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President's Message



Jennifer Lauria Clark, CPIP

Summer has arrived. I am sure that some of us are settling our end of the school year programs and preparing our children for summer camps. There is another reason our members should be happy going into the summer.

We have some very exciting news regarding our Membership statistics according to ISPE HQ as of May 1, 2013. ISPE CaSA is the largest Chapter or Affiliate in the world. This has not happened in a very long time and it is a proud moment for ISPE CaSA. We had 1291 paid members as of May 1, 2013. Thank you ISPE CaSA for making us the best and beating the long time leaders of Boston Area and New Jersey Chapters. Congratulations to our Membership Chair, Jerry "Patch" Paciorek, CPIP, and the rest of our volunteer leaders who helped make this happen.

Our continued success has not slowed down since the Technology Conference. We have had several more exciting events that have led to great networking and educational opportunities.

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President's Message

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Our events help define our Chapter and our success. Without your ideas, volunteerism, sponsorships and presence we would not be the dynamic, influential Chapter we are today. Thank you to everyone who has helped make all our events and networking opportunities possible.

Our April 6 BEST (Biotechnology, Engineering, Science, and Technology) Festival went off very smoothly under the leadership of David Smith. He worked with the state of North Carolina, pharmaceutical companies, families, and academia to help plan and execute a day surrounding STEM activities. This event is one of a kind and has made its mark on North Carolina. The Natural Sciences Museum is already talking about expanding the event again next year. About 6,500 people filtered through the museum and saw over 30 vendors showcasing Biotechnology, Engineering, Science or Technology displays and activities. Thank you to all our ISPE CaSA volunteers who helped make the day successful.

Our Annual ISPE Golf Tournament was large, fun, exciting, and wet. Thank you all for coming out to the tournament with the understanding that the rain was going to fall. We had 152 golfers come out to support the event and enjoy the day with their peers. A special thanks to Chair John Marr of the Networking Committee, their golf team (Jim McGlade, Wes Robbins, and John Marr) and all our energetic volunteers for making the day go on despite the weather.

Medicago, one word to describe an amazing new facility with technology that is innovative and hopefully going to be life saving. Thank you for hosting a plant tour that gave 60 of our Members an opportunity to see inside your facility and the intriguing process using plants to help create a pandemic flu vaccine. All were impressed with your hospitality and knowledge of the process. Thank you to Medicago and the Education Committee Chair/Co-Chair, Amy Lineberry, CPIP/Chip Chappell, and the volunteer leaders who helped make this event possible.

We had another successful Therapeutic Thursday sponsored by Kinetics at Ruckus in Cary. Networking is an important part of our organization and a lot of our jobs. Continuing to grow your network no matter what your experience level is

in the industry will help make you more successful.

"Charting the Path from a Young Professional to an Emerging Leader," Ken Ewan, Career Coach and retired pharmaceutical professional gave an inspirational and educational speech to an almost sold out crowd at the beginning of the month. Thank you, Jon Doyle (Chair of the Young Professionals Committee) and his team, who saw a Member need and planned a great event.

I wrote last month about the responsibilities we have as industry professionals to continue our path of doing the right thing and ensuring our patients are getting the best drug products we can produce. When an accident happens, the last thing a parent or child should worry about is thinking, "Did the people making this drug take any shortcuts or did the operator decide not to follow their SOPs the day it was made?" Every day we must continue to do what is right and please allow ISPE the opportunity to help train you and your staff as we provide educational opportunities.

Each newsletter I urge our members to share with us any concerns, compliments, or suggestions and would like you guys to let us know how we are doing and how we can better improve your Membership.

Thank you again to our volunteer Members who spend their time reviewing newsletters, cleaning up after events, or helping with whatever we need done to make the Chapter successful. The entire Board appreciates our good friends for

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- LeAnna Pearson, Student Affairs
- David Knorr, IT Communications
- John Marr, Networking
- Jerry "Patch" Paciorek, CPIP, Membership Development
- Jon Doyle, Young Professionals
- David Smith, BEST Fest Committee
- Bruce Craven, Technology Conference

President's Message

(continued from previous page)

staying involved and welcome fresh ideas and new faces at our Committee meetings.

