INSIDE THIS ISSUE

President’s Message ........................................................................................................................................... 2
Board List .................................................................................................................................................................. 2
Welcome New Members ........................................................................................................................................... 3
Membership Development Corner ................................................................................................................................ 4
CaSA ISPE Annual Planning Meeting Highlights ...................................................................................................... 6
EHS Update-PART 2: New EPA Boiler Rules .................................................................................................................. 10
Big Changes Coming for the 20th Annual ISPE CaSA Technology Show ......................................................................... 13
Young Professional Corner ........................................................................................................................................... 14
CaSA Member Spotlight — Todd McCulloch .................................................................................................................. 17
Upcoming Events ........................................................................................................................................................... 18

2012 Remaining Events

October 13: Resume Workshop at BTEC Center, 12:00 PM - 4:00 PM
October 18: Viral Clearance Program at BTEC Center, 2:30 PM - 7:00 PM
October 24: YP Managing Your Financial Future at BTEC Center
October 25: Therapeutic Thursday, Location/Time TBD
November 11-14: Annual Meeting, San Francisco, CA
December 6: Toys for Tots at GSK in RTP, NC
December 6: Automation Program at GSK in RTP, NC

Dedicated to Project Success
Validation
Commissioning
Quality & Compliance
Process Improvement
IT Services & Products

Local Contact:
Jennifer Lauria Clark
Cell: 919.696.2335
Jennifer.Clark@CAgents.com

Featured Sponsors

Element
Intelligent valves, sensors and controllers
www.burkert-usa.com

Oneal
The business of project success
Our full range of planning, engineering, and construction solutions consistently deliver satisfaction in the pharmaceutical industry.
Contact Us • www.onealinc.com • (919) 840-9500

Dunbar
Construction Consultants
Over 25 years of successful local Bio-Pharm experience. Put us to work for YOU.
www.dunbarcc.com 919.412.1054
President’s Message

ISPE CaSA has already started off our year with a bang. I am proud to be the President of such a great group of people and I sincerely thank you all for giving me this opportunity to help lead our Chapter in achieving a new level of success.

Congratulations to our new Young Professional members who have joined ISPE this month and made our Young Professional Group almost double in size. We welcome our 44 new members from Hospira and PCI.

We had one of our most successful Durham Bulls Family Nights August 2 with over 150 people in attendance. The weather was beautiful and many new faces got to experience our great event.

As I shared with everyone in our last newsletter, the Board was to have a Board orientation to train our Chapter leaders on the expectations and duties of being a Board Member. This happened in mid-August and our committee chairs are on board and trained to make this our best year ever. Each committee has a set of goals this year that they finalized at our Board training. They are centered on membership growth, retention and keeping the students and Young Professionals engaged along with promoting and holding exciting educational events, networking opportunities and keeping up with the current technology for our information distribution. They have all come out of the orientation fired up to plan educational and networking events that are of great interest to our local members.

Our Annual Planning Session that was held August 30 at Prestonwood was a great time for sharing and learning more about the inner workings of our Chapter. There are more details about the Annual Planning Session in this edition of the newsletter.

ISPE just hosted our monthly Therapeutic Thursday event at the Carolina Ale House in Cary, NC and it was packed. There were new faces and old friends sharing an appetizer and drink after a long day of work.

Thanks to the participation of Brad Kosiba at our Annual Planning Session; he shared a great idea for ISPE CaSA to house the ISPE Baseline Guides in a central location. We are now working on having a library of the ISPE Guides housed where our members can come and view them for reference. We will keep you posted on this location and guidelines for use.

A special shout out to our Chapter Management team Peter and Amanda from First Point Management Resources who have continually been there to staff our events and meet our endless needs. Thank you from the entire ISPE CaSA membership.

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 myself or any other Board Member know how well we are doing or what we can do to improve.

(continued next page)
President’s Message

Each newsletter you will see me thanking our volunteers 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:

1. Get involved. Let us know if you are interested in volunteering with a committee or in active leadership of ISPE CaSA. Specific committees have stated in this newsletter if they are in need of help. Membership and Tech Show 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.

