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Don’t miss it!

2012 CaSA Leadership Forum
McKimmon Center, Raleigh, NC

February 17, 2012

Register online at:
http://casaleadershipsymposium.eventbrite.com/

Annual CaSA Technology Show and
Student Poster Competition

April 10, 2012
President’s Message

Hello again. In my last letter, we were just getting into the full swing of our post-summer schedules; now we find ourselves in the middle of the Holiday Season as we prepare for the year’s end. Thanksgiving 2011 is a recent memory (and maybe a couple of extra numbers on our bathroom scales). Hopefully, everyone had the opportunity to gather with family and friends to celebrate that time of year set aside for sharing food and thoughts of the wonderful blessings we have. We celebrate Thanksgiving, and a few hours later, Christmas moves into full swing with Black Friday. I trust you survived! As 2011 comes to an end, some of you will be closing out the month with those last few unused vacation days and exciting travel plans. On the other hand, a large portion of our professional Society prepares for the often dreaded and always hectic winter shutdown schedule. I hope that as 2011 comes to a close, you have successfully met your goals and expectations for the year and see 2012 for all the potential and opportunity the New Year brings.

For those of you that attended the Annual Meeting in Texas, no explanation is needed, but if you did not go, you missed quite a trip. I cannot remember ever attending a conference in which the hotel itself was a travel destination. The Gaylord Texan was like an indoor theme park with its own indoor Riverwalk. We discovered early Sunday morning while on our walk to the meeting rooms that the Gaylord is the “official” hotel of the Dallas Cowboys NFL football team. A sea of Cowboy jerseys flooded the hotel’s atrium, and the festive atmosphere of NFL Sunday filled the public spaces with anticipation of a Cowboy win! Nonetheless, there was work to be done and meetings to attend, so off to our assigned tasks we went. The CaSA Chapter received a national award for the work done by the Membership Committee under the direction of Heather Denny for the previous year. Also, congratulations to our own Diane Darlington (NCCU) who won the poster competition for graduate students at this year’s Meeting—outstanding job, well done Diane. Our Chapter is fortunate to have Diane as an active member as she transitions from student to young professional.

The CaSA Board of Directors continues to meet monthly to attend to the business of directing the affairs of the Chapter. If you have any inclination to become involved with the inner workings of the Chapter, I invite you contact any of the committee chairs today and ask what you can do to join in and lend a hand. Be part of the future of CaSA.

Our annual Toys for Tots meeting was held on December 1 at GSK Building 5. This annual charity event is one of several ways that our Chapter serves the community at-large.

Also, as 2012 begins, there will be a joint event on January 26th held by the Young Professionals and Membership committees as a “Therapeutic Thursday.” A brewery tour is combined for a fun evening that you will not want to miss. Be sure to sign up when registration is announced. In the past, events like this have filled up very quickly—not sure if it is the “fermentation process” or the social aspect of the gathering that is so popular.

Have a Merry Christmas and a Happy New Year!

David Brande
Chapter President

2011-2012 Board of Directors

Officers
- David Brande, President
- Jennifer Lauria Clark, Vice President
- Matt Gilson, Treasurer
- Heather Denny, Secretary

Directors
- Eric Mayer
- David Smith
- Patrick Buckner
- David Knorr
- Lisa Kerner
- Andy Ferrell

Committee Chairs
- Wendy Haines, Communications
- Nancy Padgett, Membership
- Amy Lineberry, Programs
- LeAnna Pearson, Students
- Bruce Craven, Technology Show
- Blake Derrick, Young Professionals
Chapter Event Highlights

Young Professionals Leadership Seminar Overview

By Remil Aguda and Blake Derrick

The ISPE-CaSA Young Professionals group hosted a seminar on leadership at the NCSU-BTEC on October 6, 2011. Our speaker was David Abbe, Director of Engineering with GlaxoSmithKline in Zebulon, North Carolina. David described leadership lessons he learned through his professional experience over the years, taking us through his career track from an entry-level position to Director of Engineering. He emphasized that leadership abilities are most effectively learned from others and personally developed through “on the job” experiences - in projects with fellow colleagues, in interacting with technicians on the manufacturing floor, in directing, coaching, supporting and delegating projects as a manager, and as a mentor in developing employees to succeed. After his presentation, he spent ample time fielding questions and having discussions with the students and professionals. Overall, the event was a great success and our survey feedback was very positive. Stay tuned for future events we’ll be announcing soon for early 2012.
Chapter Event Highlights

Annual Meeting Overview from a Student’s Perspective

By Daniel Garrett—President ISPE Student Chapter at ETSU

Thank you to CaSA and everyone who made it possible for students to attend this year’s Annual Meeting. The lessons learned at this international meeting went beyond technical knowledge. The attendees provided a more diverse networking base than I thought possible. The Annual Meeting was an eye-opening experience because of the broad spectrum of countries, technical understanding, and professional career paths represented.

