President’s Message

ISPE CaSA has kicked off another 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.

Congratulations to our new Young Professional Members who have joined ISPE this month and made our Young Professional Group even bigger. We welcome our 18 new Members from Hospira – thank you for your support!

We had a good time at the Durham Bulls Family Night on August 26. It’s nice to have an event like this where we can include our families and colleagues. It was Military Appreciation Night, so we got to see the parachutists fly in to the ballpark.

(continued next page)
President’s Message

The board had an orientation session to train our Chapter leaders on the expectations and duties of being a board member in mid-August, and our committee chairs are on board and trained to make this our best year ever. The board is focused 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. As you’ll see on our website (http://www.ispe-casa.org/), we have a busy end to 2013 and our start to 2014 already planned, so make sure you hold those dates in your calendar.

Our Annual Planning Session, held on September 12 at Prestonwood, was a great time for sharing and learning more about the inner workings of our Chapter as well as meeting some new people. We had good energy and excitement about the Chapter and learned where volunteers are needed. There are more details about the Annual Planning Session in this edition of the newsletter.

An event that I am very excited about is our Fall Gala, coming up on October 10 at The Umstead Hotel and Spa in Cary, NC. We will be honoring Facility of the Year Award winners Novartis and Biogen Idec and will have a special Member spotlight. Registration and sponsorship opportunities are now available on our website. I hope to see you there!

It is important to hear feedback from our membership about what we are doing. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please contact me or any other board member.

(continued next page)
ISPE CaSA is also on social media, so please follow us, like us, etc. on Facebook, Twitter, LinkedIn, and Google+.

We have an awesome team of volunteers and staff who work behind the scenes to make ISPE CaSA run and I want to thank them for all their continued hard work. We wouldn’t be the great chapter we are without you!

And now, a To-Do List:

• **Get Involved.** Let us know if you are interested in volunteering on a committee or in active leadership of ISPE CaSA. Please contact info@ispe-casa.org or the chair of any committee that may interest you.

• **Share your ideas.** Send in some fresh ideas for 2013-2014 educational programs and networking events. We know that you have ideas that would make a great event so please share.

• **Come see us at the...**

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CaSA Member Spotlight: Bo Crouse-Feuerhelm

*By ISPE CaSA Newsletter Committee*

**Q:** What is your full name?
**A:** Bo Crouse-Feuerhelm

**Q:** Birth Place?
**A:** Romney, West Virginia

**Q:** College?
**A:** Attended Shepherd College from 1978-1979 in Shepherdstown, West Virginia. I am a life-long learner and participate actively in professional development and continuing education classes.

**Q:** Tell me a little about your personal life.
**A:** Married to Jeff Feuerhelm for 25 years (24 September). We met playing volleyball in Washington D.C. area. We have two great children – Cameron and Jordan. They along with our 3 dogs and 2 cats and wonderful friends are what life is all about! I enjoy my down time with them whether it is a family dinner, movie or trips together.

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**Q:** What is your present position? What do you do at your job?
**A:** Global Account Executive for M+W Group.

**Q:** How long have you been with your current employer?
**A:** 15 months

**Q:** Tell me about your career path, and how you ended up where you are today.
**A:** I began my career in Washington, DC working for the Federal Government in a typing pool. From there I rose from Administrative positions to marketing, communications, sales and account management roles.

**Q:** What is your favorite part of your job?
**A:** Engaging with our clients and focusing on solutions to the challenges that keep them awake at night. Working internationally for the last 6 years has been fascinating and a great learning experience for me. It has truly opened my eyes more widely than I had ever imagined possible.

**Q:** How long have you been a Member of ISPE/when did you first join ISPE?
**A:** Nearly 20 years.
Membership Corner

By Jerry “Patch” Paciorek, CPIP ISPE CaSA Membership Development Chair

I had a great time speaking with many of you at the CaSA Annual Planning Meeting, where I shared my excitement for the upcoming year. Having met our goal of 300 new Members last year, we have set an even higher goal to sign up 350 new Members by June 30, 2014. And we’ve enjoyed a tremendous start with 85 new Members joining our chapter since July 1, 2013.

Tracey Ryan, the ISPE Affiliate/Chapter Relations Coordinator recognized Hospira and the CaSA Chapter for the 18 new Young Professional (YP) members that were signed up from Hospira on September 4, 2013 during a recent International YP ISPE Conference Call.

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-referal-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.