2. 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 October 26. The winner of a gift card will be announced in the next newsletter.

3. Come see us…
   - At the Student Fall Resume Workshop October 11 at BTEC on NCSU Campus. More details page 15.
   - On Thursday October 18th for our Viral Clearance event. We will have speakers discussing the removal of viral contamination using specialized membranes or chromatography in order to ensure that therapeutic drugs derived from certain sources are fully rid of any viral contamination. (Novasep.com) There will be a beginner/intermediate track and an advanced track for this educational program.
   - At our networking social Thursday October 25.

Enjoy our beautiful Autumn days and take a moment to relax.

Jennifer Lauria Clark, CPIP
Chapter President

Welcome New Members

New Members who joined July 31, 2012 through September 26, 2012

Samuel Bandil
Lincoln Barber
Amber Batchelor
Justin Borchers
Gordon Brezicki
Don Brooks
Lindsay Brown
Cheryl Brucato
Chris Bunting
George Calvin
Jennifer Carmical
Josh Carter
Thomas Clawson
Kathleen Cline
Thomas Cobb
Charles Cornell
Andrew Cramer
Aaron Dancy
Michael Davis
Deidra Donn
Brittany Doyle
James Driscoll
Kathryn Faulk
Kelsey Gray
Ashley Gregory
Avery Hackett
Jessica-Lynn Harrell
Zachary Hart
Chris Helms
Glenn Herman
Daniel Kim
Andrea King
Kevin Klein
Jennifer Kuplic
Sandee Lakshmanan

Richard Lawless
Eric Levi
Sean Lewis
Charles Luce
Kristin Marks
Kyle Matika
Alexandra Morsch
Stephen Mulligan
Stephanie Nguyen
Nathan Nickolason
Benjamin Parker
Mayur Patel
Jennifer Patrick
Carmen Pericozzi
Joanna Perry
Jegan Pillai
Chantelle Pline
Katelyn Putnam
Ashley Rasavage
Carly Reuther
Douglas Ross
Brendan Schaefer
Andrew Schott
Timothy Stark
Luke Stockhausen
Stephanie Suarez Avery
Logan Talley
Rachel Thiel
Alena Tipnis
Jennifer Turner
Bailey Wagner
Patrick Wall
Allison Wallace
Andrew Weingart
Brandon West
Hey Members!

By Jerry “Patch” Paciorek, CaSA Membership Development Chair

Volunteers Wanted
Do you enjoy a challenge, like social events, and you are an energetic communicator? 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 Patch Paciorek at paciorek@cagents.com.

Refer a Friend Program
Don’t keep ISPE all to yourself. You already know that it pays to be an ISPE Member. The ISPE “Refer a Friend” program is our Member referral program, designed to encourage you to share the benefits of ISPE with your peers. For every friend you refer who joins ISPE, you’ll earn one free month membership. Credits will be applied towards your next membership renewal. Read more at http://www.ispe.org/membership-referral-program.

ISPE at the Durham Bulls Game
A gathering with food, friends, and “the field,” that is the baseball field. On August 2, 2012 155 of our CaSA ISPE members and their guests enjoyed a wonderful evening, watching the Durham Bulls win 1-0 over the Gwinnett Braves. The weather was absolutely beautiful and many of the attendees stated that they were already looking forward to next year’s game. A special thank you goes out to our Sponsors for the event: CRB and Griffin Engineering & Technical Services. If you missed this fun event, you will have an opportunity to attend the Durham Bulls CaSA ISPE Game Night in 2013.
The 2012 ISPE Membership Recruitment Challenge is On!
Let's Go Fishing for New ISPE Members

Cast your nets, recruit more ISPE Members and win prizes at ISPE's 2012 Annual Meeting in San Francisco!

There are more ways than ever for your Affiliate or Chapter to Win:

**MOST NEW MEMBERS RECRUITED**
The Affiliate/Chapter that has the most “Refer a Friend” referrals by Annual Meeting wins $500 to fund a local event or program. To learn about ISPE’s “Refer a Friend” Program, visit www.ISPE.org/Membership.

