INSIDE THIS ISSUE

President’s Message ................................................................. 2
Board List .................................................................................. 2
Membership Development Corner ........................................... 3
CaSA Member Spotlight – Wes Robbins .................................... 4
Student Chapter Corner .......................................................... 6
Highlights from the ISPE Annual Meeting ............................... 7
YP Corner: Highlights from the YP Financial Planning Event .................................................. 12
CPIP Study Group .................................................................... 13
Cryogenic Ice Fog as a Means to Induce Uniform Ice Nucleation During Lyophilization 14
20th Annual ISPE CaSA Technology Show Details .................. 16
Toys for Tots Event ................................................................. 17
Automation Forum .................................................................... 18
Upcoming Events ....................................................................... 20
2013 Advertising and Sponsorship Opportunities .................... 21

2013 Upcoming Events

January 29, 2013: Supply Chain Management Education Event (tentative date)
February 22, 2013: CaSA Leadership Forum
February 23, 2013: Casino Night
March 26, 2013: 20th Annual Biotechnology Show
April 6, 2013 BEST Day at the NC Museum of Natural Sciences, Raleigh, NC
May 6, 2013 Annual CaSA Golf Tournament at Prestonwood Country Club, Cary, NC
Therapeutic Thursdays

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President’s Message

Being a Member of ISPE CaSA in 2012 is exciting. Not only are we working very hard right here at home to provide you outstanding educational programs and networking events, ISPE International is keeping us up to date with the production of new baseline guides, discussion forums, Communities of Practice and a website with a great deal of knowledge. On the ISPE International website you can take advantage of the Membership directory, online training courses, event schedule, Communities of Practice, and Volunteer Resource pages.

We just got home from the 2012 ISPE Annual Meeting hosted in San Francisco, CA where ISPE CaSA brought home two awards for Outstanding Student Innovation and for Outstanding Communication (now divided into Newsletter and IT Committees). Congratulations to our Committee Chairs LeAnna Pearson and Wendy Haines. We also are the home to the 2012 Facility of the Year Award Winner for Project Integration for its Vaccine Bulk Manufacturing Facility (VBF) Program of Projects in Durham, North Carolina. Congratulations to Merck & Co., Inc. and all of your team to achieve this prestigious award. We are proud of your accomplishments.

I would like to take a moment and thank our entire Board of Directors for implementing a Sponsorship Program that was initiated and requested several years ago. Our Board worked hard to come up with a plan that we thought was unique to our Chapter. We are excited about its launch and hope that you will take a look at the website and see the different options there are to sponsor our Chapter events. Thank you to all of our current sponsors for your continued support.

Each event we successfully host increases the value of ISPE CaSA. Since the last newsletter we have had two successful Therapeutic Thursdays in Raleigh and Durham, a Young Professionals Financial Planning Forum, a Student Resume Workshop, a successful 3 track Automation Forum and Toys for Tots event at GSK-RTP. Thank you to our Members and non-Members who volunteered their knowledge, experience, time and resources to advance the Society and its mission.

It is important to know how our Membership understands what we are doing. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please let me or any other Board Member know how well we are doing or what we can do to improve.

In each newsletter you will see me thanking our volunteer Members who spend their time reviewing newsletters, cleaning up after events, or helping with whatever we need done to make the Chapter successful. The entire Board appreciates our good friends for staying involved and welcome fresh ideas and new faces at our committee meetings. And now a To Do List:

- Get Involved. Let us know if you are interested in volunteering with a committee or in active leadership of ISPE CaSA. Specific committees

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Membership Development Corner

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have stated in this newsletter that they are in need of help. Membership and Education are two committees that are in the most need of volunteers. Please contact info@ispe-casa.org or the committee chairs if you are interested in any of the committees.

- **Share your ideas.** Send in some fresh ideas for 2012-2013 educational programs and networking events. We will have a drawing from everyone who sends in an idea by January 4, 2013. The winner of a gift card will be announced in the next newsletter.

- **Come see us…**
  - Jan. 29, 2013 (tentative) Supply Chain Management Education Event
  - Therapeutic Thursdays
  - CaSA Leadership Forum Friday, Feb. 22, 2013
  - Casino Night Saturday, Feb. 23, 2013
  - 20th Annual Biotechnology Show Tuesday, Mar. 26, 2013

I wish you the best for the Holidays and a Happy New Year.

*Jennifer Lauria Clark, CPIP*
Chapter President

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**Celebrating Our New Members!**
By Jerry “Patch” Paciorek, CaSA Membership Development Chair

I would like to thank all of our Members that have taken the time to introduce potential new Members to ISPE and our CaSA Chapter. Your efforts have resulted in 43 new CaSA Members joining since our last newsletter was published, and bringing our total to 109 new CaSA Members since July 1, 2012.

**Volunteers Wanted**
Do you enjoy a challenge and like social events? If so, the Membership Development Committee wants you. Many people in the industry have never heard of ISPE and many of our ISPE Members do not know all of the benefits an ISPE Membership offers. Help us spread the word about CaSA ISPE. Please contact Jerry “Patch” Paciorek at paciorek@cagents.com.

**From the ISPE International Office**
Are you are looking for the perfect gift that will last long after the golf balls are lost, the sweater is returned or the fruitcake is re-gifted? Have you thought about ISPE Membership, guidance documents, recorded webinars or an invitation to your local holiday event as a great gift to give a friend or colleague? It is also a great time of year to give yourself a gift. Refer a Friend to join ISPE and get a free month of Membership. Read more at http://www.ispe.org/membership-referral-program. We just sent a renewal notice to a Member who received $209.92 of credits. His Membership renewal was just $19.08.

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**Welcome New Members**

New Members who joined September 27, 2012 through November 29, 2012

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<td>Swathi Gunuganti</td>
<td>Gillian Meyer</td>
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<td>Richard Craft</td>
<td>Cindy Hamilton</td>
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<td>Ben Hund</td>
<td>Dr. Daniel Nazarenko</td>
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<td>Jeff Hunt</td>
<td>Bob Petersen</td>
<td>Yingqiu Zhou</td>
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<td>Keith Dillon</td>
<td>Mark Hurt, Jr.</td>
<td>Lindsay Pinnick</td>
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<td>Charles Dumond</td>
<td>Chris Kim</td>
<td>Dr. Victoria Ramsauer, PhD</td>
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Member Spotlight

Interview of Wes Robbins
By Mike Kriston, Co-Chair of the Newsletter Committee

Recently, the CaSA Newsletter had a chance to interview one of our long-time Members, Wes Robbins. See what insights he was able to provide to the Chapter below!

