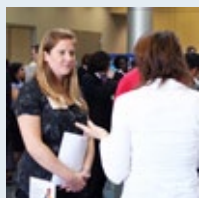
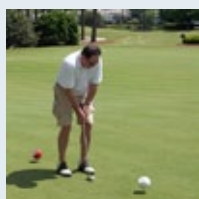




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Don't miss it!



Financial Seminar
UNC-CH School of Pharmacy
Thursday, June 9, 2011



Durham Bulls Family Night
Durham Bulls Athletic Park, Durham, NC
Friday, August 26, 2011

President's Message



Scott Billman

GIVE ME A BREAK !

A summer break, that is. With our Spring ending on a high note in the chapter we are looking forward to a fun filled summer. The 11th annual Technology Show at the RBC Center proved to be a great event. With over 1000 attendees and 16 educational sessions our Technology Show Committee once again raised

the bar for our Chapter. Carolina Hurricanes Assistant Coach Rowe was the keynote speaker and he thanked all of you for everything you do to support the healthcare industry.

The next Committee to outdo themselves was the Membership Committee and the team that planned our annual Golf Outing. This year the venue was moved to Prestonwood Country Club and we brought in enough golfers to spread out over 2 courses! I think everyone would agree that the pace of play was amazing for having 161 golfers out on the course. Many thanks to Heather Denny, Committee Chair, and Jim McGlade for organizing the event again this year.

The Young Professionals Committee is hard at work with more great events. Talk to everyone who got a chance to test their bowling skills at Sparians in Raleigh. These high tech bowling lanes step it up a notch and make bowling more fun than the last time you did midnight disco bowling. (OK, so I realize the Young Professionals out there don't actually understand that one).

The Young Professionals and Membership Committees also continue to collaborate on events such as Therapeu-

tic Thursdays. Keep an eye out for the notices so you know where to show up the last Thursday of every month to mingle with your peers in industry.

Not to be outdone, our Student Affairs Committee, led by Amy Lineberry, has had a very busy Spring. Tailoring events to the students looking for summer internships and full time employment, they put on another Career Fair in conjunction with BTEC. The event had 12 companies interviewing over 130 students for positions in industry; what an amazing opportunity for the student members of ISPE. The annual Poster Competition was held at the same event and had participation from 9 students from 4 schools: NCSU, NCCU, Campbell, and Meredith. Good luck to the students who entered as a trip to the ISPE Annual Meeting in November is on the line for the winners.

Keep your eyes open for the wave of summer events coming up in the next couple of months. The Program Committee rolled out another educational session for Reliability Excellence at the Biotech Center on June 2, the Young Professionals and the UNC-CH student chapter are putting on a Financial Seminar on June 9 at the UNC-CH School of Pharmacy, and August 26 will be the CaSA Durham Bulls Game.

No shortage of Summer activities for the CaSA Chapter. We thank you for the continued support of sponsorships and event participation. The events for the chapter are there for your enrichment. If you ever have a suggestion for a new event or an improvement for one of our existing events please reach out to any of the Board members. You can find the contact information at: <http://www.ispe-casa.org/index.html>

Scott Billman
Chapter President



**Carolina-South
Atlantic Chapter**

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- Amy Lineberry, Students
- Blake Derrick, Young Professionals
- Alan Tucker, Technology Show

Communication Committee Message



Wendy Haines

My name is Wendy Haines and I recently became chair of the Communications Committee for CaSA ISPE. Six people volunteered to serve on the Communications Committee due to the recent e-blast requesting volunteers! Thank you, CaSA ISPE members, for becoming more involved in CaSA by serving on a committee. Members of the Communications Committee are listed below.

Please send emails to: omni_tox@yahoo.com if you have ideas/suggestions regarding the website, newsletter, or social networks. We value CaSA ISPE members input and want to excel in communications regarding the CaSA ISPE Chapter.

CaSA ISPE Communications Committee Members:

Wendy Haines - Chair
 Brain Belvin
 Bruce Craven
 Megan Crum
 Diane Darlington
 Matthew Denny
 Rob Hughes
 Michael Kriston
 Stephen Rose
 Jeff Smith
 Michelle St. Peter

Wendy Haines
 Communications
 Committee Chair



Young Professionals

Committee Update

By: Blake Derrick, YP Committee Chair

Summer is just around the corner and the ISPE-CaSA Young Professionals group has been extremely busy so far! In addition to participating in the “Therapeutic Thursdays” on the last Thursday of each month with the Membership Committee, the group hosted the biggest YP social event to date at Sparians Bowling Boutique in North Hills of Raleigh on April 12th. The event featured some competitive bowling and networking with both young and seasoned professionals. A big thank you to our sponsors, CRB and Sequence Validation – without them this event would not have been possible! The YPC plans to host events of this scale on an annual or semi-annual basis as the group continues to grow. Some photos of the fun are below:

Next on the calendar will be a Financial Planning Seminar on the campus of UNC-Chapel Hill on June 9th at 6:00PM. This event will feature investment guidance and early career financial tips geared toward young professionals (but may serve as excellent reminders for experienced professionals, as well.) As always, our speaker is open to answering the group’s questions so come prepared. Please visit <http://ispefinancialseminar.eventbrite.com> to pre-register!

Finally, if you’re interested in hearing about these and other ISPE YP events we’ll be holding this year, please send a quick email to CaSAYoungProfessionals@gmail.com. We’ll be happy to add you to our list to receive email announcements as events are planned throughout the rest of 2011!



