Annual Meeting in November.

2012 Facility of the Year Events
There will be several opportunities to learn first-hand about the facilities being honored as "best in their class." These opportunities include:

- **INTERPHEX*2012*** – Attendees will be able to meet the Category Award Winners at the Facility of the Year Awards Display Area near the front of the exhibit hall of the Jacob K. Javits Convention Center in New York City, New York, USA. Team members from winning companies will be on-hand to discuss the success stories associated with these pharmaceutical manufacturing facilities. More information, including registration information, can be found at www.interphex.com.
- **ISPE 2012 Annual Meeting** – Category Winners will give presentations about their winning projects during ISPE's 2012 Annual Meeting, 11-14 November in San Francisco, California USA. The highly anticipated announcement of the 2012 Facility of the Year Awards Overall Winner will also take place during the Keynote Session of this event. Information and updates on this global event can be found at www.ISPE.org.
- **Feature Articles** – Comprehensive coverage will appear in *Pharmaceutical Processing* magazine and ISPE's *Pharmaceutical Engineering* magazine.

Comprehensive details about each of this year's award-winning projects and their support teams, plus additional information on the awards program itself, can be found at www.FacilityoftheYear.org.

About *Pharmaceutical Processing*
Pharmaceutical Processing magazine is the pharmaceutical industry's leading information provider, reporting on a full range of innovative new products, equipment, technology and trends for 28,000 engineers and managers responsible for the development, manufacture, validation and packaging of pharmaceuticals. An official sponsor of INTERPHEX, Pharmaceutical Processing distributes critical information to these professionals in a timely manner through a full range of print, electronic and online media. For information, visit www.pharmpro.com.

About INTERPHEX
Now in its 33rd year, INTERPHEX is the largest gathering for FDA regulated drug and drug delivery products for technical professionals in development & manufacturing for pharmaceutical, biologic, generic, contract manufacturing and supporting services. ISPE is the exclusive official association sponsor of this industry-leading annual event. Scheduled for May 1-3, 2012 at the Javits Convention Center in New York City, NY, USA, the event hosts more than 650 suppliers on the show floor along with an expanded conference program, featuring a high-profile roster of subject matter experts. For information, visit www.INTERPHEX.com/ISPE.

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Connecting a World of Pharmaceutical Knowledge

FDA's Grace McNally to Appear at ISPE Facilities Conference

--Event to explore lessons learned from FDA 483s in tracks focused on Biotech, Oral Solid Dosage Processing and Containment, and Process Validation--

(TAMPA, FLORIDA, USA, 26 January 2012) – ISPE announced today that the US FDA's Grace McNally will appear at the Society's upcoming Lessons from 483s: Enhancing Efficiency, Quality and cGMP Compliance Conference. McNally will add her expertise to that of other industry and regulatory experts at the two-day event, which will review recent regulatory citations (FDA-483s) and provide guidance on how the citations can be avoided. This conference will give pharmaceutical professionals the vital insights into regulatory issues they need in order to avoid the costly and damaging consequences that can result from 483 citations, such as recalls and plant shutdowns.

Educational content will address 483s in the context of biotech, oral solid dosage processing and containment, and process validation. The conference, part of ISPE's Facilities of the Future conference series, will take place in Tampa, Florida USA on 27 – 28 February 2012.

"As the technical voice of manufacturing and engineering in the pharmaceutical industry, ISPE is committed to presenting programs that facilitate relevant dialogue and the sharing of best practices among industry leaders, manufacturing experts and leading regulators," said ISPE's new President and CEO Nancy Berg. "At a time when manufacturing operations are under tremendous pressures to improve effectiveness, deliver quality and reduce costs, ISPE is responding with new programs and conference formats that feature dynamic and focused session content. Our events are developed to deliver information, discussion and networking that lead to new ideas, problem-solving and process improvement concepts that, when applied, have positive bottom-line results."

The event will feature three keynote presentations from experts in the pharmaceutical industry, including:

- **Michael Lewis, President, Eisai Product Creation Systems, USA**
  Small Molecule Researcher's View to Facilities of the Future

- **Andy Skibo, Executive Vice President, MedImmune, USA**
  Biotech Perspective on Cost Effective Operations

- **Chaz Calitri, Vice President, Global Engineering, Pfizer, USA**
  2020 Vision - the Next Generation of Manufacturing Facilities

The conference will contain three distinct tracks:

- A Biotech track led by Wendy Lambert, Director Pharma Business Support, Abbott, USA, Steven Miller, Director, Process Eng, MedImmune, USA, and Andrew Skibo, Executive Vice President, Operations, MedImmune, USA.