Q: What is your full name?
A: Wesley Nelson (Wes) Robbins

Q: Birth Place?
A: Roanoke Rapids, North Carolina

Q: What College did you attend?
A: North Carolina State University, 1984 Graduate (I was there for the '83 National Championship). Go Pack!

Q: Tell me a little about your personal life.
A: I grew up on a farm in Northampton County and graduated from Northeast Academy in 1980. After college, I worked at GE Semiconductor (RTP), Delta Airlines (RDU) and Turf Tech, Inc. (Raleigh) before joining Hydro. I live in North Raleigh and I am married to Leesa Deterding, PhD. No kids.

Q: What is your present position? What do you do with Hydro?
A: I am VP, Business Development for Hydro Service and Supplies, Inc. I oversee all sales and marketing for the company. Our Corporate Headquarters is located in Durham, NC. We have offices in Durham, NC, Gaithersburg, MD, Levittown (Philly), PA, Garfield, NJ, Wallingford, CT and Puerto Rico.

Q: How long have you been with Hydro?
A: Since March 15, 1993

Q: Tell me about your career path, and how you ended up where you are today.
A: I joined Hydro as a sales specialist handling engineered projects and lab system sales for our Durham office. In the late 90’s, engineered projects for our Maryland office were added to my responsibilities and I remained in that position for 16 years until being named Director of Sales in 2009. I was named VP, Business Development in 2010.

Q: What is your favorite part of your job?
A: There are two favorite parts to my job. The first would be working with our sales team and watching them succeed. Our sales were up significantly last year in a poor economy and that’s attributed to the team’s efforts and willingness to work harder with our clients to serve their best interest while keeping cost in check. My job is to coach and lend help to those efforts and to make sure that they have the tools and technical support needed to be competitive in our market. My second favorite part of the job is having the opportunity to meet new people and to have met the many people that I have over the years. I thrive on that and have so many good friends in this industry. I love a good 10-20 minute conversation with a complete stranger and usually find some commonality with just about everyone. I usually have a real life story to tell, and I try to make people laugh even when they’re having a bad day.

Q: How long have you been a Member of ISPE?
A: I joined in 1996. I was encouraged to get involved in a committee, so Alan Jones talked me into joining the “Vendor Committee” which planned and promoted the annual show. This later became the Tech Show Committee which I was a part of for 12 years, serving as co-chair the last four. I also served on the CaSA BOD from 2007-2011.

Q: What benefits have you realized from being a Member of ISPE?
A: Without question, the networking and connections made through ISPE. When I think about the people I have met, the overwhelming majority are people that I either met through ISPE or strengthened a relationship with through the organization.

(continued next page)
Member Spotlight

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Q: Any Mentors/Role Models that have helped to shape your life?
A: My family was a great influence on me. My dad believed in doing things the hard way just to validate it, so my work ethic comes from him. He passed away when I was 15. I had to grow up a little faster than a kid would normally, and my mom, older brothers, and a wonderful aunt were there to guide me. At 89 years of age, my mom is still an inspiration and very interested in what I do professionally. Aside from family, I have had the unbelievable fortune to meet so many great and influential people in my life. I spent time under the wings of some, while others took a moment to lend guidance or share experiences from life’s lessons. I have been inspired by many.

Q: If you weren’t involved in Pharma, what business do you think you’d be in?
A: Probably sports. I aspired to be a basketball coach in another life and chased that for a few years.

Q: What is one skill you wish you had that you don’t?
A: The skill to play a musical instrument. Drums, guitar and keyboard would have been my preference.

Q: Any hobbies? What are they?
A: I am an avid outdoorsman and love to hunt, saltwater fish, fly fish, golf and “beaching”. I like riding motorcycles and attending Wolfpack games.

Q: Do you collect anything?
A: Antiques, Roseville Pottery and gray hair. I was on a roll with the gray hair but have misplaced a lot of them in the past few years.

Q: Finish this sentence - “I need more…”
A: I need more hours in the day for whatever task is at hand. Whether it’s work, play, or spending time with family and friends, I always feel like I’m on a schedule and I wish I had more time.

Q: Favorite Food?
A: Steak and seafood.

Q: What is something that people would be surprised to learn about you?
A: My obsession with the game of basketball. I’m a “Biker.” I enjoy riding my Harley and custom motorcycles. I am an FAA Licensed Private Pilot. The “pilot” thing will send some over the edge. Don’t worry. I don’t have the time to fly much anymore so the skies are safe.

Q: Last movie you saw?
A: The Avengers. My kind of movie!

Q: For those in the early stage of their careers, what advice would you give them?
A: Hopefully, they have or will get a job that they love, as enjoying your profession is important. Seize the moment and don’t take things for granted or put off for tomorrow what can be done today. Always take the “glass half full” (vs. “half empty”) approach to life, work, and play and don’t expect a “full glass” without having worked to fill it. Regarding ISPE, get involved, meet people and take advantage of the organizations offerings. You’ll get out of it whatever you put in and the return is usually greater than the investment.

We’d like to thank Wes for his time; next time you see him at an ISPE event, be sure to say “Hi!”

(continued from previous page)
Congratulations Are in Order for the CaSA Student Chapters
By the CaSA Newsletter Committee

Congratulations to our CaSA Student Committee for winning the International ISPE Award for Outstanding Student Innovations! Congratulations to LeAnna Pearson, Chair, and Blake Derrick, Co-Chair, and the entire CaSA Student Affairs Committee. Students are our future leaders and we are proud to support and encourage them.

Speakers Requested for Student ISPE Chapter Meetings
During this time of year, we think about giving and what we can give to others and our community. What better way to “give,” than to be a speaker at one of our local ISPE Student Chapters. CaSA has Student Chapters at the following schools: Campbell University, East Carolina University, East Tennessee State University, North Carolina A & T State University, North Carolina Central University, North Carolina State University, and the University of North Carolina, Chapel Hill.

Please contact LeAnna Pearson at: ispecasasac@gmail.com
Highlights from the Perspective of CaSA’s Varied Groups

2012 ISPE Annual Meeting Synopsis: A Student’s Perspective

By Gurpreet Jawa, President of the NCCU Chapter

I was one of seven students from the North Carolina Central University Chapter of the ISPE sponsored by the CaSA to attend this annual meeting, held in San Francisco November 11-14. Most of our trip was funded by CaSA and I am sure that I speak for my fellow NCCU students in saying that we are very grateful for the opportunity. I found the meeting to be the ideal combination of learning, networking, and socializing.