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**Young Professionals
Carolina-South
Atlantic Chapter**

“Invest in Your Future!” Financial Planning Seminar

ISPE Young Professionals and the ISPE UNC-Chapel Hill student chapter invite you to invest in your future with the help of guest speaker Anna Lore, a Certified Financial Planner with Women's Financial Partners, LLC.



Come learn how to start your career off right by handling your income wisely and building a strong foundation for the future.



**Thursday, June 9th at 6:00pm
Eshelman School of Pharmacy,
UNC Chapel Hill - Kerr Hall 1001**

Cost:

Before Tuesday, June 7th: \$10

On-site Registration: \$15

Register at:

<http://ispefinancialseminar.eventbrite.com/>

Payment will be received in cash at the door. Food will be provided as well as a \$15 voucher that allows you to sign up for an introductory course on financial planning!

DIRECTIONS:

Eshelman School of Pharmacy:

<http://pharmacy.unc.edu/about-us/visit-us/directions>

*If the Pharmacy School parking lot is full, you're welcome to park at the parking garage at the Fedex Building next to the Pharmacy School parking lot on your left.

*The UNC Hospitals parking deck on Manning Drive is also available and is less than a ten-minute walk to the School of Pharmacy. Head west along Manning Drive toward South Columbia Street. Turn left and head north on South Columbia Street. The School of Pharmacy (Beard and Kerr Halls) are on the west side of the street (your left as you walk north).

Chapter Event Highlights

CaSA ISPE 17th Annual Golf Tournament

By Heather Denny, CaSA ISPE Membership Chair



What an amazing day! The weather cooperated beautifully for our 17th Annual ISPE CaSA Golf Tournament. Sun, temperature in the mid-70's and a light breeze all made for a wonderful day of golf. Over 160 participants came out to brave the challenge of the Fairways and Meadows courses at Prestonwood Country Club. This

was a record number of golfers for our first two-course tournament.

In honor of Todd McCulloch and his happy spirit and constant smile, the event theme was tropical, with a fun, bright and colorful atmosphere. Todd was instrumental in organizing ISPE-CaSA's golf tournaments and thoroughly enjoyed the game. CaSA wanted to recognize and remember Todd and awarded the team of Jason Winfield, Jason Vanderploeg, Paul Herzich and Andy Lorenc for best dressed, incorporating the tropical theme into their matching ensemble. Each player won \$100 for their fashion statement!

This year, Interphex and RL Kunz provided a Harley and a St. Thomas vacation, respectively, as prizes. Participants had the opportunity to win on two par three holes. Unfortunately, no one was able to claim victory at either hole this year. With plenty of door prizes, however, others had chances to win.

The team putting contest sponsored by McDonald York Building Company gave all team's the opportunity to win \$10,000. This too proved difficult this year, as no one went home with the money.

Did you get your picture taken with the Tiki statue? Did it bring you any luck? While no one won the big prizes, three individuals each walked away with the raffle grande prize of a \$500 credit card.

Thanks to CRB for their graciousness by sponsoring lunch and providing golf balls. Additional thanks to RDG Project Management Inc. for sponsoring the awards dinner and golf towels. With the fabulous weather, Mangan Inc.'s sponsorship of the beverage carts was well appreciated. Keeping hydrated on the golf course is critical!

Thanks to all of our hole sponsors Pharmaceutical Calibrations and Instrumentation, LLC (PCI), Commissioning Agents Inc., O'Neal Engineering, Hipp Engineering & Consulting, Cooper Electrical Construction Co., M.G. Newell Corporation, Burkert Fluid Control Systems, Hydro Service and Supplies Inc., PharmaSys Inc., Commercial Mechanical Systems, Core Dynamics, Sequence Inc., Vantage, and O'Brien & Gere.

It is the continued support from our sponsors of ISPE CaSA that enable the chapter to organize these great events. For all of you that work with these companies please take a moment your employers for their support.

A final thanks to the Golf Committee for working tirelessly to bring all of this together. This was not your typical year by creating a themed event and with the addition of a second course.

Golf Committee Members:

Nancy Padget
Sheri Davis
Terry Prince
Lisa Kerner
Heather Denny
Jim McGlade



Chapter Event Highlights

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Chapter Event Highlights

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Featured CaSA Event

Durham Bulls Family Night



What: CaSA ISPE Durham Bulls Family Night with After-Game Fireworks

Where: Durham Bulls Athletic Park, Durham, NC

When: Friday, August 26th, 2011
6:00pm - 8:00pm Buffet open
7:05pm Game starts

Cost: Adults \$15
Children (3-10) \$10

(All fans 3 years and older require a ticket for entry.)

Bring your family and come out and cheer the Bulls against the Charlotte Knights!

Enjoy an evening in the DB Corral reserved exclusively for CaSA.

Ticket price includes buffet (hamburgers, hotdogs, fried chicken, macaroni and cheese, baked beans, and potato chips, Pepsi products, lemonade, and water) and game ticket.

Space is limited and will sell out fast so get your tickets soon. See registration form on next page.

ALSO — Get your name out there by sponsoring the event. At a great value sponsorship is only \$300.