**YP SPIRIT AWARD**
This award goes to the Affiliate/Chapter that has the highest percentage of growth in YP recruitment from 31 December 2011 to 31 October 2012.
- $/€150 to fund a local YP event or program
- Free recorded webinar for all new YP recruits

**MOST YOUNG PROFESSIONALS (YPs) RECRUITED**
Awards will be given to the winners in three categories:
- Small Affiliate/Chapter (1 – 400 Members)
- Medium Affiliate/Chapter (401 – 999 Members)
- Large Affiliate/Chapter (1000+ Members)

**YP ABOVE AND BEYOND AWARD**
This award goes to the Affiliate/Chapter that has recruited the most YPs from 31 December 2011 to 31 October 2012.
- $/€250 to fund a local YP event or program
- Free recorded webinar for all new YP recruits
- Two CPIP™ eligibility application fees - total value $350/€270

There are so many fish in the sea... let's get them “hooked” on ISPE!
CaSA ISPE Annual Planning Meeting Highlights

By Matt Gilson, Vice President of CaSA ISPE

The ISPE CaSA Annual Planning Session for 2012 was held on August 30 at Prestonwood Country Club. The kick-off and introduction meeting was well attended as approximately 65 people came and enjoyed coconut shrimp, among other delicious offerings. Among the 65 people were several first time CaSA attendees as well as many new Young Professional members. This was the first ISPE CaSA Annual Planning Session to utilize ISPE CaSA’s Twitter account (@ISPE_CaSA) to publicize the event. Please follow ISPE CaSA on Twitter to get the latest news and announcements about other events.

After a mingle period at the start where the author only got one name incorrect without looking at name tags, a presentation of ISPE CaSA was given in the main ballroom. The presentation gave an overview of the Chapter organizational structure, benefits of being volunteer of ISPE CaSA, the officers and committee chairs of the Chapter, and details of what each committee does, its goals and needs for the 2012-2013 year. Attendees were encouraged to get involved where they felt most needed.

At the end of this presentation, a rousing feedback / discussion session was held where a Committee Member or Chapter Officer was placed at each table and given some questions and topics to discuss. These included items such as what people most valued about ISPE CaSA, events or topics they’d like provided by the Chapter, and ranking 5 activities put on by the Chapter from most desired to least. This provided the Chapter leadership with valuable feedback to understand what interests people the most.

All of this was followed by a reception providing an opportunity for those wanting to get more involved with CaSA to talk with those needing more people to be involved. If you missed the event and would like more information about where you can get plugged in, please look at the committee list with the leadership contact information. The best way to get involved is to help with a CaSA Committee.

I’d like to thank everyone who worked to put this event together and I’d like to especially thank those who came out to an ISPE CaSA event for the first time. Thanks for your interest and we look forward to seeing you at an upcoming event.

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

See photos from the Annual Planning Meeting on the following page...
Chapter Events

(continued from previous page)

STI Components, Inc.

Biotech, Pharmaceutical, Food & Beverage and Cosmetic processing companies choose STI for products such as:

- Hoses
- Tubing
- Aseptic Sampling
- Disposable Tubing Sets
- Stainless Steel Componentry
- Peristaltic Pumps
- and much much more...

Please visit us at
WWW.STIFLOW.COM

PHARMACEUTICAL/BIOTECHNOLOGY PROJECT SPECIALISTS

- Project Planning/Design
- Process Design
- Scheduling/Cost Estimating
- Construction Support
- On-Site Resources

BUDD HIPP
919.755.1033
www.hipp-usa.com
Technical Section

EHS Update-PART 2: New EPA rules will require an energy assessment for most facilities with boilers

By Martin E. Rock, PE, JD, LEED-AP, Past President & Board Chairman (2005-2006)

How to Determine the Status of Your Site?

Following are the key questions to determine the applicability at your site:

1. Do I have a boiler or boilers?
2. Is my boiler subject to the rule?
3. Am I a major source for HAPs (hazardous air pollutants)?
4. What size are my boilers?
5. What type of boiler do I have?
6. What fuel or fuels do I combust?
7. What are the installation dates on my boilers?

