

# **Carolina-South Atlantic Chapter**

# **CaSA News**



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# President's Message



hard for you. Plans for the Technology Conference on April 8, 2014 are in full swing with registration recently launched for exhibitors. We look forward to a great conference and great participation from our exhibitors and attendees. Our Student Affairs Committee Chair recently met with participants

from Virginia Polytechnic Institute and

Since our last newsletter, our volunteers have continued to work

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### **MARK YOUR CALENDARS!**

December 18, 2013 – Toys for Tots at Novartis, Holly Springs January 30, 2014 – Sparians Young Professionals Bowling Event February 7, 2014 – Annual CaSA Leadership Forum: "Taking Control of Your Career," McKimmon Center April 5, 2014 – TriSci Tech Expo, Raleigh, Museum April 8, 2014 – 21st Annual Technology Conference, Raleigh **Convention Center** 

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# President's Message

State University (Virginia Tech) to start the process of setting up a Student Chapter. We welcome that addition and look forward to your involvement in the Chapter. We are also gearing up for our Leadership Symposium on February 7, 2014. This promises to be another great event for all of our Members.

The Young Professionals hosted a CEO Night in November that provided insight into the path to success for some of our local CEOs. Thank you to those who participated on the panel and attended that event! That event was followed by a Therapeutic Thursday sponsored by ISPE CaSA. I hope everyone enjoyed the time to network and socialize before the Thanksgiving holiday.

We recently returned from the 2013 ISPE Annual Meeting hosted in Washington, DC where there were two Facility of the Year Award (FOYA) category winners, Biogen Idec and Novartis, competing for the top prize. We are proud of both accomplishments and highlighted these projects at the ISPE CaSA Gala in October. Congratulations to Novartis' Flu Cell Culture Facility in Holly Springs for taking home the overall FOYA prize at the Annual Meeting!

It is important for our Committee Chairs and the rest of our Board of Directors to understand what our membership values from ISPE CaSA. 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. Our contact information is on our website (www.ispe-casa.org) or you can email me at president@ispecasa.org and I will forward on as appropriate.

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.
  Information on each Committee can be found on the website.
  Membership, Students, and Education are 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.
- Follow us and participate with our social media accounts:
   Twitter @ISPE\_CASA, LinkedIn ISPE-CaSA, Facebook ISPE-CaSA, Google+ ISPE CaSA
- **Share your ideas.** Send in some fresh ideas for 2014 educational programs and networking events.
- Come see us, Toys for Tots December 18, 2013 at Novartis, Holly Springs, Bowling Event – January 30, 2014 at Sparians, Raleigh, Leadership Symposium – February 7, 2014 at McKimmon Center, Education Event – end January / early February 2014

Finally, if you're a volunteer on a Committee, if you're on our Board of Directors, if you've attended an ISPE CaSA event, if you've sponsored anything for ISPE CaSA (newsletter, event, website), if you've worked with our Student Chapters, or if you've written an article for our newsletter, THANK YOU! A tremendous amount of work goes into everything we do to keep our Chapter operating and successful. Without you, events don't happen, communications don't go out, and we don't bring value to our members. I look forward to another successful year for our Chapter and your continued support and involvement in 2014.

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

Matt Gilson President, ISPE CaSA Chapter

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# **Membership Corner**

### CaSA Member Spotlight: Rick Lawless, CPIP

By ISPE CaSA Newsletter Committee

#### Q: What is your full name?

A: Richard J. Lawless Jr., but I go by Rick Lawless, or officially, Rick Lawless, CPIP

#### Q: Birth Place?

A: Detroit, Michigan

#### Q: College?

A: University of Michigan, Ann Arbor (BS in Microbiology & BSE in Chemical Engineering) State University of New York, Buffalo (MBA)



#### Q: Tell me a little about your personal life.

A: I'm a husband to a wonderful woman named Debbie and a father to three great children: Julia (21), Kevin (19) and Mackenzie (19). Julia is now student-teaching during her last semester at Appalachian State University. Kevin and Mackenzie are first-year students at NC State and UNC-Chapel Hill, respectively. When I'm not involved in family activities, I tend to my 9-acre homestead and serve in the children's and welcome ministries at my church.

#### Q: What is your present position? What do you do at your job?

A: Associate Director, Strategic Programs at the Golden LEAF Biomanufacturing Training and Education Center (BTEC) at NC State University. I provide leadership to the professionals who take care of bioprocess services projects, student coordination, industry relations, marketing, and instructional design. I work on projects that expand BTEC's scope (partnerships, technologies, grants) and enhance its future (new facilities, marketing, strategic planning).

#### Q: How long have you been with your current employer?

A: I started working at NC State in 2006 when 850 Oval Drive was just a mud hole and BTEC was a set of blueprints.

# Q: Tell me about your career path, and how you ended up where you are today.

A: I started out developing fermentation processes for a new di-

vision of Eastman Kodak (EK). I became bored with process development and jumped to EK's Clinical Products division to do GMP manufacturing. I managed production groups that made coated webs and fluids for use in blood analyzers. We were eventually sold to Johnson & Johnson. In 1997, I loaded up a truck and moved my family to North Carolina so that I could work for Wyeth Vaccines. My first role was to start-up their new facility to produce conjugates for Prevnar vaccine. I worked there for 9 years, mostly in manufacturing management, but did a 2-year stint in quality operations when we were dealing with a consent decree. I was Wyeth's representative on the BTEC Advisory Board and eventually decided I'd like to help start-up BTEC and contribute to the growth of North Carolina's biotechnology cluster.

