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## Carolina-South Atlantic Chapter

# CaSA News



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## President's Message



Matt Gilson

What a first 5 months of 2014 it has been! I hope you've been able to enjoy and participate in some of our events recently. We really appreciate your continued support!

In April, we had one of our most successful Annual Life Sciences Technology Conference events ever. We had over 1000 people participate in excellent workshops, interaction with

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## MARK YOUR CALENDARS!

June 19, 2014 - Therapeutic Thursday at Serena, 5311 South Miami Blvd., Durham, NC

March 10, 2015 - CaSA ISPE Annual Technology Conference, Raleigh Convention Center

April 11, 2015 - Triangle SciTech Expo, NC Museum of Natural Sciences, Raleigh, NC

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## President's Message

our exhibitors, and networking events. Thank you to the committee led by Mike Putnam, our First Point Management Staff, and our sponsors and exhibitors for the tireless hours and support you provided. The effort given was clearly evident throughout the event. I'd also like to thank the speakers at the workshops and keynote session for giving of your time and experience to make this a successful event. Mark your calendar for the 2015 Technology Conference to be held on March 10th at the Raleigh Convention Center – see you there!

Later in April, the ISPE CaSA and Delaware Valley chapters held a video conference event with the FDA's Dr. Steven Kozlowski appearing in person in Upper Merion, PA and on screen at the NC Biotech Center. Dr. Kozlowski provided Regulatory Perspectives on Biopharmaceutical Quality. This event provided a rare opportunity to hear directly from an FDA representative and ask questions. It was the first time either Chapter had attempted to produce this type of event, and in spite of a few technical issues at the start of the presentation, it went very well. Feedback received after the event was very positive. Thank you to CRB, PCI, and Mangan Biopharm for sponsoring and supporting the event and for everyone who attended.

The Triangle SciTech Expo was held on April 5th at the NC Museum of Natural Sciences. It was a great day with lots of families participating in educational opportunities and activities to learn more about biotechnology in the Triangle area. Thank you to David Smith for leading this effort for ISPE CaSA and to everyone who came out to support the event. Mark your calendar now for the 2015 event to be held on April 11th.

ISPE CaSA also held two Therapeutic Thursday events in areas outside of the Triangle but within our region, the first being in Tampa on April 17th. That one was sponsored by Xcelience and CAI. The event was a successful first attempt and we look forward to another in the near future so look for announcements about that. Thank you to Sara Lewis for coordinating this for us in Tampa! The second was held in Atlanta on May 1st and was sponsored by CAI and CRB. We had a great turnout of Atlanta area members. Thank you to Jennifer Lauria-Clark and Lisa Kerner for coordinating this one. Look for another Therapeutic Thursday soon in each location! If you'd like to help us with these types of events in your area,

please contact us at [networking@ispecasa.org](mailto:networking@ispecasa.org)!

The ISPE CaSA Board of Director Election is ongoing (at the beginning of June). Look for your ballot in your email soon if you haven't already received it. If you are interested in serving on the BOD, I encourage you to get involved in a committee to learn how the Chapter runs and get some experience that will help you in that decision. It is a big commitment but it's also a lot of fun!

The 20th Annual ISPE CaSA Golf Tournament was held on May 19th at Prestonwood Country Club. Look for a full report and photos from the tournament in a future newsletter. The player registration sold out quickly. I hope everyone who participated had a great time. Thank you to John Marr and the committee for putting on a great event and to all the players and sponsors for your support!

On Thursday, May 29th, Avid Solutions sponsored a Therapeutic Thursday at Café Caturra in Cary. Thanks for the great turnout and I hope everyone enjoyed the food and wine pairings and the time catching up with colleagues and meeting new people!

Typically, the summer is a little quieter regarding events for ISPE CaSA. That will be true again this year, but be sure to come out for the Therapeutic Thursday event scheduled for June 19th at Serena Gastro pub in Durham, sponsored by Capital Projects & Facility Services.

Look for announcements about our Annual Planning Session open to all members and prospective members. This is usually held in August and provides a great opportunity to meet the Board of Directors and learn about upcoming plans for the chapter and how to get involved.

As always, I'd like your feedback on anything related to ISPE CaSA so please feel free to contact me at [president@ispecasa.org](mailto:president@ispecasa.org).