Based on this review, you can determine the status and requirements for boilers at your site. The overall scope of the Boiler MACT/GACT Energy Assessment under current law is given in the following table:

Existing boilers with heat input capacity greater than 10 million Btu per hour that are biomass-fired or oil-fired must have a one-time energy assessment performed by a qualified energy assessor.

<table>
<thead>
<tr>
<th>SCOPE OF ENERGY ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.3 TBtu/yr</td>
</tr>
<tr>
<td>Energy assessment for facilities with affected boilers using less than 0.3 trillion Btu (TBtu) per year heat input will be one day in length maximum. The boiler system and energy use system accounting for at least 50 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities, within the limit of performing a one-day energy assessment.</td>
</tr>
<tr>
<td>0.3 to 1 TBtu/yr</td>
</tr>
<tr>
<td>Energy assessment for facilities with affected boilers using 0.3 to 1.0 TBtu/year will be three days in length maximum. The boiler system(s) and any energy use system(s) accounting for at least 33 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities, within the limit of performing a three-day energy assessment.</td>
</tr>
<tr>
<td>&gt;1 TBtu/yr</td>
</tr>
<tr>
<td>Energy assessment for facilities with affected boilers using greater than 1.0 TBtu/year, the boiler system(s) and any energy use system(s) accounting for at least 20 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities.</td>
</tr>
</tbody>
</table>

In the new, proposed Rule, EPA clarified three items regarding the energy assessment as follows:

1. **Scope:** limited to only those energy use systems, located on-site, associated with the affected boilers and process heaters. The final definition for “Energy use system” was intended only to list examples of potential systems that may use the energy generated by affected boilers and process heaters.
   - EPA did not intend that the energy assessment would include energy use systems using electricity purchased from an off-site source.
   - EPA also did not intend that the energy assessment include energy use systems located off-site.

2. **Compliance Date:** Energy assessments must be completed by the compliance date (currently March 21, 2014) for existing sources.

3. **Maximum Duration Requirements:** Change the maximum time from one day to eight technical hours and from three days to 24 technical hours and to allow sources to perform longer assessments at their discretion.

(continued next page)
What is the difference between a Boiler Tune-up and Boiler System Energy Assessment?

In a boiler tune-up (sometimes called a simple audit), the assessor evaluates the boiler room, including the boiler and accessory support equipment. In a boiler systems energy assessment (sometimes called a complete site audit), energy assessors evaluate the boiler room, the steam system, and all the components throughout a facility, including steam traps, piping, valves and steam users. In terms of costs, a boiler tune-up generally costs approximately $2,500, whereas a complete boiler system energy assessment can cost several-thousand dollars, depending on the complexity and the size of the plant.

During a boiler tune-up, facilities should operate normally so that the tune-up assessor can identify visual indications of energy loss and possible operational and safety issues.

The boiler, its controls, fuel delivery, blowdown (continuous and bottom), safety valves, safety valve piping, feedwater conditioning and delivery will normally be inspected to identify inefficiencies and flag possible hazards. The tune-up includes an inventory of key equipment, to help identify energy-saving methods. Usually, the tune-up review encompasses some areas to improve engineering practices and some possible health and safety concerns.

Next, the tune-up assessor conducts a boiler efficiency analysis, sampling the products of combustion as the burner ramps from low to high fire. During this process, the tester is looking for a typical boiler load and how much time the unit stays at certain firing rates. This, along with the flue gas analysis showing percent oxygen, carbon dioxide and carbon monoxide, will determine the overall efficiency of the boiler. Since a typical boiler will consume four times its initial cost in fuel annually, this means a fuel spend in excess of $1,000,000 per year in many industrial applications. The tune-up should pay for itself in short order!