And now the To Do List:

- **Get Involved.** Let us know if you are interested in a volunteering with a Committee or in active leadership of ISPE CaSA. Membership and Education are two Committees that are in the most need of volunteers. Please contact info@ispe-casa.org or the Committee Chairs if you are interested in any of the Committees. Thank you to our new volunteers that have joined our Committees recently.
- **Share your ideas.** Please send in some fresh ideas for 2013 educational programs and networking events. We will have a drawing from everyone who sends in an idea by July 1, 2013. The winner of a \$50 gift card will be announced in the next newsletter.
- **Look out for...**
 - June 27, 2013 Therapeutic Thursday Carolina Ale House, Cary, NC (sponsored by CleanSeal Door Systems)
 - A celebration event focused on Novartis and Biogen Idec for their category wins for ISPE's Facility of the Year Award.
 - August 27-28, 2013 Biotechnology Education Intensive Training hosted by ISPE International in Durham, NC.

We hope that you find our newsletter exciting and that you are motivated to continue to attend our events and share your experiences and vision with our Chapter.

We look forward to working beside you to make our industry stronger and putting patients first every day.

Jennifer Lauria Clark, CPIP
Chapter President

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Education Committee

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IT Committee

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Technology Conference Committee

Bruce Craven
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Membership Corner

Membership Development

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

It was a pleasure meeting so many of you at our recent CaSA Technology Conference, Golf Tournament, BEST Fest, and Therapeutic Thursday events. Our Chapter Membership continues its upward trend through the efforts of each of you spreading the word about ISPE and our Chapter. Your efforts have led to 73 new CaSA members joining since our last newsletter was published and has brought our total up to 290 new CaSA members since July 1, 2012. Well done and thank you!

Speaking of your efforts, are you familiar with the benefits of [ISPE's Refer-A-Friend program](#)? For every friend you refer who joins ISPE, you'll earn one free month Membership. Credits will be applied towards your next Membership renewal. For more information, click here to visit the associated ISPE Membership web page.

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

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Congratulations to CaSA's Newest CPIP!

Rick Lawless, CPIP

Welcome New Members

These new Members joined March 23, 2013 through May 19, 2013

Chioma Abara
Razan Abdallah
Atinuke Adesina
Maryam Ali
Robert Alston
Terry Barrett
Warren Bealer
Jayanth Bhupasamudram
Latisha Blue
David Bolin
Solema Campbell
Krishnaveni Challa
John Clevenger
Burt Coats
Celena Cohen
Brittany Collins
Jennifer Hughes
Gurpreet Jawa
Jinghua Jia

Amanda Kaufman
Shilysha Davis-Dublin
Glaire Delancy
Mireille Deschamps
Wrennie Edwards
Jairo Escobar
Tim Fuller
Sushma Ghimire
Douglas Goth
Dan Gresens
Guy Grover
Ryan Hall
Thomas Hendricks
Emmanuel Henry-Ajudua
Malari Himmeger
Karen Holmes
Michael Hornburg
Courtney Huffman
Anissa Lewis

Darryl Lewis
Mingshu Li
Scott Lucas
Brittany Mathis
Danielle McCombs
Constance McDuffie
Kerifa McKenzie
Jessica McKoy
Mark Mistretta
Sheila Moss
Jeff Newhouse
Jessica Okorieocha
Jackson Pearce
Christian Pecora
Austin Percival
Leslie Phillips
James Pridgen
Aaron Quick
Hafsa Rahimuddin

Sylvette Ramos-Diaz
Tara Reich
Juan Sanchez
Alexandria Schray
Phil Shoemaker
Natan Siegel
Scott Staton
Darrell Tabb
David Taylor
Nimma Thorne
Todd Viverette
Alexis Williams
Alysia Williams
Khalia Williams
Michelle Wilson
Jasmine Young

Student Corner

7th Annual BTEC-ISPE Career Fair Draws a Full House

Published April 2, 2013 on the Biomanufacturing Training and Education Center (BTEC) website of NCSU

Almost 200 students from NC State and other area universities mingled with potential employers at the seventh annual BTEC-ISPE Career Fair on March 15. The event was attended by 192 invited students and others from the Triangle area. They visited with representatives from 18 organizations, including major biopharmaceutical firms and the U.S. Food and Drug Administration (FDA). The career fair has grown each year since it was first held in 2007 and is an important opportunity for students seeking full-time employment or summer internships in the biomanufacturing and biopharmaceutical industries. Internship and job offers are often extended in the weeks following the event.