- An Oral Solid Dosage Processing and Containment track led by Paul Egee, Product Manager, IMA North America, USA, Alan George, Product Manager, ILC Dover Inc., USA, and Raymond Scherzer, PE, PM SET, LLC, USA.

- A Process Validation track led by Joanne Barrick, Advisor, Global Validation Support, Eli Lilly & Co., USA.

For more information on this conference, including detailed agendas and registration information, visit www.ISPE.org/FacilitiesConference.

ISPE will also hold a related training course immediately following this conference. The course, titled "Managing the Risk of Cross Contamination: Applying the Risk-MaPP Baseline® Guide" will be held 29 February – 1 March 2012 at the same venue. More information on this training course can be found at www.ISPE.org/2012-Tampa-Training.

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.

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ISPE NEWS
FOR IMMEDIATE RELEASE

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Connecting a World of Pharmaceutical Knowledge

ISPE to Present Conferences Focused on Pharmaceutical Aseptic Processing

--Events to explore global evolution of aseptic processing in tracks focused on barrier isolation, vaccines, and technology innovations--

(TAMPA, FLORIDA, USA, 01 February 2012) – ISPE announced today that it will present two conferences focused on the global evolution of aseptic processing in the pharmaceutical industry. The two-day events will address the challenges companies face in producing sterile pharmaceutical products. The first conference will take place in Tampa, Florida USA on 29 February – 1 March 2012. A similar program, with a strong focus on European concerns, will be offered in Frankfurt, Germany on 26 – 27 March 2012.

Attendees will learn from leading manufacturing experts on barrier isolation, vaccine manufacturing, and technology innovations related to aseptic processing. Each track will draw heavily from the recently released, FDA-reviewed *ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Second Edition)*, the industry's go-to Guide for aseptic processing. Attendees will receive a complimentary copy of the Guide, a US$465 value.

"As the technical voice of manufacturing and engineering in the pharmaceutical industry, ISPE is committed to presenting programs that facilitate relevant dialogue and the sharing of best practices among industry leaders, manufacturing experts and leading regulators," said ISPE's new President and CEO Nancy Berg. "At a time when manufacturing operations are under tremendous pressures to improve effectiveness, deliver quality and reduce costs, ISPE is responding with new programs and conference formats that feature dynamic and focused session content. Our events are developed to deliver information, discussion and networking that lead to new ideas, problem-solving and process improvement concepts that, when applied, have positive bottom-line results."

Titled "Global Evolution of Aseptic Processing: Implementing Risk-Based Manufacturing Solutions," the conferences will feature three keynote presentations from recognized industry experts in aseptic processing:

- **William B. Wiederseim, President & CEO, PharmaBioSource, Inc., USA**
  The Market for Parenteral Products and Facilities

- **Udo J. Vetter, Vetter Pharma Fertigung GmbH & Co. KG, Germany**
  Why Vaccines Are No Longer in Vials

- **Mark Von Stwolinski, Vice President Architectural Services, CRB Consulting Engineers, Inc., USA**
  Special Presentation on the ISPE Sterile Guide by Co-Author

–More–

The conferences will contain three distinct tracks:

- A Barrier Isolation track led by Jack Lysfjord, Principal Consultant, Lysfjord Consulting LLC, USA.
- An Aseptic Technologies for Vaccine Manufacturing track led by Jeffrey Biskup, President and CEO, CRB Consulting Engineers, Inc., USA.
- A Technology Innovations in Aseptic Processing track led by Joerg Zimmermann, Director Process Development and Implementation, Vetter Pharma Fertigung GmbH & Co. KG, Germany.

For more information on these conferences, including detailed agendas and registration information, visit www.ISPE.org/2012-Aseptic-Conference (Tampa) or www.ISPE.org/2012AsepticEUConference (Frankfurt).

Additionally, related training courses will be offered in conjunction with both events:

- In Tampa, a new course titled "Sterile Product Manufacturing Facilities: Applying the new ISPE Baseline® Guide and FDA Guidance Principles to Design and Operation," will be offered immediately preceding the conference on 27 – 28 February 2012. Detailed information on this course can be found at www.ISPE.org/2012-Tampa-Training.

- In Frankfurt, two training courses will be offered immediately following the conference, on 28 – 29 March 2012. "Facility Project Management in the Regulated Pharmaceutical Industry" and "Managing the Risk of Cross Contamination: Applying the *Risk-MaPP Baseline® Guide*." Detailed information on these courses can be found at www.ISPE.org/2012-Frankfurt-Training.

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