**Carolina-South
Atlantic Chapter**

Durham Bulls Family Night

Durham Bulls Athletic Park, Durham, NC

Friday, August 26th, 2011

Registration		
Name & Guests		
Company		
Address		
City/State/Zip		
Phone		
Email		
Adults at \$15 each Children (3-10yrs) at \$10 each		
<input type="checkbox"/> My Company would like to Sponsor this event. \$300.00		
TOTAL: _____		
Pay by Check or Credit Card <input type="radio"/> Check <input type="radio"/> VISA <input type="radio"/> MasterCard <input type="radio"/> AMEX		
Name on Card	Card #	Exp. Date
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Technical Section

Choosing Project Delivery Methods for Successful Capital Projects

By Craig Crowther, PE, VP, BioPharma SBU Leader

For pharmaceutical companies, innovation, costs and time to market are critical factors for achieving a competitive advantage. As such, manufacturing facilities are a key part of a pharmaceutical firm's business strategy, and a strategic approach to delivering pharmaceutical capital projects is required. By choosing the right project delivery method for capital construction projects, pharmaceutical companies can ensure successful project delivery and meet overall business goals associated with the project.

While there are a variety of project delivery methods available, choosing the appropriate strategic approach to project delivery varies by project. The decision needs to be based on a number of factors including budget, schedule, cash flow, project complexity, risk mitigation, project team composition, and project goals.

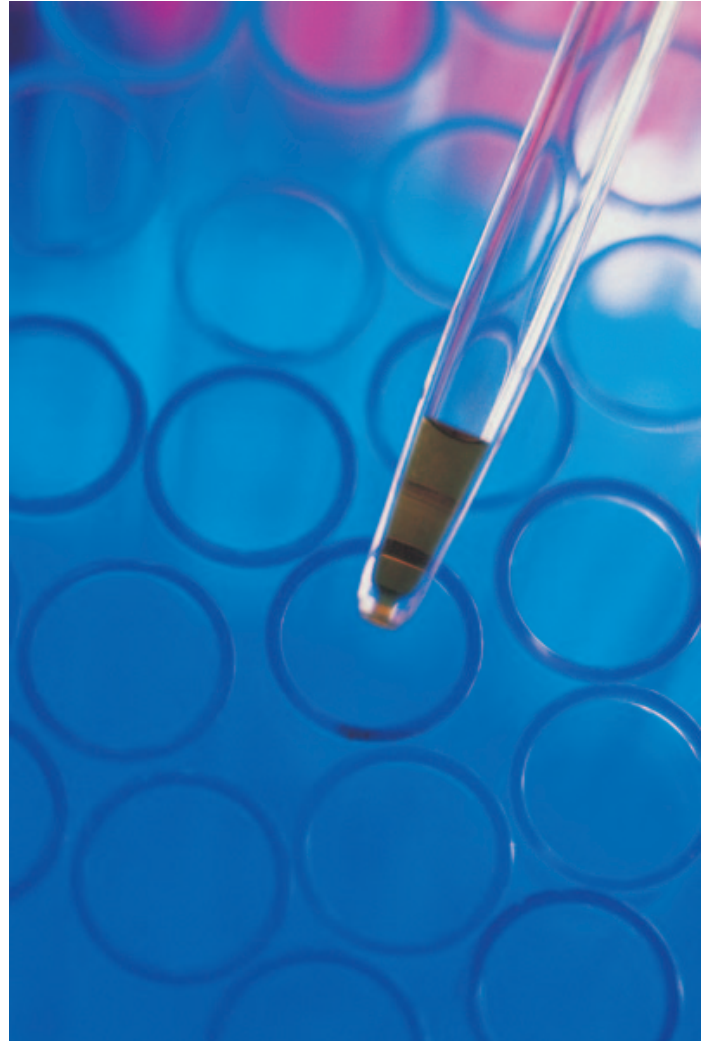
Traditionally, pharmaceutical firms retained sufficient in-house engineering and project management resources on staff. However, due to economic and competitive issues, many pharmaceutical firms have reduced their in-house capability. This is a key consideration in selecting a project delivery method.

Whether building a new manufacturing facility, modernizing or expanding an existing facility, there are a variety of approaches available for design, construction and validation. Essentially, a project delivery method is a configuration of roles, relationships, responsibilities, and sequences on a project. Here's a brief overview of some of the typical project delivery methods used in the pharmaceutical industry:

Design-Bid-Build (DBB)

Design-Bid-Build (DBB) is the most common project delivery method in the pharmaceutical industry. Owners with sufficient in-house staff contract with different entities for each phase of design, construction, and validation, as well as taking on the responsibility of orchestrating the various team members. Each step in the execution process follows the other sequentially with minimal overlap. Under the DBB approach to project delivery, the owner functions as the overall project manager and hires external engineers, consultants and contractors to deliver the project.

The owner typically starts by retaining an architect to program and develop a scope of work, then develop the project plans and specifications. The selection process for the architect can be competitive on a lump sum basis or the more traditional approach where the architect's costs are a defined percentage of the total installed cost (TIC).



The owner may have already selected manufacturing process equipment at this point. The architect generally prepares a preliminary cost estimate to assist the owner in budget development. These estimates are typically historically or empirically based.

Once the detailed design effort has been completed, pre-qualified General Contractors (GC) are invited to submit lump sum project construction bids. The DBB method often results in wide bid spreads, requiring the owner to match project scope to bid scope. Should the bids exceed the owner's preliminary budget, additional time will be required to resubmit the project for funding. If the bids are within budget a GC is selected based on a variety of

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Technical Section

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factors defined by the owner and design team. Once the GC is selected, the GC begins to hire sub-contractors for the various trades, and the facility is constructed in accordance with the contract and construction documents. The owner and architect oversee the project and work with the design team to ensure the facility is being constructed in accordance to the construction documents. Validation is then performed by a third party consultant under the owner's direction.