#### Q: What is your favorite part of your job?

A: When new facilities are needed, I really like working on the teams that program, design, and construct new labs, especially cGMP clean rooms. It amazes me that there's still no such thing as a "standard" production area – seems lots of people like to design new facilities. I also enjoy talking with students and helping them figure out what they want to do after they graduate.

# Q: How long have you been a Member of ISPE/when did you first ioin ISPE?

A: I remember getting a 10-year pin a few years ago, so I'm going to say 12 years.

# Q: What benefits have you realized from being a member of ISPF?

A: I've met many really cool people. Participating in meetings and reading articles helps keep me current.

#### Q: Why are you still involved with ISPE?

A: I have served on the Professional Certification Commission (PCC) and one of its subcommittees. These experiences have given me a better appreciation for the Certified Pharmaceutical Industry Professional (CPIP) credential and I'm looking forward to new endeavors with ISPE that benefit its Members.

# Q: Any Mentors/Role Models that have helped to shape your life?

A: Definitely. About 2,000 years ago, there was a rabbi who did

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# **Membership Corner**

things differently. I study a really good book that chronicles his ministry and explains how he can still help us.

# Q: If you weren't involved in teaching/mentoring, what business do you think you'd be in?

A: Developing educational computer games. I've had fun creating a few games that we use in my regulatory affairs/quality systems course. I can't do the art and the programming, just write the stories.

#### Q: What is one skill you wish you had that you don't?

A: I would love to be able to play the bagpipes.

#### Q: Any hobbies? What are they?

A: I make my own wine and spend a lot of time landscaping. I've been building a 3-tiered pond for the past four years. Eventually, I'll add a waterfall.

#### Q: Do you collect anything?

A: I still have all the beer cans I collected from 1976 to 1980 – lots of cans commemorating the bicentennial. I didn't drink the beer from them, of course (I was only a teenager).

#### Q: Finish this sentence - "I need more...."

A: Patience. I want everything now.

#### Q: Favorite Food?

A: When I lived in Detroit, I loved barbequed ribs. When I lived in Rochester, it was chicken wings (deep fried with blue cheese). Right now, I crave two eggs over easy, link sausage, hash browns, and biscuits from the Farmer's Market Restaurant (sorry BBQ fans!).

# Q: What is something that people would be surprised to learn about you?

A: Because I tend to do everything "by the book", people are surprised to hear that I've never served in the military.

#### Q: Last movie you saw?

A: I don't go to many movies, at least not at a theatre. I do watch them on Netflix while I'm doing something else at the same time. I think the last one was "Silver Linings Playbook".

# Q: For those in the early stage of their careers, what advice would you give them?

A: Read a journal article, take a course, or attend a seminar on some new technology at least once a month. If you don't keep up with what's happening in science and the industry, then you'll get stale. This is especially true for people who work for one company, in one facility, on one product, for many years.

#### 2013-2014 Board of Directors



Carolina-South Atlantic Chapter

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# **Membership Corner**

### Membership Development

By Jerry "Patch" Paciorek, CPIP ISPE CaSA Membership Development Chair

Our exciting membership news continues, as we have already recorded 151 new members that have joined our Chapter since July 1, 2013, which is nearly half way to our goal to sign up 350 new members by June 30, 2014.

Please remember ISPE's Refer-A-Friend Program! Earn one

free month of membership for every friend you refer. All the details are available at http://www.ispe.org/membership-refer-ral-program

Thanks for all your efforts and support in spreading the word about ISPE and the CaSA Chapter!

If you have any question about ISPE or the CaSA Chapter, please contact me at paciorek@cagents.com.

#### State of the CPIP Credential

By Amy Lineberry, CPIP, ISPE CaSA Technology Conference Committee Co-Chair and Jerry "Patch" Paciorek, CPIP, ISPE CaSA Membership Committee Chair

Most of you have probably heard the CPIP credential is "going away." This is not true ...While no new applications will be accepted as of November 30, 2013, the CPIP credential is not "going away" completely. Those who have achieved CPIP will be able to keep the credential as it moves to a "Recertification" only program. Those who have started the process can continue to pursue the CPIP credential. All testing will cease as of May 31, 2014. This decision to transition the program is a strategically necessary part of allocating ISPE resources.

After the ISPE Annual Meeting in November, I feel confident the CPIP credential will return in the near future. The

Immediate Past Chair of ISPE, Charlotte Enghave Fruergaard, has been tasked to lead a group to explore options for CPIP. I am encouraging those in the CaSA Chapter and around the world to complete the process. I cannot describe the accomplishment I felt when I received the email from Michael Phelan telling me I had passed the exam and achieved the CPIP credential. If you have any questions or concerns, please do not hesitate to contact me (alineberry@manganinc.com). If I cannot help, I will find someone who can.

For more information including a letter from the ISPE International Board of Directors on this topic and the Strategic Transition of ISPE's CPIP Program Frequently Asked Questions, please visit <a href="http://www.ispe-pcc.org/">http://www.ispe-pcc.org/</a>.