During the broader boiler systems energy assessment, assessors also will focus on the boiler room. The review extends into the overall steam system seeking opportunities for potential energy and safety improvements throughout the facility. Typically, this means gathering data regarding steam flow, pressures, temperatures, supply and return piping and support, steam traps, steam vents, ancillary piping including valves and insulation, remote condensate pumps and heat recovery; generally, seeking energy savings by identifying where the losses are occurring. The analysis of this large volume of “data” is converted to useable and manageable “information” and incorporated into the final report.

Here are a few areas likely to be of interest for possible energy savings opportunities:

Insulation and Gaskets

Initially, it is important to investigate whether the boiler has been overheating. If so, there may be problems with either the boiler’s insulation or gaskets, which could lead to damaged and unsafe equipment. Repairs are relatively inexpensive to correct these issues. On the other hand, these observations may indicate that the boiler is seriously scaled on the waterside, and may have to be acid cleaned at a fairly significant cost; or, perhaps it is now time to replace or re-tube the boiler rather than investing more into an obsolete unit.

During the energy assessment mentioned previously, the assessor is checking for specific components in the flue gas which indicate the effectiveness of the burner to efficiently oxidize the fuel. Additionally, the assessor is looking for the level of nitrogen oxides (a precursor to smog formation) and the stack temperature above the saturated steam temperature within the pressure vessel. Results could lead to recommending an oxygen sensor/transmitter in the exhaust gas. This device continuously senses the exhaust gas oxygen content and provides a signal to the controller to trim the air damper and/or fuel valve to maintain a consistent oxygen concentration as atmospheric conditions vary, thereby improving combustion efficiency. If the nitrogen oxide (NOx) level is high and the boiler is in a non attainment area for ozone (smog), a flue gas recirculation (FGR) system may be recommended. Retrofitting FGR can help reduce the boiler NOx emissions.

If the stack temperature is abnormally high, this may mean the boiler is scaled or caked with soot, inhibiting proper heat transfer. A cleaning and re-tuning of the burner will usually alleviate this problem, returning the boiler/burner package to an acceptable fuel to steam efficiency ratio. The stack temperature also may indicate that the boiler is a good candidate for a feedwater economizer, reducing the stack temperature and adding to the boiler efficiency by transferring waste energy in the exhaust gasses going up the stack to usable energy.
Technical Section

(continued from previous page)

by preheating the boiler’s feedwater makeup. As a rule of thumb, for every forty (40) degree (F) temperature drop in the stack exhaust gas, you gain one (1) percent in boiler efficiency.

Reducing Operating Pressure

A boiler system energy assessment will typically determine if it is possible to reduce the boiler’s operating pressure. Assessors look at the heating process and the existing piping layout to determine if the diameter of the piping, controls, steam traps and control valves can function well and tolerate lower pressure. If the pressure can be reduced, less energy will be used, cutting fuel costs.

Piping Conditions

A complete facility audit will review steam piping for energy losses through radiation and steam leaks. Steam loss through radiation can be reduced by insulating the pipes and associated valves.

Steam leaks are especially wasteful and should be addressed as soon as possible. Depending on the pressure in the pipe and the size of the leak, the losses can be staggering. Therefore, the time, effort and expense required to rectify the problem quickly is normally warranted.

Normally, an energy assessor will investigate the feedwater supply to the boiler and condensate the condensate recovery systems.

Feedwater System

The objective of investigation of the feedwater system is to determine if water sent directly into the boiler is free of dissolved gases such as oxygen and carbon dioxide, which can cause destructive corrosion to the boiler and condensate lines. If such gases are present, the assessor may recommend installing a deaerator. Generally, deaerators are an option if the boiler operates at 75 psig or greater, has limited standby capacity and is using 25 percent or more cold water make-up. This will greatly reduce the need for chemical treatment. Such an improvement not only saves operational cost because of the cost of the chemical additions, but also saves fuel costs because of the reduced amount of continuous blowdown required. Continuous blowdown is an energy-filled drainage of expended chemicals and corrosion sediments from the boiler in a waste effluent that is literally going down the drain unless it is reclaimed.