After my plane arrived in Dallas my first task was to facilitate one of the Sunday afternoon sessions. This was a great opportunity to meet the lecturers and to network with people interested in similar topics. This was my first Annual Meeting and I did not know what to expect of the educational sessions. The sessions were valuable in helping me to gain knowledge about each subject. The presentations were forthright and to-the-point evaluations of business situations from around the globe. Each presenter painted a picture of their interactions with vendors, regulators, and employees. This was information which only students who are ISPE members are privileged to. Lessons were learned in realizing the full spectrum of implications, along with the pros and cons of each topic represented.

The New Members’ Breakfast allowed me and other students to quickly meet other Members. This opened doors for more casual conversations. The expo and poster contest also made excellent venues for networking. I met people representing businesses from all across the USA, along with many other countries. It is rare for students to be able to meet such a diverse crowd of industry professionals all in one setting. Tuesday night at the Glass Cactus brought home the point that we really were in Texas. The Tex-Mex band played a style I had never experienced in person, and the highlight was Members from various cultures learning how to line dance.

Thank you again to everyone who made this experience possible. I also want to extend my gratitude to the students and recent graduates from NC State, and NC Central for the input on how to make our new Chapter grow. The Annual Meeting was a great opportunity to meet people from all aspects of the pharmaceutical industry. The other students from ETSU and I now have broader understandings of working in the pharmaceutical industry. Because of all these experiences we are definitely looking forward to next year’s meeting.
CaSA had a great 2011 year. We won the Grand Award for Innovation in Membership Services and we were presented a plaque at the Annual ISPE Meeting in Texas. Diane Darlington (now at Medicago) won the International Graduate Student Poster Competition. It has been several years since CaSA has had an international poster winner and we hope to continue our winning trend in years to come. With joyful tears in our eyes we saw our own Jane Brown win the Richard B. Purdy Award. This award is given to an ISPE Member that has made significant, long-term contributions to ISPE. Jane pioneered the foundation of CaSA’s student chapters, is Past-President of the CaSA Chapter, and Past-Chair of ISPE. In addition to our 3 awards, we have 2 new CPIPs in CaSA: Jennifer Lauria Clark and Amy Lineberry. From all of us in CaSA, congratulations to our winning committee and our individual award winners and certification recipients. We hope everyone has a happy and safe holiday season!

Jane Brown Wins Richard B. Purdy Distinguished Achievement Award

By Jennifer Lauria Clark, CPIP

At the 2011 ISPE Annual Meeting in Grapevine, Texas our own Jane Brown from the CaSA Chapter received the Richard B. Purdy Distinguished Achievement Award, honoring ISPE Members who have made significant, long-term contributions to the Society. Jane received the Purdy award for her consistent, dedicated and passionate service to ISPE over a period of 18 years. Jane has been a large part of ISPE locally and internationally during her tenure as an ISPE member. Since joining the Society in 1993, her continuing service to the CaSA Chapter involves serving previously on the local Board of Directors and chartering the Student Chapters in our region and internationally. Jane is a Past President of the CaSA Chapter and a long time mentor to many of the past and current board members. Jane has also been deeply involved in membership development, regulatory affairs, student and young professional development, the creation of new guidance documents, university relations, volunteer recruitment and the North American/South American Affiliate Council.

Jane has personally been a mentor to me and countless other professionals over the years. She has wisely advised many people on career paths, professional growth, and personal work-life balance. Her passion to not only serve ISPE but the Members the organization serves shows how truly deserving she is of the Purdy Award.

Jane’s pinnacle of her tenure was serving as Chair of the ISPE’s International Board of Directors. She has truly made a successful mark on the ISPE Community locally and internationally. Her efforts to charter the student chapters across the organization have specifically helped CaSA grow to the exceptional group of students, young professionals, and professionals we have today. From everyone in your CaSA family, we appreciate your time, commitment, and guidance, and we thank you for all of your amazing contributions to the Society.
The 5th Annual CaSA Gala was very successful with over 65 students, young professionals, and professionals in attendance. The Annual Gala was held at the Capital City Club in downtown Raleigh. The view was spectacular for the evening and the venue was gorgeous. Attendees were greeted with a networking reception and two wonderful presentations. We started the evening with Bill Bullock and John Balchunas from the NC Biotechnology Center. They gave a presentation on how North Carolina continues to be an ever-growing area for the Biotech/Pharma Industry. John also talked about the classes that are offered from the Biotech Center, located in RTP, for all levels of our industry from grade school through upper level management.