Finally, a short reminder that if you're not already, please connect with ISPE CaSA on social media:

LinkedIn: <http://www.linkedin.com/groups/ISPECaSA-149431/about>

Twitter: [https://twitter.com/ISPE\\_CASA](https://twitter.com/ISPE_CASA)

*Matt Gilson*

President, ISPE CaSA Chapter

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# Membership Corner

## New Members

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

We have 320 new Members that have joined our Chapter since July 1, 2013. Our goal to sign up 350 new Members by June 30, 2014 is getting ever so close.

\$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Applications can be made online at [www.ispe.org/join](http://www.ispe.org/join), click on Join Now under Industry Membership, and enter CASA2014 in the promotion code box. 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-referral-program>

This discount is not applicable to Students, Young Professionals, Academics, and Regulatory Authority / Government as these all hold discounted memberships already.

If you have any question about ISPE or the CaSA Chapter, please contact me at [paciorek@cagents.com](mailto:paciorek@cagents.com). 🏠

## Welcome New Members

New Members who joined March 22, 2014 through May 14, 2014

Nasser Al Hreed	Pravallika Godavarthi	Tommy Lewis	Linda Shaw
Priscilla Angaine	Bertha Gueta	Mark Malloy	Brandon Shealy
Anthony Bele	Leanna Gurganus	Brian Marakas	Dana Taylor
Alec Clevenger	Grace Han	Isaac Mckoy	Lisa Watts
Joe Compton	Brian Handibode	Dan McLaughlin	Reggie Williams
Justin Cook	Bill Harrison	Eric Morgan	Justin Wood
Matt Cunningham	William Hartley	Shay Nuckols	Tony Woolard
Carl Curry	Diane Heurtin	Luis Ortiz	Brandon Young
Riley DeHority	Vicky Hulland	MaryBeth Panagos	
Roberto Diaz	Ashton Hyman	Adam Pinkert	
Harish Edamadaka	Craig Kacsmar	Troy Purvis	
Johangel Figueroa	Gary Kreisler	David Ratcliff	
Jeff Frye	Rachel Leahy	Mayra Salas	



# Membership Corner

## CaSA Member Spotlight: Bill Morris

By ISPE CaSA Newsletter Committee

Q: What is your full name?

A: Billy R. Morris

Q: Birth Place?

A: Olar, South Carolina

Q: College?

A: University of South Carolina

Q: Tell me a little about your personal life.

A Grew up in South Carolina and, following graduation from high school, entered the University of South Carolina Mechanical Engineering program and joined the Air Force ROTC program. In my junior year at USC, I married my high school sweetheart, Tink (her real name is Mary Ann), and we have been a couple for quite a few years now! We have two sons, John and David. John lives in Palm Springs, CA and comes home to NC a couple of times per year. David lives close by in Clayton's River Wood Community with our one grandson Joshua and we see them fairly often.

Following retirement from Bayer Corp in 1999, Tink and I continued to live in Clayton, NC. We very much enjoy our primary home, high above the Neuse River and spend some time at condo in Myrtle Beach, SC several times a year.



Bill Morris

To stay active in retirement, in the life science Industry and beyond, I am honored to Chair the Board of PCI, to be a member of the ISPE CaSA Tech Conference planning committee for the past 5 years, and to be a member of the National Association of Corporate Directors (NACD) where I have met many new people.

My focus both in work life and retirement has been continuous improvement, to be better next year than I am this year and this approach keeps me quite busy, I am thankful to say.

I enjoy the social side of golf and look forward to the annual ISPE CaSA Golf Tournament, the PCI Charity Golf tournament for the Heart Association, and the Prestonwood CC Senior Golf Tournament (David Brande invitation, thank you) and foursomes of friends and new people throughout the year.

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

A: Retired from Bayer Corp as VP of Operations and General Site Manager of the Clayton site for 25 years. My visible legacy at this site is a cafeteria that bears my name.