On the learning side, I benefitted most from the plenary session held November 12. In particular, the opening address by the CEO and President of the ISPE, Nancy Berg, which summarized the ISPE’s mission and the direction in which she saw ISPE and the biotechnology industry headed. The industry outlook was further expanded upon by one of the next speakers, Murray Aitken, from IMS. As a student graduating this coming May, I felt re-assured to hear from Nancy and Murray that, although the biotech industry had experienced negative growth as a result of the worldwide economic recession of the last few years, all indicators pointed to a strong rebound in 2014. This point was reiterated by another plenary speaker, the very dynamic new Chairperson of the ISPE, Charlotte Frueergaard, Ph.D. She emphasized the global outreach of ISPE and I was particularly gratified to hear her goal of making ISPE as inclusive of as many countries/nations/ethnic groups as possible. The keynote speaker of the session was Stephen P. Spielberg, M.D., a gentleman with very extensive and ongoing experience in academia, industry, and now, as Deputy Commissioner for the medical products and tobacco division of the FDA. He spoke on the importance of good collaboration between regulatory agencies and biotech companies, and emphasized how such collaboration is critical to insuring that the safest and highest quality products continue to be delivered to the public worldwide.

On the networking side, I met many, many people from both the U.S. and several other countries including Singapore, Germany, India, Denmark, and Italy. I exchanged business cards with almost all of them. Since the meeting, I have begun connecting with some of them on LinkedIn as well as in other social media. I was particularly gratified to have met three people. First, Jane Brown, Director of External Advocacy at GSK here in North Carolina who very enthusiastically offered to come and speak to our NCCU Chapter. Next, Mr. Arthur Burson, Vice President of Global Engineering Services at Merck, Inc, who said he’d be more than happy to give our students a tour of Merck’s facility of the year here in NC, which makes vaccine for varicella virus. Finally, Yukti Gangwani, a Member of the ISPE Young Professionals and outgoing President of her university's ISPE Chapter in San Francisco, which won the Student Chapter of the Year award. As president of the NCCU Chapter, I wanted to get some ideas from her on what she did with her Chapter. She emphasized to me the importance of fund-raising, and I plan to make that a strong goal of our Chapter this coming semester.

Finally, on the social front, the ISPE did a good job of making sure there were ample opportunities for informally getting together, such as a nice restaurant near the conference location with breakfasts for young professionals, and the big party Tuesday night, in particular. As much as I enjoyed meeting people, especially other students, I equally appreciated the chance to get to know my NCCU peers in a setting outside the classroom and conference room. We really bonded!

Once again, on behalf of the NCCU Student Chapter of the ISPE, I wish to express my deep gratitude to CaSA for making this excellent opportunity possible through its generosity, administration and guidance.
Annual ISPE Meeting

Annual Meeting a Huge Success for Young Professionals!

By Amy Lineberry, CPIP, Chair of International YP Committee and CaSA Education Chair

Young Professionals (YPs) were a huge part of this year’s Annual Meeting. YPs were highlighted in CEO Nancy Berg’s Keynote and by Charlotte Enghave Fruergaard, the new Chair of ISPE. On Monday night, the YPs hosted a party at Jillian’s. It was a huge success with over 90 people in attendance! There was great food, networking, and pool playing. Tuesday was the big day for the YP Committee meeting and awards. The Committee was able to recruit more than 260 YPs worldwide in 2012 for a total of over 360 since the start of the YP initiative.

The YPs have been a huge part of the growth of ISPE in the past two years. At the beginning of the YP Committee meeting, the winners of the YP Recruitment Challenge were announced. CaSA won the award for the YP Spirit Award for Large Affiliate/Chapter (highest percentage of YPs recruited) and the YP Above and Beyond Award for Large Affiliate/Chapter (the most YPs recruited). This is mostly thanks to Hospira, as they helped over 40 CaSA Young Professionals become ISPE Members!

Also on Tuesday was the Membership luncheon. After hearing from the new CEO, the outgoing Chair, and the incoming Chair, awards were handed out. The highlight of the lunch was the Committee of the Year award. Two Committees won the award this year. The cGMP Conference Committee won for the outstanding attendance of over 300 people in Baltimore. The second committee to win was the International YP Committee. We won for the contribution of added growth to ISPE. The YPs are the fastest growing Membership group for ISPE.

The YP Committee also arranged for a Meet and Greet on Tuesday and Wednesday morning. This was a great way to get to know students and YPs attending the Annual Meeting.

If you missed this year’s Annual Meeting, join us for the 2013 Annual Meeting to be held in Washington, DC. Hope to see you there!!
Annual ISPE Meeting

ISPE Communities of Practice: Get Involved in Your “Community”
By Keith Gibbs, PM COP Chair

Global Communities of Practice
Global ISPE COPs are established and supported by ISPE. They include Members from all over the world. Online communities are established for each global COP (www.ispe.org/cops) enabling Members to join any or all of ISPE’s COPs and begin actively participating through participation in discussions, searching for other COP Members, and accessing valuable content developed by community members for community members. Global COPs are governed by volunteers comprising a Council or Steering Committee.

Development of the PM COP
ISPE’s Project Management Community of Practice (PM COP) was formed in 2005 by a group of PM professionals with interest in promoting project management “best practices.” Their vision was to promote the importance of quality PM practices in all aspects of the pharmaceutical industry. This includes the development and launch of new drugs and the design, construction, and commissioning of new and renovated manufacturing facilities. The PM COP has been successful in creating a body of knowledge specific to the professional needs of PM practitioners, primarily through the creation of the Project Management Good Practice Guide (PMGPG). The PM COP encourages the exchange of ideas that impacts the product lifecycle.

Mission of the PM COP
The PM COP is a dynamic forum for professionals working within the Pharma Industry who have an active interest in promoting “continuous improvement” project management by creating a body of knowledge specific to the professional needs of its Members. The PM COP is a global community of industry professionals who manage all, or parts of projects. PM COP Members have access to PM best practices, tools, techniques, and information about knowledge management, risk management, and project conceptualization and execution.

Ways to Get Involved with the PM Community of Practice
The PM COP has more than 3,000 Members who are supported by an active Steering Committee of subject matter experts (SMEs). The Steering Committee is committed to developing project management knowledge and content through discussion forums, education and training events, networking opportunities, and publications.