The DBB approach is typically used when the project is not well-defined and there is adequate time for the design and construction phases. Design-Bid-Build projects are typically competitively bid, and priced as lump sum. The competitive nature of the bidding process usually results in a competitive cost for the owner, but the quality of the subcontractors is left to the GC. Under this method, all construction and performance risks are assumed by the contractor. Scope variations resulting in change orders and schedule delays can occur if the owner's intent for the scope of work are not well defined by the architect to the contractor.

With DBB, the contractor has little influence into the project design, and opportunities for alternative approaches at bid time are minimal. In addition, the nature of DBB projects can contribute to an adversarial relationship between the owner, architect, designers and contractors. Owners run the risk of expanding significant project funds and time for detailed design only to find out the final project, as designed, is above the project budget and schedule parameters.

Design-Build (DB)

The Design-Build (DB) project delivery model is suited for pharmaceutical clients that require fast-track project delivery, and want a single point of contact for the project. The contractor and designers are hired by the owner to deliver a complete project. This model has been used extensively in the pharmaceutical industry for manufacturing, warehouses and offices.

The owner selects a DB firm from prequalified companies that have submitted designs and prices based on the project requirements. The DB firms retain their own architects, engineers and other consultants. The selection criteria are based on a combination of factors including design, price, schedule, and team. The DB firm selected by the owner is typically responsible for preparing the estimate and scope, as well as producing all construction drawings, details and specifications. The owner may provide the user requirement specifications, materials of construction, and the specifications for the manufacturing equipment. The owner may contract with a third party for validation, commissioning and qualification. Design-Build contracts are typically lump sum and based on the design that accurately meets the owner's require-

ments. The owner may be given a guaranteed maximum price based on the requirements defined by the owner.

Design-Build is utilized to reduce the project delivery schedule. The DB concept typically results in enhanced communication among the project team and a higher degree of accountability. While this is a complex delivery method, the compressed schedule and value engineering approach often result in cost savings for the owner. The DB approach is well-suited for larger, less complicated, time-sensitive projects where the owner has a clear project definition and concept prior to soliciting bids, and desires a firm price to be confirmed early in the process.

Construction Management (CM)

Under the Construction Management (CM) method, the owner will retain a firm to act as its Construction Management representative. There are a number of variations on the CM model. An architect is retained to develop a design package. Either the architect, design engineer or CM will develop a cost estimate. The CM is retained based on a fee for the specific project. The CM is responsible for managing all aspects of detail design and construction and ensures the owner's goals in terms of quality, scope, cost and schedule are met.

The CM is responsible for estimate development, construction, engineering, sub-contracts, scheduling, reporting, quality control and cost controls. Then architects, engineers and consultants are retained to develop a program. Specifications and drawing are developed for various parts of the project. Multiple construction packages are developed, and bids are solicited from various trades that then become prime contractors reporting to the CM. The owner may contract with a third party for validation, commissioning and qualification. Under the Construction Management method, design and construction activities overlap. The CM is essentially an extension of the owner and is typically referred to as "Agency CM" or "CM for Fee."



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Technical Section

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The CM model is well suited for owners that lack in-house design and construction expertise or capacity. The method also ensures consistent oversight and careful monitoring of costs and schedule. However, the CM method can result in additional upfront costs and create communication challenges between the owner, designers, contractors and CM.

Engineer-Procure-Construct (EPC)

Engineer-Procure-Construct (EPC) has emerged as a preferred choice of project delivery for many industries and is starting to gain favor in the pharmaceutical industry. With an EPC contract, the owner has a single point of contact for the project. Under the EPC model, the EPC firm handles the design, procurement of all equipment and construction materials, and construction services for turnkey delivery of the facility, usually at a lump-sum price. Typical EPC firms have all the required resources in house to ensure efficient and effective communication throughout the project. The EPC process starts with a PreConstruction effort that involves some preliminary planning and engineering to define the scope, schedule and costs of the project. The PreConstruction effort can be completed for approximately 1 to 3% of the TIC. Validation is most often managed directly by the client or through a separate validation firm to ensure this critical activity is successfully delivered. EPC firms knowledgeable in pharmaceutical facilities should be able to work with the owners to develop a validation master plan at the onset of the project and incorporate the plan into the project estimate, schedule and quality control. The EPC firm has complete responsibility for the project from start to finish.

Project scope and estimates are developed by the EPC firm. The project schedule and project budget are known before the project enters detail design or construction phases. All design and construction scope and budget risks are passed to the contractor. EPC project delivery offers the tightest integration of activities during the construction process through a structured and disci-

plined approach. In addition, communication between the design, procurement and construction teams begins immediately.

The EPC model helps align team members for optimal project performance. This often results in a collaborative, value-based construction process. The EPC model reduces project risks for the owner, delivers predictable results, and maximizes the effectiveness of capital planning.

Pricing Considerations: Guaranteed Maximum Price (GMP)

The Guaranteed Maximum Price (GMP) approach is similar to the lump-sum bid, except the general contractor (GC), CM, EPC team or the design firm submits a guaranteed maximum cost rather than a firm lump-sum bid for services. For total project delivery, the GC or EPC firm is compensated for actual construction costs plus a fixed fee. Design fees can be on a cost plus or lump sum basis. For GMP pricing, there needs to be a well defined scope and time frame.