After the Biotechnology Center presentation we enjoyed delicious food and good speakers. Brian Morrissey and Dana Tilley presented on the new expansions for the Merck facility in Durham. The facility was started in February 2010; it is scheduled for completion and to be GMP compliant in just 16 months. This is being accomplished through the “One Team” approach and Lean Six Sigma philosophy. This site has state of the art equipment and will produce the Varicella (chicken pox) vaccine. They showed the attendees how the facility has been built with modular units. The modular units were fabricated at the various supplier sites and installed at the facility in phases. The facility has also received multiple safety awards for their 1.45MM man-hours worked with no lost time. The awards received were the NC OSHA VPP Star Award, the CURT Safety Excellence Award and the Merck GES Safety Award - Best Large Project, all in 2010.

For the first time ever, a plant tour was offered in conjunction with the Gala. On Friday afternoon approximately half of the Gala attendees attended a tour of Merck in Durham, NC. Our tour of the new Merck construction began with a short safety briefing and description of
the facility. We were led through the construction offices, past the newly finished power plant to the construction site. The construction workers had been given the afternoon off and we had an unencumbered view of the plant. We first passed through the fully completed and heavily used hallway called “the spine” that connects the new facility to the existing Merck areas. On the ground floor of the facility, we saw the first of the major equipment in place and being prepared for operation in the cGMP and non-cGMP areas. The rolling racks and handling robots were in place and being prepared for readiness. The whole project appeared to be coming together at an incredible speed. The modular units containing the support systems in the ceiling were all in place.

The second floor was less complete than the first floor, but many of the cold storage rooms were fully installed and nearly ready to use. The tour then went briefly through some of the new offices for the Merck staff. We navigated back down to the “spine” hallway where the guides answered a few final questions. We began walking back to our cars and soon dispersed in the evening rain. All in all, the Annual CaSA Gala and Tour was a success and we hope to repeat this in 2012.
CaSA Committees and New Members

Welcome New CaSA ISPE Members

New Members who joined
October 1, 2011–November 28, 2011

- James Allie
- Ryan Bateman
- Joseph Brenzovich
- Brandy Buchanan
- Sabree Burbage
- Alexander Castellano
- Jeff Clevenger
- Grafton Corbett
- David Creech Jr.
- Marilyn Davenport
- Anita Deslauriers
- Lemuel Drake
- Kokouvi Ehe
- Montgomery Favret
- Tamatha Finley
- Joseph Fisher
- David Fussell
- George Gerth
- Jason Goodwin
- Joy Gray
- Boris Gueorguiev
- Michael Hall
- Kellie Higgins
- Jeffrey Holland
- Mark Holland
- Leslie Holston
- Buddy Hopkins
- Nicholas Johnson
- Richard Johnson
- Meher Juttukonda
- Rita King
- Ronald Kneisler
- Ann Lenhardt

- Darryll Lobasso
- Danielle McCaskill
- Neil McCullough
- Brian Morrissey
- Richard Nardini
- Anthony Ochieng
- Kevin O'Laughlin Sr.
- Ronald Olsen
- Brandie Platt
- Amit Kumar Potipally
- Laura Rinker
- Luis Rivera
- Yusufu Sanu
- Robert Schleicher Jr.
- Carolin Sellmann
- Desiree Shaw
- James Sparrow
- Robert Waddell
- Aubrey Walker
- Jonathan Yow
- John Zaremba

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Featured CaSA Event

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

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- Verbal recognition at event
- Sign placed at event

Gold Sponsor $500
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- Verbal recognition at event
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Silver Sponsor $250
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- Verbal recognition at event
- Sign placed at event

Bronze Sponsor $100
- Verbal recognition at event
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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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Register Online at:
http://casaleadershipsymposium.eventbrite.com/
**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.
MARK YOUR CALENDARS!

CaSA Chapter Events

- January 26, 2012 - Brewery Tour
- February 17, 2012 - CaSA Leadership Symposium
- April 10, 2012 - Annual CaSA Technology Show and Student Poster Competition
ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for your Business!

Our Chapter produces four 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.

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

Peter Kralka, Chapter Manager
1500 Sunday Drive
Suite 102
Raleigh, NC 27607
pkralka@FirstPointResources.com

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.

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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 Carolina-South Atlantic Chapter Newsletter

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omni_tox@yahoo.com

EDITORIAL POLICY

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Manuscripts should be forwarded to a Member of the Communications Committee at omni_tox@yahoo.com for review 30 days prior to publication. A brief three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment must accompany the article.

Got News?

Send it to:
omni_tox@yahoo.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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Thank you all for your continued support. Without it we could not have the wonderful support staff to get our ISPE CaSA Members the news in such a timely and professional fashion. If you have updates to your advertisements or find any other error, please contact us so that we can serve you better.