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

A: In college, I completed the Air Force ROTC program and graduated as a commissioned officer. Once out of college, I went to work for Combustion Engineering in Chattanooga TN. Forty days later, I was on active duty in the Air Force with my first assignment in remote Alaska. From Alaska (12 month



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Mike Putnam, Technology Conference  
David Smith, Tri-Sci Tech Expo

assignment), I rotated to McGuire, NJ and completed my three-year commitment in the Air Force with eight years of reserve commitment afterwards. After discharge from active-duty, I returned to work at Combustion Engineering in Chattanooga and started my reserve commitment. My reserve Wing Commander was a Plant Engineer for Cutter Laboratories. As we worked together, over time, he offered and I accepted the position of assistant Plant Engineer with Cutter Laboratories and this was my entry into the Pharmaceutical industry. After three years with Cutter, I left to go with another company as a Plant Engineer in a start-up situation and after three years with the new company, Cutter invited me to come back, this time as a manufacturing manager. In time, I became production manager and soon afterwards, Cutter decided to build a new plant in Clayton, NC. I was appointed Plant Manager for this new facility and our family moved to Johnston County, NC. With construction of the plant approximately 60% complete, Bayer Corp of Germany purchased Cutter Laboratories. Under Bayer ownership, I continued to manage this plant for the next 25 years.

Q: What is your favorite part of your job?

A: The challenge and preciseness of patient safety and the day to day interaction with dedicated, committed employees.

Q: How long have you been a member of ISPE/when did you first join ISPE?

A: I first joined ISPE in 2007, when I became Director of the Validation Academy of NC, which was a partnership between International ISPE and the Community College System of NC. I remain a member of ISPE today.

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

A: The benefits for me have been the opportunity to work with the most dedicated and committed group of volunteers that I have had the pleasure of working with, in advancing the cause of the LSI and ISPE.

Q: Why are you still involved with ISPE?

A: Over the past 5 years, along with others, I have been passionate about moving the Tech Conference to an all Life Science conference with the goal of increasing the value and participation of operating companies. This is still a work in progress.

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

A: Frank Deromedi, in particular, a boss who asked me what I wanted to do with my career when I was 28 years old. When I told

him I wanted to be a Site Manager, he told me what I had and what else I would need to become a Site Manager. 10 years later at 38, I became Site Manager of Cutter's Clayton NC plant. A second huge influence in my career was Karl Heinz Fischer, for 18 years my boss at the Clayton Plant. From 8AM-5PM, the toughest boss I have had but after five, a gracious host for the evening and preparing for the next day's challenges. Karl was a great supporter of the Clayton plant and retired in 1991 and we are still friends today. Beyond these two, I have learned from every boss I have had in my career. They were all quite different but had good qualities that I could learn from, and I did.

Q: If you weren't involved in pharma/biotech, what business do you think you'd be in?

A: It is hard for me to imagine, but a business requiring a fairly high level of team work and leadership to be successful comes to mind.

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

A: A bit more patience and collaborative approach for getting things done in groups.

Q: Any hobbies? What are they?

A: Golf, reading Leadership books, old car restoration

Q: Do you collect anything?

A: No

Q: Finish this sentence – "I need more...."

A:... focus on doing the things I don't care to do.

Q: Favorite Food?

A: Extra-thick grilled pork chop.

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

A: My favorite color is purple

Q: Last movie you saw?

A: Saving Mr. Banks

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

A: Develop a collaborative approach for problem solving, give more than you get, and focus leadership skills on benefits to others as opposed to self. ▲

## CaSA COMMITTEES

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### Young Professionals Committee

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[jdoyle@pci-llc.com](mailto:jdoyle@pci-llc.com)



# Membership Corner

## Therapeutic Thursday Summary

By Sara M. Lewis, CPIP

The Inaugural Therapeutic Thursday – Tampa Bay, held Thursday, 17 Apr 2014 from 5:30-8:00 PM.

A little background: Upon my relocation to Tampa, FL from Greenville, NC, I realized that I took for granted the great things I benefitted from CaSA involvement in the RTP, NC area; events, symposiums, training workshops, study groups, conferences, etc. After communicating with Matt Gilson about chapter leadership “down south”, the idea for local member outreach was born. I’d asked Matt about ISPE connections in the area, thinking CaSA did not extend to south Florida, but I was pleasantly surprised to hear this is CaSA territory. With the board’s support, we decided a networking event would be a good ice-breaker.