Q: What benefits have you realized from being a Member of ISPE?
A: Long-term relationships, professional development, mentoring and leadership opportunities, although these have waned significantly in the last few years. I have met people in ISPE that will be my life-long friends.

Q: Why are you still involved with ISPE?
A: Networking, pursuit of new business opportunities and professional development.

Q: Any Mentors/Role Models that have helped to shape your life?
A: I have been incredibly blessed throughout my career with amazing mentors and role models. There are so many people who have impacted my life and career from Alan Levy, whom I worked with for >8 years at CRSS and Sverdrup Corporation in Washington, D.C. area to Pat Angelino, whom I knew in DC and ultimately ended up working with him when I moved to NC in 1993 at Gilbane; to Gary Reichelt who took a chance and hired me at CRB; and Jeff Odum whom I met at Gilbane and has taught me a lot about the biotech industry.

Q: If you weren’t involved in pharma/biotech, what business do you think you’d be in?
A: I would be in forensic sciences as it fascinates me.

Q: What is one skill you wish you had that you don’t?
A: Patience

Q: Any hobbies? What are they?
A: Volleyball, biking

Q: Do you collect anything?
A: Wine corks and shoes

Q: Finish this sentence – “I need more…”
A: Patience! Keep my opinions to myself and accept the things I am unable to change

Q: Favorite Food?
A: Sushi

Q: What is something that people would be surprised to learn about you?
A: I’m an adrenaline junky.

Q: Last movie you saw?
A: “We’re the Millers.” I like comedies, adventure drama and Sci-Fi movies.

Q: For those in the early stage of their careers, what advice would you give them?
A: Treat people the way you want to be treated. Take the task given to you no matter how menial you think it is and do it well. You can learn something from everything you do!

Membership Development

Congratulations to CaSA’s Newest CPIPs!

Sara M. Lewis, CPIP and John D. Wass, CPIP
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.

(continued next page)
Novartis’ breakthrough use of innovative technology and development of a large scale manufacturing process to produce seasonal and pandemic influenza vaccines garnered them the award for Process Innovation.

Their United States Flu Cell Culture Facility in Holly Springs, North Carolina, USA, features a process that breaks with the 50-year tradition of utilizing eggs for the method of growing the virus. By developing a process based on robust, deep tank mammalian cell technology, several issues associated with traditional technology have been circumvented and offers potential advantages including: process raw materials are readily available and not threatened by pandemic events; and cell culture process utilizes closed-system bioreactors, reducing required biosafety level for the manufacturing space.

In addition to the breakthrough technology associated with their mammalian cell culture process, the Novartis team used creative solutions to other facility operations, notably their approach to Containment Convertibility, which allows the facility to operate at BSL -1, -2, and even -3 levels to reduce operating costs associated with the need to operate in higher containment modes on demand. The Facility of the Year Award Judging Panel names Novartis as winner of the Process Innovation category for forging a path in a new frontier for vaccine production.
Networking

Rush Hour Karting - Therapeutic Thursday Event Summary
By Wendy Haines, ISPE CaSA Newsletter Committee Chair

Who enjoys eating great food, networking with other professionals, and racing around a track for 8 laps in a go-kart after a work day? Everyone who came to the Rush Hour Karting ISPE CaSA Therapeutic Thursday event on July 25, 2013! A big “thank you” goes out to Bray and CRB for sponsoring the event. While everyone was enjoying food and networking, T.K. Miller split people into racing groups. Each racing group received racing instructions and the “layout” of the track. Racing was highly competitive, but the biggest winner of the night was Matthew Denny, who finished first in both heats he competed in. People were repeating the following mantras, “All is fair in love and go-kart racing and Rubbing is racing.”

(Above) Matthew Denny, the winner of both heats he raced in.
Thank You to the Newsletter Committee!
By Wendy Haines, ISPE CaSA Newsletter Committee Chair

Gracias, Merci, Grazie, Thank you! It has been my privilege to be the ISPE CaSA Newsletter Chair and one of the reasons the ISPE CaSA newsletter has been successful is due to my hard working, wonderful committee members. My committee members have “fast-tracked” edited content to guarantee newsletters are published prior to an upcoming ISPE CaSA event, written summary articles of past events, taken pictures, and provided suggestions regarding newsletter features and ways to make the ISPE CaSA newsletter better. When you read an ISPE CaSA newsletter, you only see the name of the author for a piece of content, not the people on my committee who have taken time to review, edit, and ensure each piece is “reader friendly.” Thank you, members of the ISPE CaSA Newsletter Committee, for your time and effort to make the newsletter one of the best newsletters within ISPE.