There are many ways for COP Members to contribute and to and learn from the PM community and Body of Knowledge.

By visiting the PM COP website Members can:
• Access Community Discussions monitored by PM COP Steering Committee Members to ask questions, share expertise, and find solutions to company and industry-related problems.
• Read technical articles in the most recent editions of the PM COP E-Letters.
• Download presentations, articles, and other relevant documents.
• Search for PM COP Members by name, company, Affiliate or Chapter, country, etc.
• Easily and conveniently access PM guidance documents, articles, and other valuable resources.

With so many ways to connect with PM COP Members and access valuable technical knowledge, there is no reason not to get involved. Visit today at www.ISPE.org/PMCOP and begin participating in your Community of Practice!

Local Communities of Practice
Local COPs are formed when there is a need to address issues and represent local interests in specific countries or language-based geographic regions. They must be developed in close collaboration with corresponding Affiliates/Chapters. Local COPs are not directly supported by ISPE and there are no online communities for local COPs.

Looking to establish a Local CaSA PM COP
The PM COP would like to establish a strong local PM COP in the CaSA Chapter. To make this effort successful, volunteers with an active passion for leading must be identified. This will lead to many great opportunities, primarily:
• Excellent networking opportunities with fellow PM professionals
• Opportunities to engage in detailed technical discussions with leading technical experts
• Participate in developing a Body of Knowledge that benefits individuals, companies, and the industry in general

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Congratulations to CRB:
ISPE’s Company of the Year

By the CaSA Newsletter Committee

Clark, Richardson & Biskup (CRB)

CRB was named the 2012 Company of the Year by ISPE at the annual ISPE meeting in San Francisco, California on November 13, 2012. ISPE’s Company of the Year Award honors a company that continually supports the Society’s commitment to provide knowledge and best practices that help meet the technical challenges of the pharmaceutical manufacturing industry.

CRB professionals serve as: authors of ISPE Guidance Documents, lead contributors to several ISPE Communities of Practice, ISPE Chapter Board Members, and regular speakers and session leaders at ISPE events.

The CaSA ISPE Chapter would like to extend a special “thank you” to CRB for their loyalty, participation, and sponsorship over the years. Congratulations, CRB, on a well-deserved award!

Other CaSA Awards and Recognition

By the CaSA Newsletter Committee

CaSA had a great 2012 year. In addition to Merck & Co., Inc. being the overall winner for Facility of the Year and Category Winner for Project Integration and CRB being awarded ISPE’s Company of the Year, we won two Chapter awards: Outstanding Student Innovation and Outstanding Innovation in Communications.

CaSA also won two awards regarding recruitment of Young Professionals: the YP Spirit Award for Large Affiliate/Chapter (highest percentage of YPs recruited) and the YP Above and Beyond Award for Large Affiliate/Chapter (the most YPs recruited).

Congratulations to all winners!!
Congratulations to Merck & Co., Inc.: Overall Facility of the Year Winner and Category Winner for Facility Integration

By ISPE

Merck & Co., Inc.
Vaccine Bulk Manufacturing Facility (VBF) Program of Projects

Faced with a projected production shortfall for the Varicella product franchise, Merck responded by delivering the Vaccine Bulk Manufacturing Facility (VBF) Program of Projects in Durham, North Carolina, USA. The 214,000-square-foot facility was built in record time and doubled the output of the vaccine used for Chicken Pox and Shingles.

The Merck Team used an innovative hybrid modular construction strategy that maximized off-site fabrication and equipment testing. Interesting for this application, the integrated construction execution strategy decoupled the design and construction of the building envelope and shell from interior process components, enabling parallel processes - as soon as the building shell was dried in and elevated slab poured, modules were installed simultaneously above the slab. This resulted in the ability to establish two independent work zones (above and below the slab) and saved five months on the schedule.

The team was organized as “One Team” with all Members co-located in an integrated partnership. LEAN Six Sigma principles were used throughout the project and resulted in an accelerated transfer of systems to operations. Integrating more than 200 lessons learned from the existing facility and process, the facility was delivered 40% faster than industry benchmarks.

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Contact: Mike Kriston, LEED®AP

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Highlights from the YP Financial Planning Event
By Jon Doyle, YP Committee Chair

The ISPE CaSA Young Professionals held a Financial Planning event on October 24, 2012 at North Carolina State University’s Biomanufacturing Training and Education Center (BTEC). After having dinner from Jimmy Johns, attendees networked with each other until guest speaker, Brandan Kot, began his presentation on how to prepare for the future.

Brandan is a Financial Planner for BB&T and has also spent time in the pharmaceutical industry as a sales representative. Brandan highlighted the importance of saving and planning for the future and gave specific ways to do so with the pros and cons of each. The presentation was very educational and upbeat. Many attendees referred to it as motivational once it was over. Time was allotted for questions afterward, which many had after learning the value of starting to plan early. The Young Professionals chair, Jon Doyle, stayed afterward for any attendees that wanted more counsel on how to best prepare for their future.

Look for the next networking opportunity put on by the Young Professionals at Sparians in North Hills early next year.

IT Corner: ISPE-CaSA Website Redesign Needs Your Help!
By David Knorr, IT Committee Chair

Exciting changes are coming to the ISPE-CaSA website as we are re-designing from the ground up. If you have any suggestions about what you would like to see on the ISPE-CaSA website or have any desire to get website design experience with Drupal please contact David Knorr at david.knorr@grifols.com or at info@ispecasa.org. Website design and Drupal experience not required.

Whew, sounds like a lot to learn! But what if you could join a team to attack this project as a group, like any other large pharmaceutical project? What if the international ISPE organization made comprehensive study materials available to you at no additional charge and all you had to pay for were the application and testing fees? Sounds like the 2012 ISPE CaSA CPIP Study Group!

Who We Are
We are 12 pharmaceutical industry professionals from many parts of the industry who met about two evenings a month in Raleigh from February into July to share our expertise, study the materials, answer lots of questions, and ask even more. Amy Lineberry, CPIP, and several other current CaSA CPIP’s shared their own CPIP experiences and led us through the seven knowledge domains step by step, subject by subject. Few, if any of us, made every single meeting. Most of us are still trying to find the time to do that last bit of studying before setting a test date (but some are really close!). And our first Member of the team made the grade just before the international meeting in San Francisco. But most importantly, we have all significantly broadened our understanding of our industry.