Our venue was the Players Sports Pub inside the Doubletree Hilton Westshore. Thanks to Linda Urban, Sales Manager and Michael Pagliarli, Food and Beverage Director, our first-ever

Therapeutic Thursday – Tampa Bay shaped up to be a springboard for future possibilities. The Doubletree Hilton Westshore was especially accommodating, extending happy hour specials in their Player’s Pub to us for the duration of the event. A free parking garage on premises, warm chocolate chip cookies on the way in and out, and a reserved section of the restaurant that was clearly labeled for ISPE-CaSA were among the venue perks. Considering it was our introductory event, a small turn out worked to our advantage since it made for good conversation at one large table. We had an eclectic turn-out of industry professionals and were even joined by an ISPE HQ staff member. We look forward to spreading the word for another event over summer and meeting more local industry professionals to whom we can offer the benefits of ISPE membership. ▲



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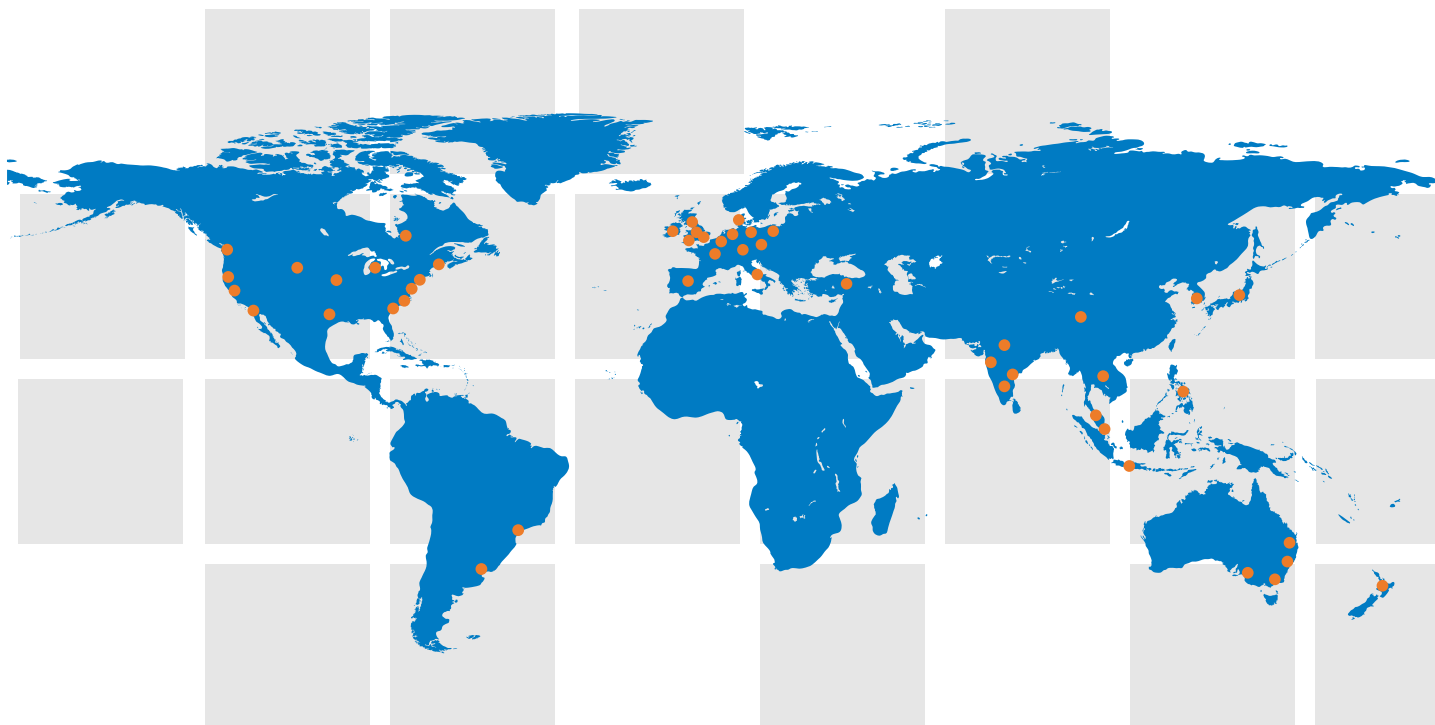


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## Membership Corner

### Technology Conference Special Feature, 21st Annual ISPE-CaSA Technology Conference: Wrap up & Thank You

By Mike Putnam, ISPE CaSA Technology Conference Committee Chair

If you attended the ISPE CaSA Technology Conference in April, you were part of a pivotal plan to refocus the event on innovative collaboration between drug manufacturers and support companies. This initiative was facilitated by a new 'Manufacturer Showcase' program where the largest drug and device manufacturers in the southeast exhibited alongside product and service providers to discuss current initiatives to improve the delivery of life-saving drugs to patients worldwide. These manufacturers not only supported the program in its first year by exhibiting, but they put boots on the ground by sending hundreds of employees to the conference. **Thank you Biogen Idec, bioMerieux, Fuji Diosynth, Hospira, Novo Nordisk, and Novartis.** A special thanks also goes to each of the corporate sponsors. Without you this conference would not be possible. We sincerely appreciate your support. Thanks to all of the attendees that chose to spend the day at the Technology Conference. As CaSA's largest event of the year, your support is vital to the continued success of the chapter.