# Congratulations to CaSA's Newest CPIP! Leena T. Asplund, CPIP

# **Student Chapter Corner**

**New Student Chapter Forming** 

By LeAnna Pearson, ISPE CaSA Student Affairs Committee Chair

Please join me in welcoming the newest ISPE CaSA Student Chapter: Virginia Polytechnic Institute and State University, also known as Virginia Tech (under formation). With 31,200 enrolled students this is the new and upcoming Chapter to watch! I met with the two students responsible for starting the Chapter, Alex Sabol and Debbie Sasso, on Friday,

November 15, 2013. I was VERY impressed with their determination and professionalism. If you are a professional in the Blacksburg, VA area or an Alumni of VT they are looking for speakers and facility tours in 2014. If you would like to help them out please contact Alex at alexs20@vt.edu or Debbie at dlsasso@vt.edu. GO HOKIES!

# North Carolina State University (NCSU) Student Chapter Spotlight

By Mary Matkovska, NCSU ISPE Student Chapter President



(Above) Commissioning Agents Social from ISPE Annual Meeting, November 13, 2013

(Right) Social event: Carolina Brewing Company tour

(Below) Site tour at Novo Nordisk, November 16, 2013



The North Carolina State University (NCSU) Student Chapter of ISPE was founded in 1995 by Jane Brown, Dan Dunbar, and Dr. Peter Kilpatrick. The first Student Chapter had nearly two dozen students, representing various departments at NCSU, such as Chemical and Biomolecular Engineering, Microbiology, and Food Science. NCSU ISPE is active in the university community by being involved in activities such as holding informational meetings, social events, and service events. The NCSU Student Chapter gives students the opportunity to learn about the pharmaceutical industry by hosting monthly dinner meetings with industry speakers, and



participating in industry site tours. NCSU ISPE Chapter has grown significantly since 1995 and now has over 400 student members in its distribution list with each general meeting being attended by an average of 30 students. The Chapter is open to university students of all majors, with most members pursuing chemical engineering, bioprocessing science, biochemistry, microbiology, biology, and chemistry degrees.

Over the years NCSU ISPE has received multiple awards. In 2010 the Chapter was recognized as ISPE Student Chapter of the Year. The former Chapter President, Brandon Berry, was a winner of the ISPE CASA poster competition, undergraduate level, in March 2012. In April 2013, Oscar Bernal was a winner of the ISPE CASA poster competition in the graduate student level.

NCSU ISPE is a very active Student Chapter through general meetings, service and social events and in 2012 the Chapter got the chance to host the Food and Drug Administration (FDA). The speakers of the meeting were John Thorsky and Pat Schafer, both are district directors, representing the St. Louis and New Orleans District offices. In the last 2-3 years, the Student Chapter has been actively engaged in the BTEC ISPE Career Fair. Student Chapter Board Members volunteered at the event and helped with event flow. Representatives from the Student Chapter also attended the ISPE Annual Meeting in Orlando, FL in 2010, Dallas, TX in 2011, San Francisco, CA in 2012, and Washington D.C in 2013.

For the remainder of the 2013-2014 school year, the Chapter will be hosting speakers from Novartis and Biogen Idec in November. The Chapter will end the semester with a tour of Novo Nordisk, located in Clayton, NC and a social event to cel-



ebrate the end of yet another successful semester. Spring semester 2014 plans include hosting at least four general meetings. The Chapter has plans to volunteer once again at the CaSA Leadership Symposium in February and the BTEC ISPE Career Fair in March and at the 21st Annual ISPE CASA Life Sciences Technology Conference in April. Another tour of a local pharmaceutical company is on the agenda but will only be available to current up to date dues-paying student members. The Chapter will celebrate the end of the spring semester with a social event.

NCSU ISPE Chapter organizes multiple service events every year. The NCSU Board officers and student members participate in the Toys for Tots drive, an event to raise funds and collect toys to distribute as Christmas gifts to under-privileged children around Raleigh and the surrounding communities. ISPE members also volunteered at local land and water cleanup projects that were part of the NC BIG Sweep.

NCSU ISPE Chapter is a highly professional, informational, and involved student organization aimed at providing opportunities for NC State students to learn about, network with, and to become involved in the strong connections NCSU and Raleigh have to the pharmaceutical industry. At the general meetings, students can gain first-hand knowledge about companies, specific job roles and opportunities, and what it takes to be successful from professionals in the field. Students are also provided the opportunities to participate in on site tours, network with professionals, and get involved with service activities. As a treat, free food is provided to all of the attendees at each general meeting.



# **Member Corner**

### ISPE CaSA Annual Gala Summary

By Jennifer Lauria Clark, CPIP and Past President of the ISPE CaSA Chapter

ISPE CaSA hosted an extremely successful Gala October 10, 2013 at the Umstead in Cary, North Carolina. Over 100 ISPE CaSA members and friends attended a celebration to support our local Facility of the Year Award (FOYA) category winners as well as a special tribute to Ms. Jane Brown.

The FOYA program showcases the pharmaceutical manufacturing industry's accomplishments in facility design, construction, and operation, while sharing the development of new applications of technology and cutting-edge approaches that it is adopting. The FOYA program celebrates the shared commitment and dedication of individuals working for different companies worldwide to enhancing patient health and safety through innovation and advancements in pharmaceutical manufacturing technology.