On a schedule driven project this allows the owner to select team members based on fees and/or labor pricing, prior to developing project details and scopes necessary to procure credible lump sum bids.

Regarding the actual construction phase, a general contractor or EPC firm can participate in a "shared savings" approach that incentivizes them to manage cost and bring the project in under the GMP. If the work can be completed for less than the GMP, the contractor and the owner can opt to share the savings according to a predetermined ratio. Additional incentives can be addressed for sharing risk of schedule, safety, and quality. If the actual costs exceed the GMP, the contractor carries that burden. These variations effectively identify project risk areas and initiate important discussions concerning project responsibilities and ultimate accountability between the project team members.

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Technical Section

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Under the GMP approach the owner is given a “not-to-exceed” cost during the project development phase for the overall project by the GC or EPC firm. The GMP approach allows the owner to establish a firm project cost earlier in the project development phase rather than soliciting a lump sum bid. Once the GMP is established, the risk of cost performance is transferred to the GC. GMP arrangements typically involve an open book approach to costs. The GC or EPC firm will prepare equipment and design packages and solicit bids from various suppliers and subcontractors ensuring the owner they are getting competitive market pricing. This information is shared with the owner for input; however, the final selection is typically made by the GC or EPC firm.

The GMP feature can be successfully implemented in most project delivery approaches; however, it requires the owner to have an internal team of sufficient size to participate in the project delivery phase and make timely decisions. At the appropriate point in the project, the owner can elect to convert the GMP to a lump sum if they are comfortable they are getting competitive pricing on the correct project scope.

Achieving Competitive Advantage through Project Delivery

Whether manufacturing, research and development or warehousing, pharmaceutical and biotech capital projects are becoming more challenging and complex. The right configuration of roles, relationships, responsibilities, and sequences is essential. The owner's ability to define and develop project requirements and scope, as well as provide project management, significantly impacts the decision process. Owners need to consider cash flow (initial and overall), opportunities for concurrent processes with other project activities, such as process design, long lead time items, and the owner's capital approval process.

Selecting the right project delivery method can be challenging, but the success of any capital project depends on it. Project objectives vary by each project, and there is not a single project delivery method that addresses every situation. While there are trade offs for each delivery method, quality, cost effectiveness and timely project delivery can be achieved. By clearly defining expectations and balancing project goals, costs, schedule, complexity, risks, and the team, pharmaceutical companies can achieve competitive advantages through project delivery.

About O'Neal

O'Neal is headquartered in Greenville, SC with additional offices in Atlanta, GA and Raleigh, NC. For more information about O'Neal, Inc., visit www.onealinc.com.

About Craig Crowther, PE VP, BioPharma SBU Leader

Craig Crowther holds a Bachelor of Science degree in Mechanical Engineering from North Carolina State University. He has over 20 years of experience in mechanical HVAC design and project management for pharmaceutical and industrial clients. His experience includes solid dosage and sterile fill manufacturing facilities, BSL laboratories and research facilities, clean manufacturing facilities, office buildings, medical office buildings, high-tech manufacturing, and warehouse/distribution facilities. Craig joined O'Neal in 1994 where his leadership abilities came to the forefront and he was appointed the managing principal of O'Neal's Raleigh office. Craig has been leading O'Neal's Pharmaceutical Business Unit for the past 10 years where he has responsibility for managing the staff and projects of O'Neal's pharmaceutical market. He also is a licensed General Contractor.



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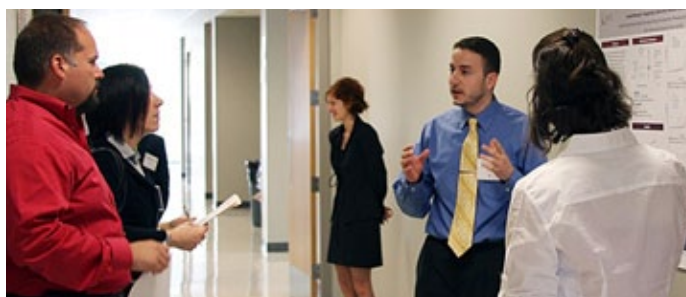
Student Section

Career Fair and Student Poster Competition 2011

By Amy Lineberry

This year's Career Fair was again held at NC State's BTEC Facility. For the past several years ISPE and the BTEC Facility have put together a great Career Fair like no other in the area. The Fair not only offers table tops showcasing the companies in attendance but also offers the companies to interview the students that are chosen by the companies in several ways. The companies can choose to hold one-on-one interviews, group interviews to assess how the students interact and work as a team or they can interview in a speed networking type format. This year the Fair was held on April 1st and over 50 company representatives from 12 companies interviewed over 130 students. Each year many students leave with follow-on interviews, an internship or job! A lot of planning and coordination is needed to pull off such a wonderful event. I would like to thank Ray Anover, Winnell Newman and the entire BTEC staff for their help, as I could not have done this without them!