The morning began with an opening message from Raleigh City Councilor Maryann Baldwin. Councilor Baldwin welcomed attendees to Raleigh and gave thanks for the tremendous impact life sciences organizations have on the local community. After her opening remarks, conference guests were introduced to XLH Network, the 2014 featured charity of the Technology Conference. XLH Network President Becky Mock educated attendees on XLH (x-linked hypophosphatemia - a rare genetic bone disorder) and explained the goal of the organization – to promote educational awareness, research, and early detection. Raffle sales, donations from attendees, and contributions from ISPE CaSA resulted in over \$6,000 being contributed to XLH Network. Five tracks of morning and afternoon educational sessions followed the opening ceremonies with topics ranging from ‘Serialization’ to ‘Regulatory Compliance in a Greenfield Startup’. Over 20 companies were represented by educational speakers including many leading drug manufacturers. ISPE CaSA thanks NCBC BPD for hosting a ‘Continuous Bioprocessing’ track as part of the conference. During the lunch hour, keynote panelists Bob Geloas (RTP Foundation), Ali Skrinar (Ultragenyx), Joydeep Ganguly (Biogen Idec), Wes Wheeler



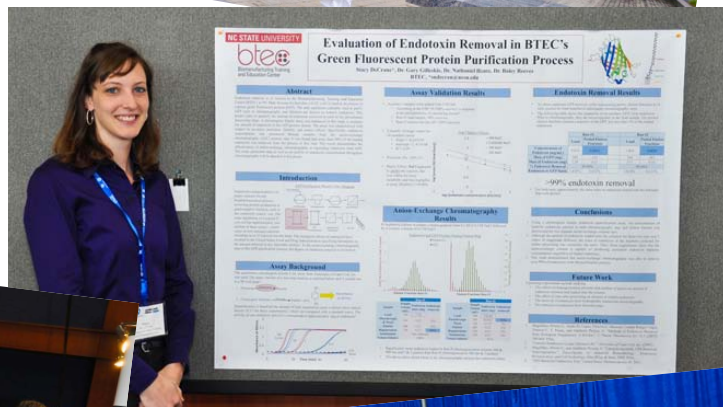
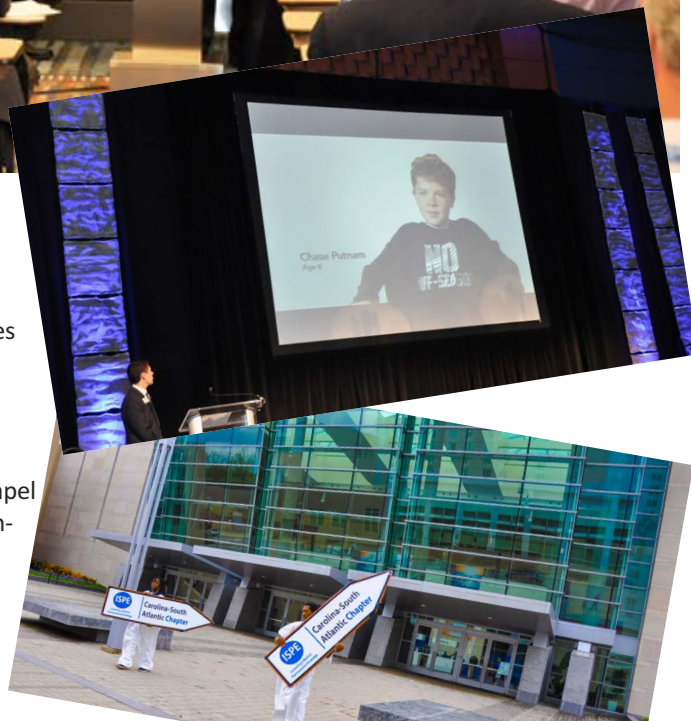