Novartis and Biogen Idec were selected as category winners for their respective companies in the Process Innovation and

Facility Integration categories, respectively. Mr. Scott Billman, Past President of ISPE CaSA and Director of Engineering at Novartis Vaccines gave a presentation detailing the success of Novartis' project team. Similarly, Mr. Jack Kane, Capital Projects Director at Biogen Idec, presented the process they used to support Biogen Idec's successful project.

Ms. Jane Brown was surprised at the Gala by being honored with an ISPE CaSA Member Award. Jane has been instrumental in the success of our Local Student Chapters, Local Chapter, and is a past chairman of ISPE International. Her commitment and dedication to ISPE CaSA is overwhelming and appreciated by all the lives that Jane has touched.

The evening was an overall success with great presentations, good food, and good company. ISPE CaSA is proud to have so much to celebrate in our local area.

(Right) Matt Gilson, CaSA Chapter President with Jane Brown, ISPE CaSA Member of the Year



(Above) Mr. Scott Billman, Past President of ISPE CaSA and Director of Engineering at Novartis Vaccines

(Right) Mrs. Jenny Brown-Chin, daughter of Jane Brown







(Above Left) Mr. Jack Kane, Capital Projects Director at Biogen Idec

(Below) Matt Gilson, CaSA Chapter President





**Everyone Enjoying the Gala** 

# **Member Corner**

# Annual ISPE Meeting Wrap-Up

By CaSA Newsletter Committee

The 2013 Annual ISPE Meeting was a great mix of educational sessions, regulatory interactions, and wonderful networking all at the Washington Marriott Wardman Park Hotel. On November 3, the Young Professionals hosted a luncheon



#### **WRAP-UP**

WASHINGTON MARRIOTT WARDMAN PARK

with a "speed leadership" activity involving teams to develop a drug, therapeutic indication, and tag-line, mission/vision all in 10 minutes and present the team's findings and this was followed by discussion of the top 3 most important items when building a manufacturing facility for biopharmaceuticals. The afternoon hosted educations sessions with the first ever Young Professionals (YPs) Educational track geared toward YPs that have less than 10 years of industry experience.

November 4 provided to be an exciting day with the plenary session to start the day with talks from the incoming

International ISPE Chair, Damian Greene and followed by an overview of ISPE by ISPE's CEO, Nancy Berg. Next, Dr. Janet Woodcock, FDA Director, Center for Drug Evaluation and Research, spoke about the state of the FDA and its reorganization. Julie Kim, General Manager of Biotherapeutics for Baxter Healthcare Corporation, followed Dr. Woodcock's question and answer session and spoke of the state of Baxter and their facility being built in Covington, Georgia. Patient stories of who have benefited from Baxter's therapies reminded the audience of why we are all in this business – the patients.

The last part of the Plenary Session was the recognition of the FOYA Category Winners, followed by the overall FOYA Winner. CaSA ISPE is proud to congratulate **2 FOYA Category Winners** who facilities are within the CaSA Chapter: **Biogen Idec and Novartis**. Congratulations to both companies for their FOYA Category win. Sadly, there can only be 1 overall winner and the **2013 Overall FOYA Winner is the Novartis**, Holly Springs US Flu Culture Facility. Congratulations to the entire Novartis team on their win.

Some of the overall conference highlights included the following events: Global Regulatory Summit, Executive Series, Educational Sessions, the Exhibit Hall, Annual Charity Run, and the International Student Poster Competition. The Annual Awards luncheon was held on Tuesday, November 5 to recognize those who have contributed greatly to ISPE and her

successes. The lunch was a great conduit into the Tuesday night networking event at the Newseum. We were glad to see fellow CaSA Chapter members in Washington and we look forward to seeing everyone at the next Annual ISPE Meeting in Las Vegas, October 12-15, 2014.



Young Professionals Luncheon at the Annual Meeting

### Welcome New Members

#### New Members who joined September 15, 2013 through November 17, 2013

David Ball
Christi Ballard
Patrick Bastek
Heather Bennett
Tim Brantley
Diana Castano
Zack Collins
Ryan Cook
Steve Crooks, CIH, CSP
Zach Culberson
Will Darrigrand
Stacy DeCrane
Daniel Deese, PE
Chris Dela Cruz

Phillip DeMuth
George Drelich
Mike Dunbar
Jose Gonzalez
Cara Goodwin
Kent Gordon
James Hamilton
Tracy Hendrick
Misty Hill
Greg Howell
Zack Jackan
Sid Jain
Achyut Kathuria
Mohammad Khan

Mike Kinney Bill Knight Mani Vinay Kumar Kotipalli Travis Kowalke Matthew Krey Timothy LeJeune Sonic Li Yao Luu Brendan McKelvy John McKinney Crystal Mersh Sharon Moon Jeremy Moore Rachid Mouhallil
Emily Nelson
Thomas Nguyen
Tina Nguyen
Danny Pate
Thomas Penna
Evan Pike
David Poindexter
Rupshika Rajasekaran
Maria Rawindraraj
Dale Robson
Ethan Simmons
Rob Sommers
Hon. Mary Squires

Alandra Strain
Christina Thomas
Tony Thomas
Matthew Turney
Joshua Tyson
Vinitha Venugopalan
Amanda Walter
David Ward
Jennifer Weaver
John Willenbrock
Don Wiscaver
Carl Woods









# Novartis Vaccines and Diagnostics

# United States Flu Cell Culture Facility

Novartis's breakthrough use of innovative technology and development of a large-scale manufacturing process to produce seasonal and pandemic influenza vaccines earned them the 2013 Facility of the Year Award for Process Innovation and led the Facility of the Year Awards Judging Panel to select this project as the 2013 Overall Winner.