Welcome New Members
New Members who joined July 20, 2013 through September 14, 2013

Brooke Bernard
Andrew Bitner
Mike Brown
Brendan Cameron
Chance Carpenter
Hannah Carroll
Jessica Cotton
Jacob Cowart
Monica Danala
Diane Darlington
Chelsea Daughtridge
Penney De Pas, MA, CAE
Joe DePalo
Victoria Divon
Alex Drennan
Alex Earle
Emily Engeman
Aziza Fadadi
Dana Fisher
Katy Fitzgerald
Alberto Flores
Cal Foshee
Derek Frick
Sarah Gadbois
Jordan Galatrito
Dale Garrison II
Ray Gesling
Amy Gordon
Jeremy Guill
Upma Gulati
Laura Hardesty
Jeanne Hathaway
Rich Heeter
Shane Holland
Yuzhe Hu
Jamie Johnson
Jrinath Kashi Ranganath
Phillip Kostelic
Dr. Julie Lautens
Callie Longo
Grant Madinger
Robert Mancino
Gina Marsee
Mark McGinn
Brian Miller
Christi Mitchell
John Oroz
Jason Ott
Ashley Overcash
Devansh Parikh
Prerna Pherwani
Amanda Pons
Bryan Prince
Charlie Queen
Wendi Raig, m1
Andrew Ray
Chris Redpath
Jessa Ren
Steve Roese
David Rowe
George Sharpe
Joseph Shim
Aishwarya Sivakumar
Rachel Snyder
Phillip Stanford
Nancy Stowe
Stephanie Summe
Gamya Suryapalli
Matt Talivorian
Del Turnham
Wahala Wahala
Shane Welsh
Kasi Wetherington
Stephen White
Christon Wiles
Shinhae Yoon

Newsletter Committee Members
Diane Darlington
Matt Denny
Mike Kriston
Kimberley Parker
Rich Stanfield
Michelle St. Peter
John Vaughn

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Follow us:
Annual ISPE CaSA Planning Session
By Heather Denny, Vice President of ISPE CaSA Chapter

Speed rounds…. That was the format to learn about this year’s exciting plans for ISPE CaSA. Our committee chairs shared their plans with members at the Annual Planning Session on Thursday, September 12. Sixty-two registrants and participants (and several walk-ins) first heard from our President, Matt Gilson. Matt provided an overview of the organization and introduced this year’s executive board, committee chairs and our new management staff from First Point Management Resources. After Matt’s comments speed rounds were in full force with committee chairs hopping from table to table as the bell chimed. Based on the volume in the room, attendees were quizzing the committee chairs about future plans. All committees are looking for new members so if you were there and heard something you liked, please reach out to that committee chair. If you were not there it is not too late! The committees and contact information are listed in this newsletter please reach out if you would like to learn more.

All attendees were entered and one lucky winner, Karin Cleary, went home with an iPad-Mini. At the conclusion of the business portion, everyone enjoyed Southern inspired appetizers including shrimp and grits, chicken and waffles, and a little barbecue. The crowd must have enjoyed the food and conversation as the crowd did not thin out even as our advertised ending time came and went.

If this event is any indication of the year to come, you want to update your calendar now and make sure you do not miss the next ISPE CaSA event! 🎉

Karin Cleary won an iPad-Mini.
Technical TIP

“There are no personnel allowed in a Zone A space.”

Just one of many items covered during the HVAC design course recently presented by ISPE in Durham, NC.

--
Jerry "Patch" Paciorek, CPIP Project Manager, Commissioning Agents, Inc.ISPE CaSA Membership Development Chair

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OCTOBER 10, 2013
ISPE-CASA GALA

Sponsored Reception: 6-7 (Open Bar)
Plated Dinner: 7-9 (Beer and Wine)

Introductions
Biogen Idec Presentation
Novartis FOYA Presentation
Member Recognition
Adjournment

Sponsorship Opportunities:

Platinum: $1,750*
- Exclusive table for 8 guests
- Weekly e-blasts
- Table tent recognition
- Signage at event
- PowerPoint recognition