(Marken), and Kevin Day (Sequenom) discussed a variety of topics including the growth of biopharmaceuticals as a result of the new RTP expansion plan. Afternoon product demonstrations followed the panel discussion with innovative technologies showcased on the main ballroom stage. Closing ceremonies featured an ISPE member recognition award presented to Billy Morris. With deep roots in the biopharmaceutical community, Billy has been instrumental in the success of the Technology Conference and the ISPE CaSA chapter. Thank you Billy! As conference activities concluded, the party was just getting started at the networking reception hosted by Chapel Hill's Top of the Hill Distillery. Nitrogen ice cream, organic Carolina moonshine whiskey, and of course those beloved barbeque infused hushpuppies topped the list of favorites by conference attendees. Music by local pianist Martha Cecka and illusions by magician Francis Ignacio entertained guests throughout the night. It was a great day of education, networking, and collaboration between industries. Our hope is that this event continues to grow and spark new and innovative technologies that make a difference in the lives of patients around the world.

As you can imagine, the Technology Conference requires a tremendous amount of planning and our committee has already begun efforts to ensure the 2015 event builds from the momentum this year. Mark your calendars for March 10, 2015 and please email [techconference@ispecasa.org](mailto:techconference@ispecasa.org) if you would like to become more involved with conference planning.

Thanks and I look forward to seeing you at a CaSA event soon! 📌



# Student Corner

## ISPE CaSA 2014 Student Poster Competition

By LeAnna Pearson, ISPE CaSA Student Affairs Committee

The Annual ISPE CaSA Student Poster Competition was held on April 7, 2014 at the Sheraton Imperial during the exhibitor reception of the 21st ISPE CaSA Life Sciences Technology Conference. We had five student competitors from the following universities: North Carolina State University (NCSU), East Carolina University (ECU), and University of North Carolina at Chapel Hill (UNC-CH). The graduate winner was Peter Petrochenko from UNC-CH with a poster entitled "Laser 3D Printing with Nanoscale Resolution: Improving Biocompatibility and Mitigating Toxicity from Photoinitiators". The undergraduate winner was Francesca Lynn from NCSU with a poster entitled "Studies on the Purification of scFv from Escherichia coli using Ion Exchange Chromatography". All students who competed can now attend the ISPE Annual meeting and compete at the International Level. Both the undergraduate and graduate winners receive an all-expenses paid trip to represent the ISPE CaSA Chapter at the 2014 ISPE Annual Meeting.

**Graduate Winner: Peter Petrenko**

**Laser 3D printing with nanoscale resolution: improving biocompatibility and mitigating toxicity from photoinitiators**

Recent developments in laser-assisted 3D printing using two-photon polymerization (2PP) allow for previously unattainable submicron resolution and show promise for creating 3D cell scaffolds for regenerative medicine and tissue engineering applications. A significant barrier to using 2PP for biological applications exists due to the toxicity of photoinitiators required for polymerization. The goals of this study were to 1) demonstrate two approaches for creating nanotextured, porous 3D scaffolds using 2PP, and 2) develop a model system to evaluate in vitro cell responses, such as cell growth, protein adsorption, and toxicity, to nanoscale variations on material surfaces or to residual chemicals used in scaffold fabrication. The first approach involves printing a 3D scaffold from a urethane diacrylate-based elastomer, removing residual toxic substances and seeding cells. The second approach involves trapping cells directly in a methacrylamide-modified gelatin matrix. Results from the first method indicate that stable scaffolds with porosities of over 60% can be custom

printed to fit standard 96-well plates. Human bone marrow stromal cells grown on 3D scaffolds exhibited increased growth and proliferation compared to smooth 2D scaffold controls. Scaffolds adsorbed larger amounts of proteins due to a greater surface area and allowed cells to attach in multiple planes and infiltrate the porous scaffolds. Results from the second approach indicated some dead MG63 osteosarcoma cells in encapsulated regions. In order to mitigate photoinitiator toxicity, 3 antioxidants – Trolox (water-soluble vitamin E), vitamin C, and glutathione – were used. Preliminary results demonstrated decreased cytotoxicity. The data indicate that 2PP is a promising technique for fabricating custom 3D scaffolds, including the potential for cell encapsulation.