Their United States Flu Cell Culture Facility in Holly Springs, North Carolina, USA, features an innovative process that breaks with the 50-year tradition of utilizing eggs for the method of growing the virus. The facility utilizes a ground-breaking cell culture technology that offers many potential advantages over the traditional manufacturing process for flu vaccines.

The proprietary technology at Novartis's United States Flu Cell Culture Facility enables flexible and fast start-up of vaccine manufacturing, offering rapid response to potential pandemic influenza threats while fulfilling the need for seasonal influenza vaccines. This project introduces a promising new path for vaccine production, and exemplifies the type of advancements in pharmaceutical and biotechnology manufacturing technology that the FOYA program seeks to recognize. In honor of this accomplishment, Novartis is named the 2013 Facility of the Year Awards Overall Winner.

# Please join us in congratulating the 2013 Facility of the Year Awards Overall Winner!

For full details about this truly innovative project, please read the feature story in the January/February 2014 issue of *Pharmaceutical Engineering* Magazine.

For more details, visit www.FacilityoftheYear.org









### **Key Project Participants**

#### Designer/Architect/Main/General Contractor:

Jacobs, Cincinnati, Ohio USA

#### Designers/Architects/Planners:

- Flad Architects, Madison, Wisconsin USA
- · CRB Engineering, Cary, North Carolina USA

#### Construction Manager:

· Jacobs, Cincinnati, Ohio USA

#### Project Controls:

RGD Project Management, Inc., Cary, North Carolina USA

#### Main/General Contractors:

- BE&K Building Group, Inc., Raleigh, North Carolina USA
- CRB Builders, Gary, North Carolina USA

#### Piping and HVAC Subcontractor:

· Gamewell Mechanical, Salisbury, North Carolina USA

#### Piping Subcontractors:

- · JJ Kirlin, Raleigh, North Carolina USA
- · Kinetic Systems, Inc., Durham, North Carolina USA
- · DSI, Morrisville, North Carolina USA

#### **HVAC Subcontractor:**

AC Corporation, Greensboro, North Carolina USA

#### **Automation and Control Suppliers**

- RoviSys, Aurora, Ohio USA
- Siemens Industries, Morrisville, North Carolina USA

#### Major Equipment Suppliers/Contractors

- · ABEC, Bethlehem, Pennsylvania USA
- · Groinger & Co., GMBH, Crailsheim, Germany
- York Johnson Controls c/o VCS, West Chester, Ohio USA
- Integrated Process Engineers & Constructors, Inc., Fort Atkinson, Wisconsin USA
- Stellar Energy Systems, Raleigh, North Carolina USA



**Category Winner for Facility Integration** 

# Biogen Idec Flexible Volume Manufacturing (FVM) Facility

The very nature of clinical manufacturing, smaller batch volume requirements, and less predictive outcomes requires an adaptable, flexible manufacturing platform. To fulfill this requirement in a cost effective manner, while reducing time to delivery of clinical material, Biogen Idec constructed the Flexible Volume Manufacturing (FVM) facility, located at Research Triangle Park (RTP), North Carolina, USA. The facility produces treatments for neurodegenerative diseases, hemophilia, and autoimmune disorders.

The FVM facility integrates into the RTP site, utilizing fixed equipment in existing 2K Small Scale Manufacturing and 15K Large Scale Manufacturing facilities without impact to existing manufacturing operations, creating a hybrid network of fixed and single use equipment to accomplish variable product demands. The facility features a 100% single use flow path in a validated closed system.

The manufacturing methods employed at the FVM facility provide for a flexible multi-product environment, with less capital investment, reduced utility demands, and increased speed through the product pipeline as compared to traditional manufacturing methods. Biogen Idec's bold new methods and resulting success earned them the top spot in Facility Integration.





# ISPE Annual Meeting Student Perspective

By Sarah Brown

As a Chemical Engineering student, I have been to various conferences before, but my experience at this year's conference was outstanding. Although I was a first time attendee, I was pleasantly surprised to see the high level of interactions and networking even outside of scheduled seminars and events. I enjoyed meeting students from other chapters and young professionals who willingly shared their experiences on how they successfully transitioned into their industry after graduating from college. Some of my favorite events included the "speed-networking" breakfast, the young professional's dinner at Southern Hospitality, and the social event at the Newseum in downtown Washington D.C. All of these events put me in close proximity with some of the most influential and experienced directors and senior management with highly rated biotechnology and biopharmaceutical companies. This was great to me because it took away the pressures of formalities and allowed everyone to get to know each other in a relaxed atmosphere. However, networking was not the only thing I liked about this year's conference, I also enjoyed the industry related seminars and regulatory talks that discussed and addressed current practices and success stories for other professionals to learn from. My favorite presentations included the plenary talk by Janet Woodcock, Current Regulatory Issues: QbD, Q7, by Christine Moore, and many other leadership and training seminars provided from the young professionals track. As a senior from NC State University I also enjoyed this year's vendor exhibition because I was able to expand my material and equipment network that will be extremely beneficial and useful as references and providers for my senior design project with Biogen Idec. Overall, I was very satisfied with the time I spent away from classes for this conference and I am honored that I was chosen to go by CaSA on a reimbursed student discount. Although I graduate in May, I plan to stay active within the international organization and look forward to next year's annual meeting in Las Vegas, Nevada!