Enroll!
The 2013 CPIP Study Group will be enrolling soon. Why not take this opportunity to advance your knowledge of the industry from Product Development to Product Retirement, from Quality Systems to ICH Guidelines? Whether you are a veteran looking to better understand topics outside your areas of expertise or a Young Professional looking for a good foundation on which to build your career path, the 2013 CPIP Study Group could be your ticket to broader industry knowledge, a very valuable commodity in an industry changing as fast as ours. Join the team, we can get there together!
Lyophilization is an important downstream process for stabilizing pharmaceutical compounds. It involves removing water and solvents from a product by sublimation and desorption to levels, which will not support biological or chemical reaction. It is an excellent method to extend the shelf life of sensitive compounds for storage and transportation without subjecting them to detrimental high temperatures, and the only method available for a majority of compounds of biological origin. Consequently, lyophilization continues to be indispensable to the pharmaceutical industry despite its high cost and complexity.

The process of lyophilization consists of two major steps: freezing of solutions, and drying of the frozen solid under vacuum via sublimation and desorption. The drying step is further divided into two phases: primary drying (ice sublimation) and secondary drying (desorption). A successful lyophilization cycle can be defined by dried product that is visually and functionally acceptable, with short reconstitution times, potent active ingredients and increased shelf life. Control and repeatability of the cycle is inherently critical towards achieving consistently good product quality. Lyophilization technology is seeing a growing demand for improved process control due to the high value of the drugs being lyophilized as well as FDA initiatives like Quality by Design and PAT. Consequently, the industry has been quick to adopt and develop technologies that facilitate improved control of key process parameters. Controlling ice nucleation during the freezing cycle of lyophilization is one such parameter that is currently under investigation as a means towards more robust and scalable lyophilization cycles.

Importance of ice nucleation temperature

The onset of freezing or ice nucleation is one of the most important steps in the lyophilization cycle. For non-aseptic systems it is often a particle or impurity that serves as the nucleation point allowing ice crystals to grow and the product to freeze. However, in aseptic systems of high purity it is not uncommon for the product to cool well below its freezing temperature without ice crystal formation as there are no particulates available for ice nucleation—a process known as supercooling. Substances that cool below the freezing temperature without becoming solid are referred to as supercooled. The degree of supercooling determines the ice crystal structure, which in turn characterizes product resistance (resistance to water vapor flow through the product) during the drying cycle. Increased supercooling has been shown to form more numerous, smaller, ice crystals, resulting in higher product resistance and hence increased drying times. Studies have shown a 1 - 3% increase in primary drying time for every 1°C decrease in ice nucleation temperature1,2. Supercooling of vials during freezing can thus increase cycle times and operating costs.

Lack of uniformity in ice nucleation temperature caused by product supercooling can lead to vial-to-vial variability in ice crystal structure. Product vials which nucleate at higher temperatures dry faster than the ones that nucleate at lower temperatures, making it difficult to have a drying cycle that is optimal to all vials. This causes problems like vial breakage and melt back, and decreases overall yield and product uniformity.

Ice fog as a means to induce uniform vial-to-vial ice nucleation

One approach for reducing supercooling and controlling ice nucleation temperature is to introduce nucleating particles into the supercooled solution. A particularly advantageous nucleating particle is ice in the form of an ‘ice fog’ introduced into the freezing chamber3. The concept of temperature-controlled ice nucleation was earlier suggested by T.W. Rowe in 1994. A cryogenically created fog containing microscopic ice crystals is introduced into the lyophilization chamber after the vials have achieved the temperature at which nucleation is desired. The ice crystals subsequently make their way into the vials, and induce nucleation inside the vial. Although this technique has found success on a laboratory scale it has proven difficult to scale up to commercial lyophilizers. The difficulty is not only forming the ‘ice fog’ and ensuring it is sterile, but also uniformly distributing the ice fog rapidly throughout the freezing chamber so that all vials are properly seeded with nucleating ice particles.
The collaborative work of Linde and IMA Life has been to develop a means to produce and distribute an aseptic ice fog that nucleates all vials in a short time frame. This work has resulted in a novel means to produce and distribute a sterile ice fog that is applicable to laboratory, pilot, and production scale lyophilizers. This scalable cryogenic ice fog technology provides a much-needed degree of control during lyophilization and thus facilitates application of Quality by Design principles in this crucial downstream operation. The ice fog is created external to the chamber and is introduced and circulated through the chamber. The ice fog apparatus uses an ejector circuit consisting of a port for introducing ice fog into the freezing chamber and another port for recycling fog out of the chamber, with the ejector motivating the gas flow, and liquid nitrogen being the cold energy source.

The method can be retrofitted to existing freeze dryers and does not require the freeze dryer chamber to be a pressure vessel.

Conclusion

In summary, ice nucleation during vial freezing in lyophilization is an important process parameter that should be controlled. The scalable cryogenic ice fog technology as described here, can be utilized on laboratory, pilot, and production scale lyophilizers to induce uniform ice nucleation and eliminate vial-to-vial variability. Testing conducted by IMA Life and Linde using excipients such as mannitol and sucrose as well as actual customer product has shown clear indication of the positive impact of induced nucleation.

About the author

Frank Demarco is Product Manager, Freeze Drying Systems for IMA Life North America, based in Tonawanda, NY. Frank has managed engineering and technology groups within IMA (formerly BOC Edwards) for the past 20 years. He can be reached at frank.demarco@imalife.com.


Technical Tip from IPS

Working through the details of material and operator movements can minimize the risk to both product and personnel. A common operation like scooping material out of a nearly empty drum could require the operators to stick their heads into the drum. The operators could develop back problems or be overly exposed to the material they are scooping. From a product perspective, there is a good potential during the scooping that the drum could be tipped over or that particles from the operator’s person could fall into the material. Therefore, ergonomics of operations should be considered when doing risk assessments.

Erich Bozenhardt, P.E.
BioProcess Engineer
Integrated Project Services - IPS
20th Annual ISPE-CaSA Technology Show

Lights, Camera, Technology! Save the Date: March 26, 2013!
By Mike Putnam, Co-Chair of the 2013 CaSA ISPE Technology Show

Picture this…it’s a beautiful March morning as you leave the outside world and enter through the palatial glass entryway. As you arrive, your eyes wander in awe at the dazzling floor-to-ceiling windows casting light onto lavish granite detail. You continue your journey through the extravagant facility and arrive at three gorgeous ballrooms featuring soaring ceilings, custom alcoves, and accommodations fit for royalty. Sound like somewhere you’d like to be? Well, that’s exactly what you will experience at the upcoming 20TH ANNUAL ISPE CASA TECHNOLOGY SHOW!