**Undergraduate Winner: Francesca Lynn**

**Studies on the Purification of scFv from Escherichia coli using Ion Exchange Chromatography**

Antibodies are glycoproteins produced by white blood cells which are used to neutralize potential threats in the body. They consist of four polypeptide chains: two heavy chains and two light chains which are connected by disulfide bonds and form a Y shape. Antibodies have a constant part (Fc) and a variable part (Fv). There are many therapeutic and diagnostic applications for antibodies. However, they are limited in their therapeutic application because they are too large to penetrate many membranes in the body. The single chain fragment variable (scFv) consists only of the variable antigen binding regions (VH and VL). This is advantageous because they retain the same antigen binding properties of the full antibody while being small enough to penetrate more membranes in the body. For example, scFv has been shown to penetrate tumors more effectively. Protein A binds very specifically to the Fc (constant) region of antibodies, so it is used as the main form of purification. However, since scFv only consists of the variable regions, it does not have the same affinity for Protein A that the full antibody does. A different approach must be taken to purify scFv. In this case, a method of purification using ion exchange chromatography was developed. ▲



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## Technology Corner

# Can We Counteract Counterfeit?

By NNE Pharmaplan Journalist

As is the case with other types of piracy, pharmaceutical companies have an obvious interest in protecting their products and brands against fraud. But the question is just how to manage it?

A critical factor is to ensure product authenticity in the entire supply chain from production to consumer – or, in fact, from the raw material supplier to the actual patient.

To respond to this problem, both the pharmaceutical companies and countries, like the EU and U.S., have drafted several pieces of ‘serialization legislation’ to ensure the integrity of the individual product’s original packing.

The U.S. House, Senate and President have recently voted and signed new legislation called ‘The Drug Quality and Security act’ (H.R. 3204) which has two initiatives in one bill; ‘Drug Compounding Quality Act’ and ‘Drug Supply Chain Security Act’. This gives pharmaceutical manufacturers new challenges.

### Managing a Serialization Program

Developing and running a global Serialization Program is a major challenge and risk for pharmaceutical manufacturers. Apart from the difficulties associated with complying with the multitude of current regulatory requirements, many programs are still being formulated with unclear deadlines. Manufacturers clearly need to take action now to implement their Serialization solutions and many have. However, the magnitude of implementation with respect to the number of packaging lines and the resources needed is baffling. Equipment suppliers are not coping with the spike in demand and Serialization software-solution suppliers often are in disarray as they attempt to scale-up their operation and software. These factors make it critically important for companies to build a Serialization Program that can corral all the suppliers with a clear objective and mandate. Lastly, a good engineering approach has to be implemented to ensure schedules, scope and budgets are in check.

As part of the new law, the U.S. has given manufacturers, wholesale distributors, dispensers, re-packers and Third-Party Logistics Providers different deadlines to comply with the new requirements. For example, Manufacturers must serialize products four years after enactment – likely in 2017. Product Identifiers must be a 2D data matrix for packages and linear or 2D data matrix for a homogeneous case. At the same time, the information must be human readable to the consumers.

The EU has been taking similar actions. EFPIA, the European Federation of Pharmaceutical Industries and Associations, recommends pharmaceutical companies to use a 2D data matrix code containing a unique serial number in addition to the product-specific information. If scanning reveals that the code in question is not in the system – or has already been scanned once – the product is counterfeit. This method is available to all links in the supply chain, from the producer to drug wholesale dealers, pharmacies, supermarkets and even the

individual patient, who can check the product via the internet or a smart phone.

The problem is that there is still no common international legislation between EU, NAFTA or other organizations. So, individual countries have started their own rules and legislations. Turkey, for instance, was one of the first to require that every individual package bears a unique code (also called serialization). As a consequence, pharmaceutical companies dealing with international customers will have to consider a variety of local regulatory requirements.

Various existing and future rules for labelling and identification technologies may require extensive conversion of packaging lines and may prove very costly if the strategy is wrong. “We’re talking millions of dollars in investments for some companies”, says Lars Olsen, Senior Consultant of Finished Products, NNE Pharmaplan, Denmark.

“The major pharmaceutical companies like Novo Nordisk are already at the forefront and have contributed to the development of international guidelines that will ensure product identity all the way from production to the consumer. But, many small and mid-sized companies fail to deal with the problem in time and risk being left holding the bag if they get off to a bad start,” he says.