Also, as part of the day we hold the Annual Student Poster Competition. This year we had 9 students compete at the Graduate and Undergraduate Levels. Many of the area schools were represented: NC Central University, NC State University, Meredith College and Campbell University. The posters that were presented were exceptional and a great showcase of the research that our students do each and every year. The winner from the Graduate level this year was Diane Darlington from NC Central University. Diane has been very active in ISPE over the past several years and she is currently pursuing her Master's Degree in Pharmaceutical Sciences and graduated this May. The Undergraduate winner was Spencer Leggett from NC State University and he is currently pursuing his Bachelor's Degree in Chemical Engineering with minors in Biotechnology and Bio-Manufacturing. He will be graduating in May 2012. These students won an all expenses paid trip to the 2011 ISPE Annual Meeting in Dallas/Ft. Worth. While there they will be competing in the International Student Poster Competition. I am positive that they will represent CaSA well. I would also like to thank my Co-Chair LeAnna Pearson and the judges for the competition for their help. The abstract for each student's poster can be found on the page following.



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Student Section

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Student Poster Competition Winner Abstracts

Diane Darlington Abstract

Exploration of the Cytotoxicity of Selenite on Stably Transfected PC-3 Cells with Bacterial Selenocysteine Synthase Gene

Selenium is an essential nutrient for human health, but it becomes toxic at elevated levels. Selenium can be incorporated into the amino acid selenocysteine, which can then be incorporated into proteins. Selenocysteine is identical to the common amino acid cysteine, except that the sulfur of cysteine is replaced with selenium. Though sulfur and selenium share many properties, the selenium of selenocysteine is fully ionized at physiological pH whereas the sulfur of cysteine is not. Under normal physiological conditions, incorporation of selenocysteine into proteins is highly regulated, but when higher concentrations of selenium are introduced to the body, selenocysteine can become incorporated non-specifically. We hypothesize that overexpression of bacterial selenocysteine synthase, the rate-limiting enzyme in the pathway for the formation of selenocysteine, can lead to an over-production of selenocysteine which can be non-specifically incorporated into proteins and subsequently cause cell death. PC-3 prostate cancer cells were stably transfected to carry either the full bacterial selenocysteine synthase (selA) gene or a truncated version of the gene which only contains the conserved selenocysteine synthase motif. After treatment with sodium selenite, cell viability and mRNA expression levels were compared between transfected and wild type PC-3 cells. Results indicate that overexpression of the truncated selA gene, but not the full-length gene, can increase the sensitivity of transformed PC-3 cells to selenite, and can cause higher expression levels of a variety of selenoprotein genes as well as genes related to selenocysteine production and incorporation of selenocysteine into proteins compared to wild type PC-3 cells.

Spencer Leggett Abstract

Virus Purification: A Demonstration of Anion-exchange Monolithic Chromatography Columns

Spencer Leggett and Dr. Gary L. Gilleskie
Golden LEAF Biomanufacturing Training and Education Center (BTEC), 850 Oval Drive, Centennial Campus,
North Carolina State University, Raleigh, NC 27695-7928, 828-442-3520, salegget@ncsu.edu

Virus purification is an integral part of vaccine production. Although traditional methods like packed-bed chromatography and ultracentrifugation may accomplish the task, CIM monolithic chromatography columns from BIA separations offer multiple advantages. Solute mass transport in a monolith is convective, and monoliths provide extremely high binding capacity for viruses (up to 1014 VP/ml). Monoliths also provide accelerated process development as well as an increased manufacturing capacity all while preserving virus biological activity.

In the experiments performed at BTEC, the purification of bacteriophage lambda in clarified lysate was studied using CIM-QA monoliths. The CIM-QA monoliths are anion-exchange devices based on a quaternary amine chemistry. Viruses are negatively charged at neutral pH and bind to anion exchange devices. For comparison, packed bed quaternary amine chromatography columns were also used for virus purification. After each purification, a plaque assay was performed on appropriate purification fractions to determine the amount of bacteriophage recovered in the process. In addition, host cell DNA and protein, 2 main contaminants in the phage lysate, were measured. After multiple trials were completed it was found that the monoliths and packed bed columns performed similarly from a purification standpoint; both provided good separation of bacteriophage from host cell DNA however, the flowrates that could be sustained in the monoliths was 5-6 times greater than that of the packed bed columns. This results in a processing rate 5-6 times greater in the monoliths as compared to the packed bed columns. Further experiments are in progress to fully understand the capabilities of monolithic columns.

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Student Section

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Student Section

ISPE Perspective from Student Chapter CaSA Presidents

By Wendy Haines

Interview with:

Matt Hawksworth (MH) - Campbell University (CU) Chapter President

Sam Millard (SM) - East Carolina University (ECU) Chapter President

Jarrett Wyatt (JW) - East Tennessee State University (ETSU) Chapter President

Makendra Umstead (MU) - North Carolina Central University (NCCU) Chapter President

Alex Doane (AD) - North Carolina State University (NCSU) Chapter President

Peter Petrochenko (PP) - University of North Carolina (UNC-CH), Chapel Hill Chapter President

How did you hear about ISPE?

MH

I heard about ISPE from my Chapter's Faculty Advisor, Dr. Daniel Shin, when he announced the meetings in his class.

SM

During my sophomore year one of my professors approached our group of bioprocess engineers with the intention of starting an ISPE Student Chapter at ECU. Until this point I was completely unaware of ISPE, but as I read into it, it became more and more appealing.

JW

I heard about ISPE through Purdue University College of Pharmacy and thought our school needed an organization that represented the pharmaceutical industry.

MU

I heard about ISPE as a student in the Department of Pharmaceutical Sciences at North Carolina Central University. Former NCCU student, Hadassah Watson, served as the 2008-2009 President during ISPE's first year as an active chapter on campus. Her focus was to increase the visibility of the organization and its benefits.