Reception: $1,500*
- 2 Guests
- Signage at event
- Power Point Recognition

Gold: $950
- 4 guests
- Signage at event
- PowerPoint recognition

Silver: $500
- 2 guests
- PowerPoint recognition

* Limited Sponsorship Opportunities

To Register for this event
please visit our website:
www.ispe-casa.org

Costs of Event:
Members: $125 each
Member + Spouse/Guest: $225 per couple
YPs/Students: $125 each
Non-Members: $150 each
ISPE-CaSA GALA
Sponsor Form
October 10, 2013 * The Umstead Hotel, Cary, NC
Sponsored Reception: 6-7pm (Open Bar)
*Plated Dinner 7-9pm (Beer & Wine)

*Please Print or Type
Company Name: ________________________________
Contact Name: ________________________________
Phone Number: ________________________________
Contact Email: ________________________________
Mailing Address: ________________________________
City, State, Zip: ________________________________

Payment Information: (Please note that no sponsorship is confirmed until payment has been received and processed by ISPE-CaSA. Upon receipt, you will receive a confirmation email).

☐ Check # __________ (Please make checks payable to ISPE-CaSA, 1500 Sunday Drive, Suite 102, Raleigh, NC 27607-5151)
☐ Credit Card
Card Number ____________________________
Ex. Date: ____________ CVV ____________
Signature: ________________________________

Billing Address: ________________________________

Name of Attendees (First, Last, + ISPE Member # if applicable)
Deadline to submit names of attendees is 3:00pm, Thurs. October 3, 2013

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In order to be included in the PowerPoint Presentation & Signage, you must email your company logo to: info@ispecasa.org no later than October 3, 2013 at 3:00 p.m. If you have any questions contact: Daya A. Relli @ info@ispecasa.org or call 919-573-5442

Sponsorship Opportunities
Check One:

☐ Platinum: $1,750*
  • Exclusive table for 8 guests
  • Weekly e-blasts
  • Table tent recognition
  • Signage at event
  • PowerPoint recognition

☐ Reception: $1,500*
  • 2 guests
  • Signage at event
  • PowerPoint recognition

☐ Gold: $950
  • 4 guests
  • Signage at event
  • PowerPoint recognition

☐ Silver: $500
  • 2 guests
  • PowerPoint recognition

*Limited Sponsorship Availability

Menu Options:
• Grilled Beef Tenderloin
• Sautéed Grouper
• Vegetarian
Establishing your Credentials: 
Overview of the ISPE CPIP Credential

By Jon Doyle, ISPE CaSA Young Professionals Committee Chair

Looking to further your professional development pathway and unlock greater career opportunities for you and your company? Come to the NC State Biomanufacturing Training & Education Center on November 21 for an overview of the ISPE Certified Pharmaceutical Industry Professional (CPIP) credentials held by the ISPE Young Professionals. Current CPIP holder Amy Lineberry will be leading the event discussing who is eligible, what the Credential means, and how CPIP benefits you as a professional.

This free event is open to ISPE Members and non-members who are interested in gaining a competitive advantage and enhancing credibility in the life sciences industry. After the event, attendees are encouraged to attend the ISPE Therapeutic Thursday at Natty Greene’s located on South Glenwood Avenue.

MARK YOUR CALENDARS!

October 10, 2013 - CaSA ISPE Gala, Umstead, Cary, NC
October 24, 2013 - TT, Carolina Ale House, Raleigh, NC
November 3-6, 2013 - Annual ISPE Meeting, Washington, DC
November 21, 2013 - Young Professionals Event followed by TT, Natty Greene’s Pub & Brewing, Raleigh, NC
December 5, 2013 (tentative) - Toys for Tots followed by Educational Event, TBD
December 19, 2013 - Therapeutic Thursday, Location TBD

AND 2014!

February 7, 2014 – Annual Leadership Symposium (Career Development), McKimmon Center, NCSU Campus, Raleigh, NC
April 5, 2014 – TriSci Tech Expo, Museum of Natural Sciences, Raleigh, NC
April 8, 2014 – Annual ISPE CaSA Technology Conference, Raleigh Convention Center
May 19, 2014 – Annual ISPE CaSA Golf Event, Prestonwood Country Club, Cary, NC
Technical Section
Evaluating Virtualization of a Control System for use in a Production Environment

by Michael Baldauff, Staff Automation Engineer – Fujifilm Diosynth Biotechnologies U.S.A., Inc.

As control systems age considerations must be made on the lifecycle of the control system and how the system will be maintained in the future. One of the considerations is the hardware platforms available that will run the system. As this hardware ages, how should the system be replaced? Should the existing hardware on a production Distributed Control System (DCS) system be replaced with standard PCs and server hardware, or should the installation be moved to a virtual system?