Condensate Return System

Energy assessors also will examine the condensate return system, and how much (hot) condensate is being returned to the boiler’s feed tank. Hotter is better, as it takes less energy to turn condensate back into steam when the condensate returns with much of its sensible energy. Returning more condensate back to the boiler can, therefore, lead to hundreds of thousands of dollars in annual savings because the burner does not have to add as much (fuel) energy to bring the boiler water back to the boiling point.

As a general rule of thumb, for every eleven (11) degree (F) rise in the feedwater temperature there is a one (1) percent rise in boiler efficiency.

Steam Trap Audits

Steam trap audits are typically performed during a boiler system energy assessment. There are many well-documented success stories of achieving steam trap energy savings through better management of these devices, and in some cases this function can be automated for continuous control.

(continued next page)
Generally, steam traps perform the following functions:

- Prevent water hammer
- Return condensate to the boiler
- Improve the quality of the steam for further processes or uses
- Help in the removal of air and dissolved gasses from the steam, thus removing insulators, corrosive effects, and inefficiency.

Essentially, steam traps can fail open or fail closed. If they fail open, the result has the same effect and cost as a steam leak. If they fail closed, the result is not separating condensate from the steam—leading to water hammer, corrosion, and structural failure. This condition also can lead to line freezing depending on the climate.

By finding, documenting and testing the individual traps, the assessors look for traps that are “blowing through,” pressurizing the condensate line(s) causing possible water logging of the heat user and cutting down on system efficiency and performance. This situation can also result in excessive venting and energy loss through the condensate receiver/boiler feedwater tank.

The other critical issue assessors look for is water hammer, which occurs when steam condenses in a horizontal section of the steam piping. Steam picks up the water as it travels approximately 10 times faster above the fluid, forming a wave or “slug” of water which is hurled at high
velocity into a pipe elbow or other restrictive device, such as a valve, tee, etc., creating a loud hammering noise while severely stressing the pipe. In some cases water hammer is of sufficient force to fracture the pipe, causing the condensate to flash into steam, expand over 1,600 times its volume and result in major damage for anything in its destructive path. Therefore, this part of the assessment serves an important preventive function that can result in better safety and system reliability, plus potentially considerable savings.

The Return on Your Investments

What return on investment (ROI) can be expected?

The tune-up or energy assessment reports document where the key energy losses are occurring and what can be done to address the energy and financial losses, potentially returning thousands (sometimes millions) of dollars to the customer in the form of fuel savings.

Given the cost of corrections or retrofits, the installation costs, and the possible costs due to downtime, the energy assessor or installing contractor can evaluate and document the ROI. Management can then determine which corrections or retrofits make good economic sense in terms of budget or time for the desired return on the investment.

Bottom Line: The EPA is requiring these boiler tune-ups and energy assessments but they may actually save money at your site. Managing these reviews properly and selecting a good assessment team will go far in ensuring those gains.

Martin E. Rock is a registered professional engineer (5 states) and a licensed attorney (2 states). He serves as President & Senior Principal with OMNI Professional Environmental in Research Triangle Park, North Carolina. He was a Member of ISPE for over 10 years, including a previous tenure as Chapter President of the ISPE-CaSA Chapter.

Questions or comments on this article can be submitted to the author at omni.professional@gmail.com
Big Changes Coming

By Bruce Craven, CaSA Technology Show Committee Chair

You spoke and we listened. At the completion of this year’s Technology Show, the committee sent out surveys to both our exhibitors and attendees and received great participation. The feedback was helpful in determining what we did right, what everyone would like to see again (also what they would not), and suggestions for improving the event. First let me say thank you to all the participants and secondly—we heard you loud and clear. The biggest and most repetitive comment was that exhibitors and attendees all wanted to see something new and different. It seems were ready to go the “next level,” while keeping the same positive aspects of the current event. Since the completion of this year’s event, the Technology Show has continued to work and develop a plan to respond and deliver.