AD

I heard about ISPE through a previous NCSU ISPE President, Nick Armstrong, several years ago. He told me it was a great way to get involved with the industry so, being an underclassman, I tried out the next meeting.

PP

At a UNC-CH ISPE Student Chapter information session given by a current student member.

What made you want to serve as the Chapter President?

MH

After seeing what ISPE had done for me the previous year, I wanted to play a larger role in helping others benefit from it as well.

SM

I have experience in leading groups of people which I learned mainly through Boy Scouts, where I achieved the rank of Eagle; so serving as the chapter president seemed to be a perfect fit for me. Plus I am fairly tall and have a deep voice which helps considerably. Mainly though I wanted to see this chapter get started off right and not fall apart as I have witnessed through other collegiate organizations.

JW

I enjoy taking on challenges and accomplishing new feats, starting up a new organization would allow me to learn new things and try to set a good foundation for the next generation of leaders of ISPE at my school.

MU

Through my previous interactions with ISPE, I realized that the greatest benefits of the organization could only be realized if I was fully involved. Serving as Chapter President provided a wonderful leadership opportunity. But more importantly, it gave me the ability to bring education and networking opportunities to students on campus, encouraging fellow students to become involved in ISPE.

AD

I received a lot of opportunities and knowledge from my years as a member of our chapter. Therefore, I wanted to continue the chapter's goal of spreading the knowledge and experience to other students at NCSU so that they may benefit and learn from ISPE as I have.

PP

Me and my peers were seniors and everyone was dreading job searches. ISPE seemed like a great aid for job searches and networking opportunities.

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Student Section

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List and explain the 3 most important things you have learned from being an ISPE Student Chapter Member.

MH

The number one thing I learned from ISPE is the importance of communication; it is a characteristic vital for success in many areas in the pharmaceutical industry. Aside from just being able to clearly and effectively communicate one's thoughts and ideas, to be able to make a good first impression is essential for making new acquaintances. This practice of networking is helpful for expanding one's contact base and therefore one's resources, which can benefit both you and your associations. This is always emphasized at the annual CaSA ISPE Student Leadership Forum.

As chapter president, part of my role was to lead the monthly meetings. This was useful in helping me to develop my leadership and public speaking skills.

My chapter participated in a few events this year and during the planning and execution of those events I came to understand that everyone has been gifted in some way and everyone is able to contribute to the success of the team with proper direction and leadership. The leader plays the vital role in organizing the team so that everyone's best qualities are utilized.

SM

The 3 most important things which I have learned from being an ISPE student chapter member are: Networking is everything in this industry, There are always numerous opportunities to expand one's knowledge through ISPE, and membership doesn't have to end after graduation. While our chapter did not have as many events as we may have wanted, I feel we were all able to learn that networking is very important in this industry. Our chapter attended the 18th annual ISPE-CaSA Life Sciences Technology Show and I feel that the atmosphere at the event not only showed us how networked everyone in the industry is, but also allowed our chapter members to network with everyone else. Another thing I have learned is the numerous opportunities to expand my own knowledgebase through ISPE-sponsored activities. There were so many programs which I wished my schedule would have allowed me to attend, but knowing there is always an opportunity available through ISPE is a comforting thought. Finally learning that membership doesn't have to end after I graduate was truly gratifying to learn. I am graduating from East Carolina University in less than a week, so I was only able to be a student member of ISPE for a year. Knowing that I can continue to participate in ISPE events after I have graduated makes me happy.

JW:

1. The pharmaceutical industry is a small world.
2. There are a plethora of opportunities for professionals and students alike when they are a part of ISPE.
3. It allows for an avenue to share ideas about how to improve the industry.

MU:

1. Opening your mouth can open doors. It is often said that, "sometimes it is not what you know, but who you know." It is important to talk to industry professionals who can serve as potential mentors and inform you of opportunities that can further your career.
2. The pharmaceutical industry involves many disciplines; not just "science" and "engineering." The industry draws on expertise from law, engineering, science, manufacturing, international relations, business, marketing, human relations, and more. You name the discipline; it is likely it has a role in bringing pharmaceutical products to the consumer.
3. Knowledge is truly empowering. By attending the ISPE Annual Meeting and other ISPE events, I was able to learn information about the industry in the United States as well as internationally. As a result, I believe I am more equipped to make an impact as a young professional in the industry.

AD:

1. How to network: I have learned through constant reminders and practice of how to network with my peers and industry professionals. I learned the value of having a network by being a member of my student chapter.
2. The vastness of the Pharmaceutical industry: Through several years of attending meetings and networking events, I have been exposed to many areas that I did not realize existed. The industry is a huge and it has been great to learn about so many different sections of industry that can commonly be overlooked by students.
3. Veing involved pays off: By being a member and board member of our student chapter, I have been awarded many amazing opportunities. These opportunities would not have been available otherwise. For example, I attended the annual meeting where I received a stack of business cards from important industry leaders, which will be a valuable resource as I come closer to graduation.

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Student Section

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PP:

1. Talking to employers in person is more important than having a perfect resume.
2. First impressions are critical to getting a job offer.
3. There are many opportunities in the pharmaceutical/biotechnology industries and they become more apparent if you attend the job fairs and expos.

Explain what you would say to non-ISPE students to encourage them to become members.