FUJIFILM Diosynth Biotechnologies, USA (FDBU)

ABB distributed control system was configured and installed in 1996 to control batch operations and control clean utility distribution. Since this time, the DCS system has been expanded as the facility has expanded to cover a larger range of products and services (see list below).

1. Additional controllers added for new equipment.
2. A refold suite and new production reactors were added.
3. New clean in place (CIP) systems were added.
4. A new single use cell culture line was added.
5. A new water for injection, WFI, subloop was added.
6. New purification and cell culture product suites were added.

During this time, there have been 5 changes in company ownership which have made continuity and priority of system upgrade plans fluctuate with capital availability.

Timeline:
- 1996 - Installed ABB Advant MOD HP-UX (UNIX) Distributed Control System.
- 2001 - Microsoft Windows XP Released
- 2005 - Upgrade from UNIX platform to Microsoft Windows Platform - ABB stops selling UNIX operator workstations.
- 2006 - Start ABB Upgrade to Windows XP
- 2010 - Sales of Microsoft Windows XP ended – October/2010
- 2014 - Extended Support for Microsoft Windows XP ends - No more security updates

Currently the production DCS system is used for automated batch operations, such as CIP and Steam in place (SIP) in Fermentation, Cell Culture, Buffer Preparation, Media Preparation and Purification Areas. To help assure repeatability and consistency of operations for Fermentation and Cell Culture, the DCS is used for automated production batch operations. The system is also used for Clean Utilities Distribution and Monitoring to help assure continued operation and quality of clean utilities. The system can be used to page out critical and non-critical alarms on systems such as Environmental Chambers and production systems that are not continuously monitored by production or utility operators.

Some hardware running the Microsoft Windows operating system on the plant DCS system is 8 years old and is no longer supported by the manufacturer. When hardware failures occur, some of the server components can no longer be replaced as they have been obsoleted. The vendor operating software is currently running on a Windows 2003 Server and with Windows XP operator stations. Most of the batch portion of the distributed control system is running the ABB Advant MOD control system software platform, which runs on the HP-UX 10.20 UNIX operating system. Unfortunately, HP-UX 10.20 does not have an option for virtualization. Proprietary communication cards utilized with the Advant MOD DCS systems are additional hurdles that prevent virtualization from being a viable alternative for upgrading systems on the HP-UX platform. These cards used for the Advant MOD systems, referred to as RTAB’s, connect the MOD DCN communication ring with communicating workstations and MOD controllers such as the ABB AC460 controller. These have been typically installed in the server or workstation in an ISA or EISA I/O slot.

The proprietary HP-UX systems must be converted to run on the ABB 800xa Production Manager to continue to run on the Windows operating systems for long term viability of the system. Running the Advant MOD DCS system forces reliance upon the used/refurbished hardware market to support hardware that is no longer available in the new or remanufactured market from HP, the sole source provider of the hardware required to run HP-UX. Dwindling support of the Advant MOD system can also be felt as those trained on the 30 year old technology system, retire or change jobs adding fuel for the need to upgrade these systems. As fewer and fewer of the obsolete manufacturing DCS systems remain in the manufacturing industry, companies reduce staff or redirect staff to work on the more modern versions of the systems and only a select few retain the knowledge which can solve problems on these older systems.
A clear upgrade path must be considered to keep control systems in a state where plant personnel, control system manufacturers and control system integrators can help maintain and troubleshoot these complex control systems.

In 1996 the control system was installed as part of the then new Biotech manufacturing facility. In 2005, hardware sales ended that supported the HP-UX 10.20 system. In 2006, the upgrade to Windows XP began and nine years angidpscer that, the extended support for Windows XP by Microsongidp9fsc will end in 2015. The end of extended support to an operangidp9fng system means that any new security vulnerabilingidp9fes found by the community at large will not addressed by Microsongidp9fsc, and no patches will be provided to resolve the issues. The users will need to address these problems on their own. The above illustration is an example of the unavoidable lifecycle of some computer operangidp9fng systems, unngidp9fl you consider virtualizangidp9fon of your systems.

We need to ask a few quesngidp9fons: Does hardware dependence ever end? How can we avoid the need for conngidp9fnual songidpscware upgrades to be able to support hardware which will eventually fail? Why/how should this be avoided?