What’s New for the 2013 Show

The 20th Annual Technology Show date has been set for Tuesday, March 26, 2013. Not really a big change, a couple of weeks earlier than this year, but the next part is where the excitement builds. To go “bigger,” “better,” and “more exciting,” we are moving the event to the new Raleigh Convention Center (RCC) in downtown Raleigh. Yes, you read that correctly and yes we did listen to the reasons some of you were opposed to going to the RCC. Remember, we heard you and we have tried to accommodate as many of the suggestions as possible. I believe you are going to be impressed.

A Quick Glance at What’s Under Veil

- Moving to the Raleigh Convention Center
- Later start time—to help alleviate some of the potential traffic issues
- Better food, more food—food, snacks, drinks provided all day at no charge
- Internet access throughout the event for everyone
- Easy parking—we are renting a parking deck for the day
- Keynote Speaker—this is going to be a great surprise
- Fewer and more defined training tracks—better training rooms and speaking environments
- Expanded exhibitor spacing

There are many more changes, big and small, but since we have several of these to write, there will be time to provide additional details and information as we move closer to our show date—March 26, 2013. Please be sure to look for a Technology Show update in each future newsletter as we will be spotlighting key changes and information about our show. Also, if you would like to be a part of our Committee, please contact me. We have many opportunities for you to help us build the 20th Annual Technology Show.

See you soon.

Look How CPIP now offers:

- Streamlined eligibility requirements
- Earlier access for Young Professionals
- Greater focus on pharmaceutical-specific knowledge and skills

Set yourself apart in the pharmaceutical industry and become a CPIP today.

For more information visit: www.ISPE-PCC.org
Young Professionals Corner

Managing Your Financial Future: Financial Basics and Developing Your Own Strategy—OCTOBER 24TH

Make plans and bring a friend to attend the YP sponsored evening talk planned for Oct 24th. The topic is “Managing Your Financial Future—Financial Basics and Developing Your Own Strategy.”

Join us for a light dinner at BTEC and listen to Brandan Kot of BB&T Financial Services talk about strategies to manage your savings. A Question and Answer session will follow the talk.

More information on this event will be forthcoming.

Sponsorship and Table Top Exhibit Opportunities Available
WWW.ISPE.ORG/TRAINING

ISPE 2012 TRAINING SERIES
CLASSROOM TRAINING
Aquire and Develop New Skills for Your Career

FACILITIES AND OPERATIONS
Chicago, Illinois USA
24 – 27 September
Water (New Course); Sterile Manufacturing (New Course); Facility Project Management (New Course); Clinical Trial Materials (New Course); GAMP® 5 and HVAC

Silver Spring, Maryland USA
17 – 18 October 2012
Risk-MaPP and Bio Manufacturing Facilities

Berlin, Germany
22 – 25 October
GAMP® 5, Clinical Trials and Oral Solid Dosage

San Francisco, California USA
11 – 14 November
Turning QbD Into a Reality (New Course and Guide); Quality Risk Management (New Course) and GAMP® 5

Tampa, Florida USA
3 – 6 December
Water (New Course); Modern C&Q, Cleaning Validation, Project Management (New Course); Sterile (New Course); GAMP® 5 and Auditing

GLOBAL GMP SOLUTIONS
WWW.ISPE.ORG/2012ANNUALMEETING
REGISTER NOW!
WWW.ISPE.ORG/2012ANNUALMEETING
Resume Workshop
October 13, 2012

Event Details
Come out and get your resume ready!!! There are lots of events coming up that you will need a polished resume for: the Annual Meeting, Internships, Co-Ops and the 2013 BTEC Career Fair! There will be lots of handouts and ample time to have your resume reviewed and polished! Light refreshments will be provided by Panera Bread.

What: Resume Prep Session
When: October 13, 2012
Where: NC State BTEC Center
850 Oval Drive, Raleigh NC
Time: 12pm-4pm (session length depends on attendance)
RSVP: Please RSVP to ispecasasac@gmail.com by October 10th. Registration will also be allowed at the door.

WE NEED STUDENTS AND PROFESSIONALS FOR THE SESSION
Viral Clearance Event

BTEC NC State Centennial Campus
(850 Oval Drive)
Thursday, October 18th, 2012
2:30PM – 7:00PM

Register Here!