MARCH 26, 2013 is the big day and there are many differences from previous years. The first obvious change is our venue. ISPE CaSA has secured over 60,000 sq. ft. at the Raleigh Convention Center (RCC), providing many new opportunities for the event.

Exhibitors
Exhibitors will be assembled throughout the facility in three separate areas. Corporate exhibitors will showcase their products and services in Ballrooms B & C, while non-profit organizations and colleges will exhibit in the ballroom lobby.

In conjunction with the Tech Show, an open-to-the-public life sciences career fair will be held in a dedicated area adjacent to the ballroom lobby. As a result of increased conference space, corporate exhibitors have options to select standard 6' tables, premium 8' tables, or premier 10'x10' booths. Exhibitors also have many new sponsorship opportunities ranging from attention-grabbing wall projections of their company’s logo to 20-minute product demonstrations on a private stage inside the ballroom. Keynote presentations will be delivered in Ballroom A over a mouthwatering lunch buffet sure to satisfy your taste buds.

Educational Sessions
Educational Sessions will be held just down from the ballrooms in five spacious breakout suites featuring state-of-the-art audio/visual equipment. Next door to the breakout suites is a private, full-service business area where show attendees can retreat to check email or take care of pressing work.

Networking Reception
As the day winds down, exhibitors and show attendees will gather in the ballroom lobby for a Networking Reception featuring gourmet cuisine and live entertainment. The reception will be the perfect setting to cap off an electrifying day of seminars and business discussions.

EXHIBITOR REGISTRATION IS NOW OPEN.

Your chance to attend the grand event is here. The Tech Show Committee has been working diligently to make this gathering the best one yet, but we certainly can’t do it without you. Our goal is to utilize this platform to showcase the life sciences capabilities of corporations, non-profit organizations, and universities throughout the ISPE CaSA Chapter. We expect record attendance as many organizations have already secured their spot.

Please finalize your plans to attend by visiting the exhibitor registration site today at www.ispe-casa.org/2013. Thank you and I look forward to seeing you there!
Got News or Story Suggestions for Upcoming Newsletters?

Send it to:
whaines@manganinc.com

Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

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**CaSA Event Highlights**

**Annual Toys for Tots Event**
*By the CaSA Newsletter Committee*

On December 6, 2012, 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 agreed 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 a sergeant from the US Marine Corps, who came to pick up the toys. He expressed his appreciation for our donations.

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.
CaSA Event Highlights

Automation Forum 2012 Highlights
By Amy Lineberry, CPIP, Brad Kasiba, CPIP & Keith Gibbs

After the Toys for Tots Event on December 6, over 40 Young Professionals and Professionals came together to learn and discuss issues related to Automation in the Pharmaceutical Industry. For those wanting to hear about an introduction to automation, a track on Automation 101 was available. John Hannon of Commissioning Agents and Keith Gibbs of Innovative Process Solutions “integrated” their views on the Basics and Benefits of Automation for the Life Sciences Industries. John provided “input” and gave examples of automation control scenarios to assure attendees were able to acquire data they could process while Keith provided supervisory oversight. Keith then delivered “output” to the group to identify applications and plug-ins to each individual’s job function. The group was responsive and the session “closed” with “open” discussion and Q&A.

The second track on Cloud Computing and Virtualization gave three approaches to the topic. First, Andy Robinson, Avid Solutions, gave an overview of the pros and cons, ups and downs of moving applications to the cloud. The cloud is viewed as less reliable moment to moment, though perhaps more professionally managed in the long run than local IS solutions. Poor choices might be primary historians that could lose original data in an outage and plain password protected data with high intellectual property exposure that could be stolen by criminal “neighbors” on your cloud servers. Better choices could well encrypt volumes for offsite backup and secondary historians.

Next, Andy presented Carlos Aponte’s (Eisai) slides on a proposed project to place a testing and development environment in the cloud. This would be a carefully controlled replicate of a production environment in which to vet new processes and recipes without compromising production schedules. By leveraging cloud space, they would only pay for space when they needed it and take advantage of someone else’s well managed data cen-
CaSA Event Highlights

(continued from previous page)

ter on demand. Absent a need for the highest levels of uptime assurance, this can be an appealing use of cloud space.

Finally, Michael Baldauff, Fujifilm Diosynth Biotechnologies, talked about non-cloud virtualization of older systems. The combination of the historical lag by OEM’s in adopting new computer Operating Systems and customers avoiding system architecture upgrades leads to aging systems running critical processes. One alternative to frequent (remember pharma manufacturing thinks in decades!) replacement these systems is to virtualize them on modern infrastructure. While this can be challenging, it is a viable alternative if the vendors are cooperative and practical challenges such as anti-malware coverage can be solved. Of course for those of us old enough to remember Yogi Berra, this begins to feel like mainframe déjà vu all over again!

The third and final track offered an overview and case study of an MES system implemented at Novo Nordisk in Clayton, NC. Novo Nordisk is a leader in the industry, providing a complete product portfolio of insulin and GLP-1 products and offers easy-to-use insulin delivery systems. A couple of the main objectives of the project were to harmonize MES and manufacturing processes through one central NovoNordisk core and reduce infrastructure operation costs. The MES system allows for a paperless electronic workflow.

Thanks to all the speakers for sharing their knowledge of Automation with the group. Also, thanks to the sponsors, CAI, CRB, and NNE Pharmaplan for their support of our event. Also, thanks to GSK for hosting the event.

Keep this CaSA Committee Member list handy so you can easily contact them when you need them!

Education Committee
Amy Lineberry, CPIP
Amylineberry@speclineconsulting.com

IT Committee
David Knorr
David.knorr@grifols.com

Technology Show Committee
Bruce Craven
bcraven@manganinc.com

Membership Committee
Patch Paciorek
Paciorek@cagents.com

Networking Committee
John Marr
John.marr@crbusa.com

Newsletter Committee
Wendy Haines
whaines@manganinc.com

Young Professionals Committee
Jon Doyle
Jdoyle@pci-llc.com

Biofest Day Committee
David Smith
davidglennsmith@gmail.com

Student Affairs Committee
LeAnna Pearson
ispeCaSAsac@gmail.com

CaSA COMMITTEES

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Jdoyle@pci-llc.com

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davidglennsmith@gmail.com

Student Affairs Committee
LeAnna Pearson
ispeCaSAsac@gmail.com

MEASURE, MONITOR AND VALIDATE IN LIFE SCIENCE ENVIRONMENTS

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www.vaisala.com/lifescience

phone +1 800 683 8374
sales@vaisala.com
Upcoming Events

MARK YOUR CALENDARS!