“There is a huge variety of drug coding, labelling technologies and rules”, states Lars Olsen. “Many companies do not realise the importance of an impartial international partner. Many suppliers sense a lucrative market for equipment for counterfeit solutions, but some of them are just trying to sell hardware or partial solutions to the pharmaceutical companies who are going to convert their packaging lines to print the new codes on the packages. It’s not sufficient to deal with the technology – a lot of other issues need to be considered as well”.

“Often a pharmaceutical customer needs help to implement the new coding requirements ‘all the way through the entire supply chain’. Here, the first step is to educate the employees and train the various departments to cooperate. Next, a strategy and a change analysis should be prepared, dealing with the physical changes regarding available space and procedures, the effect they will have in the organisation, and required changes (e.g. to the IT system). A working group for the entire project should be appointed who can prepare an investment and implementation plan based on the analysis results. Project management, IT process experience and technological experience are other important aspects”, says Lars Olsen.

As previously mentioned, efforts are ongoing to reach international consensus on labelling. Some international guidelines, backed by the pharmaceutical companies, have been prepared. These guidelines are much needed as a long-term solution to combat counterfeit drugs, and the pharmaceutical world is awaiting guidelines from the US Food and Drug Administration (FDA) as well as the EU. ▲

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## **ISPE Announces Development of New Drug Shortages Prevention Plan for the Pharmaceutical Industry**

**(TAMPA, FLORIDA, USA, 28 April 2014)**— ISPE, the International Society for Pharmaceutical Engineering, announced today that it will work with stakeholders world-wide to produce a Drug Shortages Prevention Plan to guide the pharmaceutical and biopharmaceutical industry in establishing reliable, robust and resilient supply chains that provide quality medicines to patients without interruption. The Plan, which will be based on ISPE research with the input of its membership, company leaders and regulators, will serve as a roadmap that when implemented, can significantly reduce drug shortages. The Plan will address optimal organizational strategies, such as aligned governance and communication practices, effective manufacturing and quality systems, and appropriate measures of supply chain robustness and quality. This effort addresses rising concerns around drug shortages within companies, among global health authorities, and for patients who depend on a reliable and available supply of quality medicines.

The ISPE Drug Shortages Prevention Plan will be the Society's second major output on this topic since launching its Drug Shortages Initiative in 2012. This second phase of the Initiative is aimed at addressing the root causes of drug shortages to prevent delay of supply. The [2013 survey](#) provided clear evidence that mitigating shortages requires a holistic approach that encompasses both the organizational and technical issues affecting drug manufacturing and quality. "How much of the increasing number and severity of incidents of drug shortages within our industry are fundamentally tied to a lack of understanding, or even concern for, the risk profiles of our current supply chain structure?" commented Andy Skibo, Regional VP, Biologics Supply, AstraZeneca/MedImmune. "I therefore welcome ISPE's initiative to tackle the root causes of shortages for the benefit of all stakeholders— ISPE Members, industry companies, regulators and health authorities, third-party providers and patients."

The ISPE Drug Shortages Prevention Plan will provide a key component of the Society's input to a European multi-association task force, moderated by ISPE, which intends to provide EMA a proposal and plan that address the prevention of drug shortages due to manufacturing quality issues. "I'm delighted to be collaborating with colleagues from the Parenteral Drug Association to deliver our proposal to the EMA later this year, and appreciate the support we are receiving from EFPIA, EGA, AESGP and PPTA as well as regulators representing the EMA, the UK, Irish, Spanish and French national agencies," said Dr. John Berridge, ISPE's Advisor and inter-Association task force moderator.

In 2012, ISPE formed a Drug Shortage Task Force in order to help stakeholders better understand the root causes of global drug shortages and to define mitigation strategies that can help prevent drug shortages. In ISPE's initial approach to this challenge, the group led a comprehensive survey in 2013 that revealed multi-factorial causes of drug shortages, as well as success strategies for avoiding supply interruptions. Those companies that have adopted organizational drug shortage prevention strategies, including contemporary governance, progressive cultures and effective quality systems, were successful in the avoidance of drug shortages and supply interruptions. "Our research findings indicated that, while shortages are often the result of quality systems or related deficiencies, what was equally profound was that those companies with dedicated and sophisticated systems for avoiding drug shortages were clearly more successful in avoiding supply disruptions and shortages," said Nancy Berg, ISPE's President and CEO. "Recognizing the impact of these success strategies motivated ISPE



## Carolina-South Atlantic Chapter



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