By Alysia Williams

The opportunity to attend the ISPE 2013 Annual Meeting proved itself as an invaluable learning experience. There were many professionals, young professionals, and students who lent themselves as vessels of expertise to provide information which I will use as I pursue my career. It was incredible to engage in multiple Young Professionals education sessions and clearly understand the topics of discussion due to the various courses that I have taken while attending North Carolina Central University. My time at the Annual Meeting was well spent and I would encourage all of my colleagues to attend in the future.

By Jennifer Carmical

I had a wonderful time at the Annual Meeting, and I feel it was educational and conducive to furthering my career. I was able to connect with several pharmacists in industry positions, like Karl Manning from PharMEDium, Joseph Iacobucci from Clinical Systems Inc., and Rafael Rodriguez, the production manager for a company in Venezuela called Proyecto Araguaney. All of the people I met encouraged me to pursue a career in the pharmaceutical industry, and several expressed the feeling that there are not enough pharmacists involved in the development and study of drugs now. I had one person in particular tell me that his company used medical doctors in their studies, even though pharmacists would be better suited to the role, due to the fact that there aren't enough pharmacists interested in this career path to apply for these types of jobs.

The educational sessions were interesting and useful, especially the one titled Effective Project Leadership. The speakers were inspiring and knowledgeable, Rick Gunderson from Merck in particular. He spoke about the project he led that produced Hepatitis B vaccine in China, saving thousands, if not millions, of lives. He brought the ultimate goal of the industry to the forefront: saving lives. I feel honored to have heard him speak. There was another session about Global Supply Chain Security that I found relevant to myself as a future pharmacist, which dealt with how to keep the products we produce safe, from the factory to the patient. I was unaware that such a large percentage of medical products were diverted to the "black market" or just stolen and later reintroduced into the supply chain without any effort to properly store or transport them. The act being put forth to Congress should help with this problem, but it will not solve it. There is still a lot that needs to change.

I really appreciate the support afforded to me and my fellow student chapter members by CaSA in attending this event, since we could not have possibly sent as many people there with our limited funding. This conference has given me opportunities that I could not have attained on my own, and connections that I feel will benefit me for the rest of my career. Thank you so much, and I am already looking forward to attending again next year.

#### By Maria Matkovska

I attended the 2013 ISPE Annual Meeting in Washington D.C - Ray Anover, ISPE NCSU advisor, Sarah Brown, NCSU Vice President, Jamie Sigmon, NCSU Public Relations Chair and myself, represented the ISPE Student Chapter from NCSU. On Sunday, I attended the Young Professional/Student Luncheon and Orientation and I met many active students and young professionals, who presented their posters at the International Student Poster Competition and Professional Poster Competition on Monday. I also attended many educational sessions, which were on the following topics: Biomanufacturing, Executive Series: Baxter Facility Case Study, Process Validation and Advanced Aseptic Processing II.

The main focus of the first class I went to was Quality by Design (QbD) that must be implemented in future facilities. Design issues such as system closure risk analysis, hybrid process/facility design, implementation of Controlled Not Classified spaces, and "fast track" delivery for facilities implementing new technologies were discussed. The speakers at the Baxter Facility Case Study session gave an overview about the new, state-of-the-art manufacturing facility that will be built in Covington, Georgia - the challenges related to design and construction of a massive facility were addressed. At the Process Validation course, available and practical approaches to some of the most significant challenges to implementation throughout a product's lifecycle were explained. Finally, the Advanced Aseptic Processing II course went over the practical aspects of technology transfers that cover both the dosage form and the clean room concepts that define the process. It was also discussed how a selection of pump types for fillfinish can lead to interesting results.

Overall, I really enjoyed the 2013 Annual ISPE Meeting. I have gained new knowledge about the Pharmaceutical industry and built a stronger professional network.

#### By Abhishek Agrawal

The Annual ISPE Meeting started with a "meet and greet" session for all the young professionals. This was a great opportunity as I got to mingle with other young professionals. Student posters were admired by people from all around the world, which was amazing. People who were interested in my poster took photographs of my poster for their future reference. It was an awestruck moment to see experts who have so much experience reviewing my research. I can't even put to words the networking opportunity! People were so friendly and professional at the same time, and they were willing to help you. Overall, the Annual ISPE Meeting was an unforgettable experience. Thank you, LeAnna Pearson, for your support in making this happen!

#### By Jamie Sigmon

The ISPE Annual Meeting is an excellent experience for students who are interested in pursuing a career in the pharmaceutical industry. At the November 2013 meeting in Washington DC, there were educational sessions, networking opportunities, nightly social events, vendor demonstrations, and prize giveaways.