2013 Events

- **January 29, 2013**
  Supply Chain Management Education Event (tentative date)

- **February 22, 2013**
  Leadership Symposium at McKimmon Center, NCSU Campus, Raleigh, NC

- **February 23, 2013**
  Casino Night at Capital City Club, Raleigh, NC

- **March 26, 2013**
  20th Annual Biotechnology Show

- **April 6, 2013**
  BEST Day (Biotechnology, Engineering, Science, and Technology) at the NC Museum of Natural Sciences, Raleigh, NC

- **May 6, 2013**
  Annual CaSA Golf Tournament at Prestonwood Country Club, Cary, NC

Save the date:

2013 CaSA Leadership Symposium: “Take Control of Your Career"

The 2013 CaSA Leadership Symposium: “Take Control of Your Career,” will take place on Friday, February 22, 2013, at the NCSU McKimmons Center.

The all-day event will center on career planning and leadership development for students and young professionals working in the pharmaceutical manufacturing and services industry. The day will include networking opportunities and local industry speakers while offering a great venue to connect and learn about career paths in the pharmaceutical industry.

Sponsorships are still available for Platinum, Gold, Silver and Bronze levels—and we would love to hear from those interested in participating as either an industry mentor or speaker. We would especially like to thank Novartis Vaccines and Commissioning Agents for providing support as a Gold Sponsors.

Please contact Blake Derrick at derribf@kellyservices.com for more information. Keep an eye out for official registration details to be available in early January!

Don’t forget Therapeutic Thursdays!

Therapeutic Thursdays are held on the last Thursday of the month at Ale Houses located in cities around the Triangle area.

Please contact Amanda Wujcik at awujcik@ispe-CaSA.org if you are interested in sponsoring this fun networking event.
2013 Advertising Opportunities

Opportunities for Advertising in ISPE CaSA 2013 Electronic Newsletter

As with 2012, our Chapter will produce six e-newsletters in 2013. As you know, we send out the newsletters via e-mail and via Web link to all of our Chapter Members throughout the Southeastern U.S., which reach top-notch pharmaceutical, biotechnology, and bio-science professionals and managers. These newsletters are also posted on our website so your ad can be accessed by interested visitors to our site.

With a growing circulation, your ads should enhance their visibility and provide better return on your investment. The cost for a full color business-card-sized ad will be $650 per year. We are continuing to have the opportunity for four front page ads for an additional $350 per year for six issues. The front page ads will be offered on a first-come first-served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad; a hot-link can be added to your submitted ad file for an additional $500 for the entire year.

You may choose one of the special offers below:

- **$1,000** Full-color ad for six issues on the front page of each newsletter
- **$650** Full-color ad for six issues (not on the front page)
- **$200** Full-color ad in 1 newsletter of your choice (not on the front page)
- **$500** Adding a hot link for directing customers to your website by a simple click

We will continue to find better ways of advertising and hope you will take advantage of these opportunities and advertise in the 2013 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2013 please fill out this form and send to the ISPE-CaSA Headquarters via email (info@ispecasa.org) or fax to (919) 787-4916. If you have any questions or need additional assistance, call (919) 573-5442 or email info@ispecasa.org.

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE-CaSA Newsletter Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5” x 2”) may contain your logo or other artwork.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!

ISPE CaSA Annual Sponsorship Program and A La Carte Options:

January 1, 2013-December 31, 2013

ISPE CaSA has put together a comprehensive list of sponsorship opportunities. As you are planning for 2013 please consider how you will support the Chapter. New for 2013 we are offering 4 annual sponsorship packages that provide a comprehensive offering of sponsorship, registration for attendance and advertising. When considering these options please compare against total expenditures in prior years, not just sponsorship.

We will continue to offer individual sponsorship and advertising opportunities which are also listed below.

Please contact Amanda Wujcik at info@ispecasa.org if you have questions or are interested in participation.

Benefits of Annual Sponsorship

The Annual sponsorship program allows ISPE CaSA to provide exciting and innovative educational and networking events for our Members. These sponsorships fund programming and operations for the Chapter.

This new program will significantly reduce the individual requests for sponsorships throughout the year by creating packages that will provide sponsors consistent market exposure for the entire year. In addition, the program provides savings for you while serving to provide a year-long budget for your planning process. Sponsorship is only available to Chapter Members.

Quarterly or bi-annual payment plans will be accepted. On the following pages you will find our four levels of annual sponsorship and the additional a la carte opportunities.

(continued next page)
2013 Advertising Opportunities

**Platinum Sponsorship**
$10,000

**Technology Show**
- Corporate Sponsor Package.
  Includes: Exhibitor Registration Fee (Premium Table on Ballroom A&B Wall, Name recognition in all pre-show advertising and publications related to the Technology Show, Full Page Ad in Technology Show Program, Logo in Show Program, Advertising on Ballroom Projection Screens, Name on Technology Show bag, Signage at Registration Desk and Networking Reception)

**Educational Events and Plant Tours**
- Sponsorship at all events/plant tours
- Logo on event flyer, name and logo on table sign, full screen name and logo on projection display
- Typically 3-4 Education Programs and 2 Plant Tours
- 10 complimentary registrations, specific program uses to be determined by sponsor ($50 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

**Gala Event**
- Event Sponsorship
- Logo on event flyer, name and logo on table sign, full screen name and logo on projection display
- 4 complimentary registrations ($100 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

**Casino Night**
- Premiere Event Sponsorship
- Logo on event flyer, full screen and name on projection display
- Annual Sponsor signage
- 4 complimentary registrations ($$75 value per registration—Note does not include event registration list)

**Durham Bulls**
- Event Sponsorship
- Logo on event flyer, logo on signage at event
- 6 complimentary registrations ($15 value per registration)
- Annual Sponsor signage
- Event Registration List

**Sparians Networking Event—January 2013**
- Event Sponsorship
- 4 complimentary registrations ($40 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