Purchasing a new set of hardware, costing on the order of tens of thousands of dollars now at its end of life, will allow extension of the control system life another 5-7 years. Expecting that in the near future hardware and software produced will no longer run the obsolete operating system, but where do we go from there?

Upgrading to the Windows 2008 Server operating system and the Windows 7 operating system require that the DCS operator graphics be redeveloped using PG2 graphics. Development and validation is expected to require an investment of hundreds of thousands of dollars.

Legacy systems:

In 2005 HP discontinued sales of its HP-UX 10.20 B2600 workstangidp9fons which were the last model supported by ABB to run the ABB Advant MOD DCS system. This began the inevitable task of upgrading the songidpscware plangidp9eorm to keep up with supported hardware. Three workstangidp9fons out of about 20 HP-UX operator stangidp9fons remain to finish the upgrade to a complete Windows interface and historian system. The ABB Batch 300 MOD songidpscware remains as a controlling part of the system. Two MOD UP-UX historians are also required to collect the producngidp9fon data logs of the system. This batch porngidp9fon, although it seems small performs a major role in the system and is costly and ngidp9fme consuming to replace under the ABB 800xa Producngidp9fon manager which runs on a Windows operangidp9fng plangidp9eorm. This replacement project is ongoing, but should be completed early next year. We are now looking at the imminent obsolescence of Windows XP and Windows 2003 Server hardware. New Dell workstangidp9fons no longer natively support windows XP without virtualization.

The Virtual Solution:

First we have to consider if the control system vendor software and required hardware platform supports virtualization. The hardware should be considered first. Any proprietary hardware must be able to connect to native
Ethernet interfaces or other virtually supported I/O ports such as com ports. ABB answered this question by providing a new externally Ethernet connected RTABs to resolve the proprietary interface problem. Secondly the software needs to be considered. Virtualization is a relatively new technology to be used in a production control system and not widely accepted. The answer from ABB therefore was not direct, and took a few weeks to determine because the vendor documentation at that time did not fully cover all topics completely. A meeting was held with knowledgeable ABB personnel that helped drive the decision to allow the system to be installed on a virtual system.

There are many advantages of virtualization. Most system backups are easier. Restoration of a server can take minutes in some cases instead of hours or reloading the software on a new piece of hardware. Test systems are easier to build. Virtual servers are hardware independent and portable. The Power consumption of a virtual system is lower because the number of physical machines has decreased. The virtual system can have a smaller footprint when multiple servers are involved. The following figure helps illustrate how a number of hardware servers can be consolidated into a smaller number of servers containing a number of virtual machines. Outdated operating systems such as Windows XP and Windows 2003 server become hardware independent. Training systems can be easily built if the processor and memory of the hardware platform permits. Many of the control system manufacturers have used this technology to conduct training because of the portability of the virtual systems. Within minutes they are able to switch from one version of their training system to another just by stopping and starting a new virtual machine. This allows a manufacturer to teach a class to one customer running one version of software and the next day they could be teaching another customer on the same hardware with a different version of software or even different control system software product.

Some additional advantages of virtual systems include easier administering as remote desktop. Restart of the system is faster avoiding the hardware tests and bios checks of a traditional hardware server. Higher uptime diversity is also a plus for the virtual systems when choosing a system with multiple blade servers such that if a hardware server fails, the virtual machines can restart on a backup server that has a copy of the machine installed. Systems can be quickly rebuilt in disaster situations where a roaming profile or system registry is corrupted. Virus protection software can be installed on virtual management system operating layer to help protect operating systems running on the virtual machine (VM) layer which may no longer be updatable.

The virtual system can run multiple different operating systems on the machine layer, old and new. Upgrading a system can be done totally offline by making a copy of the existing virtual systems and upgrading the software machine by machine. On the day of the upgrade cutover the old VMs data can be backed up and be shut down and the new VM brought online and data backups restored quickly to bring the system back up into operation with very little down time.

Some disadvantages of virtualization include the Hardware/Software License Costs being more expensive in cases where you have a large system and need redundancy. There are unknown compatibility issues and fewer implementations of these systems in the control system environment and additional training is needed for support personnel. The installed system is more complex because of the additional virtual management system, operating layer which manages the virtual machines. If designed improperly, the virtual system can put too many eggs in one basket. If the hardware running multiple virtual machines would fail, the whole system could be lost. Careful consideration must be made when designing the hardware platform to assure it is fault tolerant for a production system.
In this case moving to a virtual environment allows one to escape from the hardware dependencies of Windows XP and 2003 server, but is flexible enough to allow the old and new Windows operating systems to run. A moderate amount of initial investment is required, but in the long term, this will be the lower cost alternative postponing upgrades that are required to run on new server and workstation technology, as long as the new operating systems can continue to be virtualized on the chosen platform.