While at the meeting I was able to attend education sessions related to manufacturing technology, facilities and design, and quality systems. I also enjoyed the chance to interact with vendors in the exhibition hall and I even won a Kindle Paperwhite from the prize drawing. The nightly social events were a fun way to relax and mingle with other ISPE members. The highlight of my experience was meeting many young and seasoned professionals from the industry. As a result, I made contacts from all over the world including Mexico, Japan, China, Switzerland, Denmark, UK, US and more.

I am very thankful to ISPE and the Carolina South Atlantic Chapter for the opportunity to attend the 2013 Annual Meeting. I plan to attend future meetings and I'm looking forward to Vegas!

#### By Chanel Wilson

The ISPE Annual Meeting was an eye-opening experience. Big Pharma can sometimes seem very vague and removed from scientists and professionals. The ISPE Annual Meeting makes it known that pharmaceutical sciences is much more than Biomanufacturing and Biotechnology. They are comprised of great people who love their company and have a true and invested interest in recruiting new faces into industry. Many times I felt overwhelmed with the thought of my education not meeting the standard required by industry. Fortunately prior knowledge, the young professional sessions, and many opportunities to network informed and prepared me to go into more advanced lectures. Afterward, I knew I had a great foundation and feel ready to become a true Young Professional. This is an experience that everyone who is a Member or who wants to become a Member should have. ISPE Rocks!

# **Young Professionals Corner**

Sparian's Bowling, January 30,2014

By Jon Doyle, Young Professionals Committee Chair

The ISPE Young Professionals are hosting an exciting night of networking and bowling January 30, 2014 from 6:30 to 8:30 at Sparians in North Hills. The evening will include unlimited bowling, appetizers and a cash bar. Keep an eye out for the ISPE event email for registration details. If you would like to sponsor this event please contact Jon Doyle at jdoyle@pci-Il.com. Be sure to tell your friends and coworkers to come out for some fun too!





# CaSA ISPE Toys for Tots Breakfast

December 18, 2013 7:30am - 9:00am Novartis (Multipurpose Room) 475 Green Oaks Parkway Holly Springs, NC

Come one and come all and bring your unwrapped toy(s)! Network with colleagues and embrace the giving spirit. Please bring you photo ID and RSVP prior to the event.

www.eventbrite.com/e/ispe-casa-annual-toys-for-tots-tickets-

9297181119?utm\_campaign=new\_eventv2&utm\_medium=email&utm\_source=eb\_email&utm\_term=eventurl\_text

# **Student/Young Professional Corner**

# 2014 CaSA Leadership Symposium: "Taking Control of Your Career"

By LeAnna Pearson, ISPE CaSA Student Affairs Committee Chair

The 2014 CaSA Leadership Symposium: "Taking Control of Your Career" will take place on Friday, February 7, 2014 at the NCSU McKimmons Center.

This event will center on leadership development for all career levels of students and young professionals working in the pharmaceutical manufacturing and services industry. The day will include a Keynote speaker, networking opportunities, speaker panels on "how to get hired" and "what makes a great leader." This is a great venue to connect with professionals that can change your career or help guide you to your innovate path to leadership.

Sponsorships are still available for Platinum, Gold, and Silver levels and we would love to hear from those interested in participating as either an industry mentor or speaker. Please contact Jennifer Lauria Clark, CPIP at Jennifer.Clark@CAgents.com for more information.

We are creating a resume book from this event. If you want your resume to be viewed by top companies in the area, please send your resume to casaleadershipsymposium@gmail.com All levels of experience are welcome to participate (your information will be confidential). The deadline for resume submission is March 1, 2014.

# **Technology Corner**

# 21st Annual ISPE-CASA Technology Conference

By Mike Putnam, ISPE CaSA Technology Conference Committee Chair

Exhibitor registration for the 21st annual ISPE CaSA Technology Conference is now open! On April 8, 2014, over

1,000 attendees and 200 exhibitors are expected to converge on the downtown Raleigh Convention Center for what's quickly becoming the Southeast's largest gathering of life sciences professionals. The planning committee is working diligently to ensure the 2014 event is better than ever. A key initiative of the committee is a program that engages drug and device manufacturers by gaining an understanding of their training needs, technology requirements, and industry 'hot topic' interests. Feedback from manufacturers will allow the committee to structure the conference in a way that maximizes effectiveness for all attendees.



Manufacturer employees should email techconference@ispecasa.org to learn more.

Quick facts about the 2014 conference:

- 21st Annual Technology Conference date is set for Tuesday, April 8, 2014
- Hosted at the Raleigh Convention Center
  - New for 2014...Manufacturer Showcase area
  - Exhibitor Registration opened Tuesday, November 12, 2013
  - Attendee Registration opens Tuesday, January 14, 2014

Please look for more details about the Technology Conference in future newsletters as we spotlight key features and information in each issue. In the meantime, visit www.ispe-casa.org/2014 to register your company to attend. The conference is expected to be a sellout, so act fast. Thanks and I'll see you there!