MH

The concept that return is determined by ones investment holds true for ISPE; if you invest the time by becoming a member and participate in chapter's events, better yet playing a larger role as an officer, you can be sure to expect returns. I've witnessed some of my fellow chapter members find jobs after networking at ISPE events.

SM

I would tell them of the little I have learned while being a member and the opportunities available to them if they join. I feel it has been difficult to encourage others in our engineering department because they feel it is just for Bioprocess or Biomedical Engineers, when in reality I have learned that the industry is comprised of many varying types of engineers, scientists and businessmen. So, I have been able to better convince other engineers by explaining that everyone can work in this industry and if one does want to pursue a career in this field it only makes sense to join.

JW

Even if you aren't currently interested in the industry, this organization would allow you to see what goes on in the industry and meet new people that may spark that interest and if not that, make you a more seasoned individual who will one day be a pharmacist.

MU

If you are looking for a way to increase your knowledge base of the pharmaceutical field, speak to professionals in a comfortable setting, make valuable connections with your peers, develop the early stages of your career, and best of all, have fun, then you need to join ISPE!

AD

To a student who is interested, or even remotely interested in Biotechnology, Pharmaceutical, or similar careers, I would strongly encourage them to attend a meeting. The time invested in being a student member of ISPE has an enormous return on industry knowledge and

your professional network. If you wish to become more involved in an academic club, ISPE is a great choice as there are over 100,000 professional members who all love students! It is a great way to become connected with the industry as you are preparing for your career.

PP

Choosing a career is a tough task for someone coming out of college. ISPE gives you the chance to network with young professionals who recently entered the industry, lets you look around and tour surrounding facilities. In addition, it lets you get noticed by participating in poster competitions and local chapter meetings.

Explain why you will continue to be involved in ISPE as a Young Professional

MH

The pharmaceutical industry is really not as big as it may seem. I've been in the industry for about a year and frequently come in contact with industry professionals I met at past ISPE events. I recognize the importance of networking in this industry and remaining involved in ISPE as a Young Professional is a great way to do that.

SM

I will continue to be involved with ISPE as a young professional for as long as I am allowed to because it has already shown me so much in only a year's time. I have learned many things about the industry and how ISPE can improve my career and its development.

JW

I think it allows for opportunities not available in other organizations.

MU

ISPE will help me remain current on industry practices, provide training, networking, and leadership opportunities which will certainly aid me in developing a successful career in industry.

AD

I will definitely be continuing my ISPE membership as a Young Professional for three reasons. First, the network continues to grow once you have graduated and there is no such thing as a network that is too large. Second, I want to provide the same opportunities to future students after I have entered the industry. Finally, ISPE is a strong resource for industry news and standards.

PP

I will continue to be involved with ISPE for the social and networking opportunities available at local area chapters for young professionals.



Upcoming Events

Therapeutic Thursdays Networking Event: June 30, 2011 at the Carolina Ale House in Wake Forest

By T.K. Miller

When I joined CaSA ISPE three years ago, I sat back and watched and waited for opportunities to connect with fellow members. There were large events, such as a golf tournament and the Durham Bulls Game. I joined the membership committee, and there the idea of a more regular networking event was born. We decided that on the last Thursday of each month we would host a networking event, and someone suggested the name "Therapeutic Thursdays (TT)". Our first event was held at the Carolina Ale House in Cary, NC; 18 people came and during the evening the conversation turned to keeping it at that location. We held the second and third events in Cary with 20 and 22 people attending, respectively. Next, people suggested having TT locations be on a rotating schedule between several different cities. The fourth event was held at the Carolina Ale house in Briar Creek with 20 folks in attendance and the May 19 (date moved due to Memorial Day) was held at The Cleveland Draft House in Garner, NC. The June Therapeutic Thursday event will be on June 30, 2011 at the Carolina Ale House in Wake Forest.

The interesting thing about TT is that most of the attendees are one-time attendees. So, when people get into the habit of repeating, it will grow. Please come out and join us! Any questions or comments can be sent to TK.Miller@Bray.com.



The CaSA ISPE Therapeutic Thursdays are proudly sponsored by Bray.



Details Coming Soon for the Following Events:

- CaSA ISPE Annual Planning Meeting
- Event at Biogen Idec
- CaSA ISPE Annual Gala

Casa Charitable Contributions

CaSA ISPE organizes top-notch educational and networking events, but we also "give something back" annually. Due to recent weather related disasters that have affected the United States (deadly tornados) and elsewhere in the World (the Tsunami in Japan), CaSA ISPE donated \$2000 to the NC Branch of the Salvation Army Tornado Relief Fund and gave the ISPE Japan Affiliate \$2000 to help with Tsunami relief efforts.

CaSA ISPE donated \$2080 (raised from mulligans and the raffle at the 2011 Annual CaSA ISPE Golf Tournament) to the American Heart Association in memory of a beloved CaSA Volunteer, Todd McCulloch. CaSA also donated \$100 to the McCulloch Masters Classic, held on April 9, 2011

organized by Todd's son, Jacob McCulloch at the Quail Ridge golf course in Sanford, NC, where Todd lived and was a member.

A \$100 donation was made to Hospice of Wake County, NC in memory of Alex Russell, a fellow engineer and father of Jane Brown, Past CaSA ISPE President and Past Chairman of ISPE.

Thank you, CaSA ISPE members, for your attendance and participation in CaSA events which allows us to contribute to causes that improve lives.



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ISPE Carolina-South Atlantic Chapter Newsletter

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