About the Author

Michael Baldauff, Staff Automation Engineer – Fujifilm Diosynth Biotechnologies U.S.A., Inc.

FUJIFILM Diosynth Biotechnologies is an industry-leading biologics Contract Manufacturing Organization with locations in Research Triangle Park, North Carolina, USA, and Billingham, UK. Recognized leaders in microbial-derived biologics, the two sites offer over 25 years' combined experience in the development and manufacture of recombinant proteins, vaccines and monoclonal antibodies, expressed in a wide array of microbial, mammalian and insect cell culture systems.

Michael Baldauff joined what is now FUJIFILM Diosynth Biotechnologies 13 years ago which was then part of Covance. Michael has 23 years of Automation and Controls experience and is a member of the International Society of Automation (ISA) and ISPE and currently serves as Vice President of ISA District II and holds a CAP certification. The ISA is a nonprofit organization that helps its members and other automation professionals solve difficult technical problems while enhancing leadership and personal capabilities.

He has a Bachelor’s Degree in Electrical Engineering from the University of Minnesota Institute of Technology.

For more about ISA or FDBU you can visit www.isa.org or www.fujifilmdiosynth.com.

References:
http://fujifilmdiosynth.com
IT Corner

By David Knorr, ISPE CaSA IT Communications Committee Chair

Did you know the CaSA Chapter is only one of four Chapters nationwide that owns and maintains its own website? In the last year, we have built our own website. The address for our new website is http://www.ispe-casa.org. Please update your favorites list or bookmarks with the new website.

We regularly update the site with current CaSA event information and information about new Members. You'll also find information about Chapter volunteer needs. Changes to the website during the upcoming year will include providing more information about the Chapter and the Chapter benefits, information about the CPIP program including a list of Chapter Members who are CPIP-certified, and a Member anniversary page.

Because we maintain our own site, we are able to improve and enhance it based on Chapter Member suggestions. Let us know your suggestions for ways to improve the website.

If you missed the CaSA Annual Planning Meeting held at Prestonwood Country Club in Cary, NC on September 12, you missed a great opportunity to provide suggestions to the Chapter. During the meeting, any attendee who offered a website suggestion or link was entered into a drawing to win a $25 VISA gift card. Mark Mistretta of New Brunswick/Eppendorf was our winner.

We are also now on Facebook (ISPE-CaSA), Twitter (@ISPE_CASA), Google+, Pinterest (ispecasa) and Linkedin (ISPE-CaSA group). Please join, follow, and share our information with your friends and colleagues if you haven't already done so.

We are also offering advertisements on our website. If interested, more information can be found on our website or by contacting us at info@ispecasa.org. But hurry! The number of advertisements available is limited.

Educational Corner

CaSA ISPE Education Update
by Ash Patel, ISPE CaSA Education Committee Chair

In December we will be hosting an education event in conjunction with the Toys for Tots drive. The date is tentatively scheduled for December 5, and a location is still being determined December, and a location is still being determined. This is the first education event for the 2013/2014 ISPE CaSa operating year.

We are planning on engaging key speakers from various functions within the industry. We will also enhance our delivery for the broader groups within the biotech industry that do not get regular presentation opportunities within ISPE. Some of those functions are Supply Chain Operations, New Product Operations, Process Optimization and many more.

I am currently looking for volunteers to help me put together exceptional education programs. Please contact me at ash.patel@biogenidec.com or call me at 919-236-9930.

Technology Conference

21st Annual ISPE-CASA Technology Conference
By Mike Putnam, ISPE CaSA Technology Conference Committee Chair

What a difference a year made for the 2013 ISPE CaSA Technology Conference! New venue, nearly one thousand attendees, live entertainment, over 200 exhibitors, industry leading speakers, cutting edge technology...the list goes on and on, making it hard to believe how much the event has improved over the years. From the time the conference was held in March, the planning committee has continued their efforts to make 2014 even better. Here are a few quick facts to know about the 2014 conference.