Presentations By:

Kathryn Martin Remington, Ph. D.
Principal Scientist
BioReliance

Nathan Roth, Ph. D.
Sr. Director, Pathogen Safety
NC, R&D
Grifols

Registration Pricing

*Sign up 4 people and get the 5th person FREE!
(Must all be in the same price category: Member/Non-Member/YP)
Contact Amanda info@ispecasa.org to register the 5th person!

Member - $50
Non-Member - $75
Young Professional - $20
Student – FREE (members only)

*Note for Students: On the registration page you will be required to include a billing address, however you will NOT be asked for payment information.*
CaSA Member Spotlight

Todd McCulloch, 1961-2010

On May 23, 2010, we lost a beloved family member, John ‘Todd’ McCulloch to a massive heart attack. Todd was an active Member of ISPE for many years and served on the CaSA Chapter Board of Directors, as Chair of the Membership Committee and provided leadership, support and coordination to several of the Chapter’s golf events. Todd enjoyed serving the Chapter but moreover he enjoyed every opportunity to contribute to the Chapter’s success and be around others.

Todd’s professional career encompassed many aspects of instrumentation compliance. After graduating from ECU, he worked at Burroughs Wellcome and then Wyeth Vaccines. In 1997, he joined PCI where he played a vital role until his passing in 2010. His cheerful personality, positive outlook and exuberance always made the work day enjoyable.

Most everyone in our industry knew Todd as the guy with the big smile and a big heart. No one was ever happier to see others enjoying themselves more than Todd. He was an avid golfer and present at every CaSA golf outing.

What we remember when we think of Todd is his positive outlook on life. Todd loved life and he wanted to see everyone around happy and full of positive energy. He was passionate about everything including his service to the ISPE CaSA Chapter. Todd always knew what to say or do to brighten the day or cheer someone up when they needed it most or at least interject humor or embarrassment to deflect our minds from whatever burden. That was his trademark. One of his main daily goals was to ensure that others were happy. His heart and soul showed in all that he did.

On September 20, 2012 PCI held its annual golf event in Todd’s memory at the Neuse Golf Course in Clayton, NC. The event raised over $10,000 for the Triangle’s American Heart Association through player donations and PCI donations. This is a true testament of how Todd touched everyone’s lives, professionally and personally.

We will forever be grateful that Todd was part of our Chapter, and part of our lives. All the memories we have shared with him will forever be cherished and remembered. Todd will permanently live in all our hearts. We can rest assured that Todd is always looking down on us and smiling...just like we remember.

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.
**Upcoming Events**

**MARK YOUR CALENDARS!**

### 2012 Events

- **October 13, 2012**
  Resume Workshop at BTEC Center, 12:00 PM - 4:00 PM

- **October 18, 2012**
  Viral Clearance Program at BTEC Center, 2:30 PM- 7:00 PM

- **October 24, 2012**
  YP Managing Your Future at BTEC Center

- **October 25, 2012**
  Therapeutic Thursday
  Location and Time TBD

- **November 11-14, 2012**
  Annual ISPE Meeting, San Francisco, CA

- **December 6, 2012**
  Toys for Tots at GSK in RTP, NC

- **December 6, 2012**
  Automation Program at GSK in RTP, NC

### 2013 Events

- **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**
  Biofest at the NC Museum of Natural Sciences, Raleigh, NC

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

---

**Therapeutic Thursday Sponsorship Opportunities**

Is your company looking for a way to “get your name out” amongst industry professionals? Have you considered sponsoring a CaSA ISPE Therapeutic Thursday Event? Your sponsorship money would go to the food/appetizers for this monthly event along with the opportunity to talk about your company.

Therapeutic Thursdays are held on the last Thursday of the month at Ale Houses located in cities around the Triangle area. **Our next Therapeutic Thursday will be on October 25.**

Please contact Amanda Wujcik at awujcik@ispeCaSA.org if you are interested in sponsoring this fun networking event.
ISPE CaSA Chapter
E-Newsletter Ads

Newsletter Ads Work for your Business!

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!

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.