# ISPE CASA LEADERSHIP SYMPOSIUM SPONSOR FORM

February 7, 2014 \* The McKimmon Center Raleigh, NC

	*Please Print or Type		
	Company Name:		
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	nyment Information: (Please note that eived and processed by ISPE-CaSA. Upon rec	no sponsorship is confirmed until payment has been eipt, you will receive a confirmation email).	
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# Name of Attendees (First, Last, + ISPE Member # if applicable) Deadline to submit names of attendees is 12:00pm, Thurs. February 6, 2013

Attendee	Company	Email Address	ISPE Member #
1.			
2.			
3.			
4.			
5.			
6.			

# SPONSORSHIP OPPORTUNITIES

### **Platinum - \$1,000**

- Audience
   Recognition at event
   (stand up and be recognized)
- Table Tents at Event
- 6 Attendees (Total)
- Plus all benefits below

#### Gold - \$500

- Table top exhibit
- Large Signage at Event
- Logo on all marketing materials including weekly e-blasts
- Resumes of all attendees
   who submit a resume
- 4 Attendees (Total)
- Plus all benefits below

#### **Silver - \$350**

- Signage at event
- Verbal recognition at event
- Power Point Slide Recognition
- 2 Attendees

# 21<sup>st</sup> Annual ISPE-CaSA Life Sciences Technology Conference

Tuesday, April 8, 2014 • 10:00 am - 7:00 pm

Raleigh Convention Center • Raleigh, North Carolina

**Registration**: ISPE Members \$55 / Non-Members \$75

Early Bird Rates: ISPE Members \$35 / Non-Members \$55



- Source state-of-the-art technology
- Discuss novel applications and solutions with over 200 exhibitors
- View product demonstrations in person
- Network with more than 1,000 industry professionals
- Participate in industry-specific informational sessions
- Enjoy food and beverages throughout the day

For more information and to register, please visit: www.ispe-casa.org/2014



Carolina-South Atlantic Chapter







#### Advertising Opportunities in ISPE CaSA 2014 Electronic Newsletter

The ISPE CaSA Chapter produces six e-newsletters per year. ISPE CaSA sends 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 Web site so your ad can be accessed by interested visitors to our site.

The cost for a full color business-card-sized ad is \$750 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional \$750 per year for six issues. Space limits the number of front page to only **four**, and is offered to the first four paid advertisers 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 \$500.00 for the entire year.

You may choose one of the special offers below:

- \$1,500 Full-color ad for six issues on the front page of each newsletter (\$250/issue)
- \$ 750 Full-color ad for six issues (\$125/issue)
- \$200 Full-color ad in 1 newsletter of your choice
- \$500 Adding a hot link for directing customers to your website by a simple click

We continue to improve the ISPE CaSA website and will be producing the newsletter in an HTML format vs. PDF format for 2014.

We hope you will take advantage of these opportunities and advertise in the 2014 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2014 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. Deadline for 2014 advertisers to be in the February 2014 issue is January 27.

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. Artwork should be sent directly to <a href="mailto:newsletter@ispecasa.org">newsletter@ispecasa.org</a>.

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!

#### **Carolina-South Atlantic Chapter**





# Electronic Media ISPE-CaSA.org

Now you can reach www.ispe-casa.org audience by advertising on our website. A limited number of advertising spots are now available so don't delay. Contact the ISPE Carolina-South Atlantic Chapter to reserve your space. (Please note: ISPE-International-forbids website ads on our chapter's home page, so they are on subsequent web pages.)

To learn more about this opportunity, contact Penney De Pas, Chapter Manager, at 919-573-5442 or <a href="mailto:pdepas@ispecasa.org">pdepas@ispecasa.org</a>. If you are interested in signing up for the program, please complete the form and return to <a href="mailto:pdepas@ispecasa.org">pdepas@ispecasa.org</a> or fax 919-787-4916. Advertisements are sold on a first-come first-served basis.

#### SPECS OF ADVERTISEMENT:

Top Placement Ad 120 pixels wide by 240 pixels high; File formats accepted: .GIF, .JPG, .SWF Bottom Placement Ad 240 pixels wide by 400 pixels high; File formats accepted: .GIF, .JPG

	12 months	6 months
240 x 400 Vertical Rectangle	\$500	\$300
120 x 240 Vertical Banner animated	\$400	\$250
120 x 240 Vertical Banner - non animated	\$300	\$200

□ 240 x 400 Vertical Rectangle ad 6 Months, \$300
 □ 240 x 400 Vertical Rectangle ad 12 Months, \$500

		<ul> <li>□ 120 x 240 Vertical Banner animated ad 6 Months, \$250</li> <li>□ 120 x 240 Vertical Banner animated ad 12 Months, \$400</li> <li>□ 120 x 240 Vertical Banner - non animated 6 Months, \$200</li> <li>□ 120 x 240 Vertical Banner - non animated 12 Months, \$300</li> </ul>				
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# ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for Your Business!



Our Chapter produces six enewsletters per year, and we depend on the support of our advertisers. We send out the newsletters via email 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 info@ispeCaSA.org

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

1500 Sunday Drive, Suite 102, Raleigh, NC 27607 Tel: 1-919/861-4531 • Fax: 1-919/787-4916 whaines@manganinc.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 whaines@manganinc.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: 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.

#### A word to the ISPE CaSA Newsletter advertisers:

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.