• 21st Annual Technology Conference date has been set for Tuesday, April 8, 2014
• Hosted at the Raleigh Convention Center
• Exhibitor Registration opens Tuesday, November 12, 2013
• Attendee Registration opens Tuesday, January 14, 2014

Please look for more details about the Technology Conference in future newsletters as key features and information will be spotlighted in each issue. There are many opportunities for you to help build the 21st Annual Technology Conference. If you would like to be part of the planning committee, please contact Mike Putnam, Technology Conference Committee Chair (mike_putnam@sequencevalidation.com).
The health of ISPE depends, in part, on its ability to continually attract new members. ISPE CaSA Chapters at area colleges attract and engage Student Members, many of whom go on to join the ranks of ISPE’s Young Professionals. In order to fulfill the requirements of their charters and function at their best, these Chapters need your help!

Below is a list of the active ISPE CaSA Student Chapters:

- **Campbell University (CU)**
- **East Carolina University (ECU)**
- **East Tennessee State University (ETSU)**
- **North Carolina Central University (NCCU)**
- **North Carolina State University (NCSU)**
- **University of North Carolina, Chapel Hill (UNC, CH)**

Both the NCCU and NC A & T chapters need an Industry Advisor. This is typically a seasoned industry professional (alumni or supporter of school) that can answer questions, help in obtaining speakers, and occasionally come to Chapter meetings.

ISPE CaSA is trying to revive the Clemson University Student Chapter. Clemson University would need an Industry Advisor who would be willing to devote a little extra time to get the Chapter back up and running.

Additional volunteer needs include the following:

- **Co-Chair** for Leadership Symposium – **February 7, 2014** at McKimmon Center (NCSU campus)
- **Co-Chair** for Student Poster Competition – **April 8, 2014** at Raleigh Convention Center
- **Co-Chair** for the management of Student Chapters

You can help to shape the career path of a student with as little as one hour a few times a year! Please consider volunteering in one of the positions listed above. For more information, or to sign up, please contact LeAnna Pearson at ispeCaSAsac@gmail.com.
Introducing the New ISPE CaSA Chapter Management Staff

By Penney De Pas, MA, CAE, ISPE CaSA Chapter Manager

**Penney De Pas, MA, CAE**  
**Chapter Manager**

Penney De Pas joined FirstPoint Management Resources’ (FPMR) predecessor management firm, Olson Management Group, Inc., as an account executive in August 1985. Over the previous five years, she served as executive director of the Arts Council of Wilson, the Ohio Regional Association of Concert and Lecture Enterprises, and the Ohio Organization of Orchestras. In her tenure with the management firm, Penney has developed extensive experience by having served over 35 different client associations, professional societies, and licensing boards in the capacity of executive director, executive secretary, deputy director/associate executive director, acting/interim director, convention/conference manager, advocacy director, publications director, and now, Chapter Manager with ISPE-CaSA. Penney was awarded the designation Certified Association Executive (CAE) in 1992 by the American Society of Association Executives. She earned her MA degree in arts and museum administration from The Ohio State University and her BA degree from Elmira College in French and art history. In addition to her association accomplishments, Penney is a results-and-productivity coach, artist, dancer, and author.

**Daya A. Relli**  
**Meetings Administrator**

Daya Relli joined the FirstPoint Management Resources team in 2012. She has worked with a statewide certification commission, providing membership services, data management, and continuing education review. She has also provided membership services for a national testing organization and meeting planning services for a national association in the clinical research field. Daya has extensive project management, human resource, accounting, and marketing experience, having worked for several years as an office manager for an architectural firm, and has been deeply involved in running community non-profit groups.

**Stephanie Ricker**  
**Communications**

Stephanie Ricker joined FirstPoint Management Resources in 2010 and has provided editorial, writing, and membership services for associations including several medical and certification organizations. She has extensive experience with communications and publications, having worked as an editor for a biotechnology and pharmaceutical sales training company and as an associate editor for a fiction-editing company. Her writing has been published in several non-fiction and fiction venues, and she is currently a feature writer for Success by Association, the magazine for the Association Executives of North Carolina. Stephanie graduated with honors from Campbell University in 2009 with a BA in English.

Peter Kralka and Amanda Wuczick are no longer affiliated with ISPE-CaSA and have been assigned other duties at FPMR. We wish them well in their new endeavors and thank them for their past service.
Advertising Opportunities in ISPE CASA 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. The number of front page ads is limited to only four, and is offered on a first come first served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad; a hot-link can be added to your submitted ad file for an additional $500.00 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
- $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.

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!
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 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!

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.