**Toys for Tots**
- Annual Sponsor signage
- Recognition on all event communications
- Sponsor ribbons on name badges
- Event Registration List

**Annual Planning Session**
- Annual Sponsor signage.
- Recognition on all event communications
- Sponsor ribbons on name badges
- Event Registration List

**Leadership Symposium**
- Event Sponsorship
- Logo on event flyer, name and logo on table sign, full screen name and logo on projection display
- 2 complimentary registrations ($20 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

**Young Professionals**

**Education Events**
- Event Sponsorship
- Typically 7 events per calendar year.
- 6 complimentary registrations ($20 value per registration)
- Recognition on all event communications
- Sponsor ribbons on name badges
- Event Registration List

**Career Fair**
- Event Sponsorship
- Recognition on all event communications
- Sponsor ribbons on name badges
- Event Registration List

**Resume Workshop**
- Event Sponsorship
- Recognition on all event communications
- Sponsor ribbons on name badges
- Event Registration List

**Newsletter**
- Business Card Ad. 6 times per year, full color, 3.5” x 2”
- Hot Link from business card ad
- “Sponsor” spotlight

**Website**
- 240 x 400 Vertical Rectangle Ad for 12 months

(continued next page)
2013 Advertising Opportunities

Gold Sponsorship
$7,500

Technology Show
- Color Quarter Page Ad in program
- Educational Events and Plant Tours
- Sponsorship at all events/plant tours
- Logo on event flyer, name and logo on table sign, full screen name and logo on projection display
- Typically 3-4 Education programs and 2 Plant Tours
- 8 complimentary registrations, specific program uses to be determined by sponsor ($50 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Durham Bulls
- Event Sponsorship
- Logo on event flyer, logo on signage at event
- 4 complimentary registrations ($15 value per registration)
- Annual Sponsor signage
- Event Registration List

Sparian Networking Event—January 2013
- Event Sponsorship
- 2 complimentary registrations ($40 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Toys for Tots
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Annual Planning Session
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Career Fair
- Sponsor ribbons on name badges
- Event Registration List

Resume Workshop
- Sponsor ribbons on name badges
- Event Registration List

Website
- 120 x 240 Vertical Banner—animated for 12 months
- Annual Sponsor Recognition with Hyperlink

Silver Sponsorship
$3,000

Technology Show
- Quarter Page Ad in program
- 2 complimentary registrations ($20 value per attendee registration)

Educational Events and Plant Tours
- Sponsorship at all events/plant tours.
- Name and logo on table in sponsor group on projection display
- Typically 3-4 Education Programs and 2 Plant Tours
- 4 complimentary registrations, specific program uses to be determined by sponsor ($50 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Golf
- Hole Sponsor—Deluxe
- 1 complimentary registration ($75 value per registration)

Gala Event
- Event Sponsorship
- Logo on event flyer, name and logo on table sign, full screen name and logo on projection display
- 2 complimentary registrations ($100 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badges
- Event Registration List

Casino Night
- Premiere Event Sponsorship
- Logo on event flyer, full screen and name on projection display
- 1 complimentary registration ($75 value per registration)
2013 Advertising Opportunities

**Durham Bulls**
- 2 complimentary registrations ($15 value per registration)
- Annual Sponsor signage

**Sparians Networking Event—January 2013**
- Event Sponsorship
- 1 complimentary registrations ($40 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badge

**Toys for Tots**
- Annual Sponsor signage
- Sponsor ribbons on name badges

**Annual Planning Session**
- Annual Sponsor signage.
- Sponsor ribbons on name badges

**Leadership Symposium**
- 1 complimentary registrations ($20 value per registration)
- Annual Sponsor signage
- Sponsor ribbons on name badge

**Young Professionals Education Events**
- Event Sponsorship
- Typically 7 events per calendar year.
- 3 complimentary registrations ($20 value per registration)
- Sponsor ribbons on name badges

**Career Fair**
- Sponsor ribbons on name badges

**Resume Workshop**
- Sponsor ribbons on name badges

**Website**
- Annual Sponsor Recognition with Hyperlink

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**Bronze Sponsorship**

**$1,500**

**Educational Events and Plant Tours**
- Sponsorship at all events/plant tours.
- Name and logo on table in sponsor group on projection display
- Typically 3-4 Education programs and 2 Plant Tours
- Annual Sponsor signage
- Sponsor ribbons on name badges

**Golf**
- Hole Sponsor

**Gala Event**
- Annual Sponsor signage
- Sponsor ribbons on name badges

**Casino Night**
- Annual Sponsor signage Durham Bulls
- Annual Sponsor signage Sparians Networking Event—January 2013
- Annual Sponsor signage

**Toys for Tots**
- Annual Sponsor signage
- Sponsor ribbons on name badges

**Annual Planning Session**
- Annual Sponsor signage.
- Sponsor ribbons on name badges

**Leadership Symposium**
- Annual Sponsor signage
- Sponsor ribbons on name badges

**Young Professionals Education Events**
- Event Sponsorship
- Typically 7 events per calendar year.
- Sponsor ribbons on name badges

**Career Fair**
- Sponsor ribbons on name badges

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**Newsletter**
- Business Card Ad. 6 times per year, full color, 3.5” x 2”

**Website**
- 120 x 240 Vertical Banner non animated for 12 months
- Annual Sponsor Recognition with Hyperlink
Our Chapter produces six e-newsletters per year, and we depend on the support of our advertisers. We send out the newsletters via e-mail and via web link to all of our Chapter Members throughout the Southeastern U.S.

That means you get targeted access to top-notch pharma, biotech, and bio-science professionals and managers. These newsletters are also posted on our website so your ad can be accessed by interested visitors to our site.

Best of all, the cost is only $650 for your full color, business-card-sized ad for six insertions. That’s only $650 for targeted advertising in full color for an entire year!

Ask About
HOT LINKS!!

Would you like to have targeted customers simply click on your ad and get right to your website? A hot-link can be added to your ad, connecting readers directly to your company website for an additional $500.00 for a whole year.

If you are interested in advertising with the ISPE CaSA e-newsletter, please contact our Chapter headquarters at:

ISPE-CaSA
1500 Sunday Drive
Suite 102
Raleigh, NC 27607
919-573-5442
info@ispeCaSA.org

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE CaSA Communications Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5” x 2”) may contain your logo or other artwork. Artwork should be sent directly to pkralka@FirstPointResources.com.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG or TIF formats are easiest for us to work with. Space is limited, sign up today!