The career fair, co-sponsored by the Carolina-South Atlantic Chapter of the International Society for Pharmaceutical Engineering (ISPE), is held each spring at BTEC. An invitation-only event, candidates are selected and invited by one or more of the organizations participating in the event. This year, participating employers included AbbVie Bioresearch Center (formerly Abbott), Biogen Idec, bioMerieux, Commissioning Agents, Inc., Catalent, the FDA, Fujifilm Diosynth Biotechnologies, Genentech, Hospira, Hyde Engineering and Consulting, Kelly Scientific, Merck, NNE Pharmaplan, Novartis Vaccines, Novo Nordisk, Novozymes, Pharmaceutical Calibrations and Instrumentation, LLC., and PharmaSys.

Students from NC State, UNC-Chapel Hill, Duke University, Campbell University, Eastern Carolina University, NC Central University and other institutions attended the event. They are typically studying chemical engineering, biology, pharmaceutical sciences, biochemistry, chemistry or biomedical engineering.

ISPE-CaSA is a volunteer society of technical professionals in the FDA-regulated pharmaceutical and medical device manufacturing industries. The Chapter is committed to the advancement of the educational and technical efficiency of its nearly 1300 members through forums for the exchange of ideas and practical experience. ISPE-CaSA also sponsors student chapters at several universities in the region, including NC State.

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Technology Conference Special Feature

20th Annual ISPE-CaSA Technology Conference: Wrap up & thank you

By Bruce Craven, ISPE CaSA Technology Conference Committee Chair

How did you like the new venue for this year's conference? I truly hope that you were able to experience the new venue that was unveiled at this year's 20TH ANNUAL ISPE CaSA TECHNOLOGY Conference! Your Committee tried to deliver the event you asked for and we truly are hoping that we delivered. The changes we implemented this year were not a small undertaking and I can honestly say there is much excitement already gathering for 2014.

When we announced the plans for the new venue back in September of 2012, our focus was to incorporate your suggestions for improvement over last year's event, as well as to improve upon the annual legacy of providing a successful conference. So why did we do all of this? Our goal for this year was to take what we have learned over the past five years and use that knowledge to make an event that gives back 110% to you, the members of our technology community. Our industry, our science, and our organization are changing around us and this event needed to change with them. You have been asking for something new and different – this was the start of that change.

Key improvements included:

- Move to the Raleigh Convention Center
- Later start time
- More and better food
- Internet access throughout the event for everyone
- Keynote Speaker
- Fewer, more-defined training tracks
- Expanded exhibitor spacing

So now that the “warm and fuzzies” are out of the way, let me get down to the details about our event and share with you some examples. First and foremost, I need to give special attention and thanks to the Corporate Sponsors and recognize them for their contributions and involvement with our conference.

To all of our sponsors and exhibitors, this show is not possible without you and your support – Thank You.


Because of that support and involvement, we had a total of 854 registered attendees at this year's event. We also saw almost 100 people arrive on the day of the event to either walk through the exhibits or attend the Career Fair/HR event. This fact is most important, since we were trying to provide an event that would “do it all” for everyone by bringing the technology and experience of service/equipment providers, life sciences corporations, non-profit organizations, and universities throughout the ISPE CaSA Chapter together for one day of networking and training.

Each change and opportunity was the result of suggestions from our attendees and exhibitors from past events and we will continue that effort in the future. The participation in this year's surveys exceeded our expectations and we are extremely thankful for each and every praise and suggestion that was given. To show our appreciation, we held a drawing for 2 iPads Minis and the winners from the survey participants were Joanne Meloro (IPS) and Jose Lane (JCC) – Congratulations!

By now, you will have noticed that this edition of the Newsletter highlights the 2013 Technology Conference. Within its pages, there are articles written about specific aspects of the conference, as well pictures. Please take time to read through everything and make plans to attend next year's event on April 8, 2014 at the Raleigh Convention Center – it will be even better!

In closing, I want to thank the individual Committee Members and CaSA ISPE Board, both present and past, for supporting me as we began this journey of change and expansion. This undertaking could not have been possible without their guidance, time, support and encouragement. I also want to say a special “thank you” to Mike Putnam, Technology Conference Co-Chair and my personal friend, for all the hard work and extra effort he put toward this event – we could not have done this without you. Finally, thank each of you for the past two years and granting me this opportunity to serve and be a part of something bigger than myself. I have enjoyed the ride and I look forward to experiencing the CaSA ISPE Technology Conference for many years to come.





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Technology Conference Special Feature

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Technology Conference Special Feature

20th Annual ISPE-CaSA Technology Conference: A Platinum Hit!

By Mike Putnam, ISPE CaSA Technology Conference Committee Co-Chair

For those up to speed on traditional wedding anniversary gifts, you know that the “big 20” calls for platinum. On March 26, 2013, that’s exactly what the 20th Annual Technology Conference served up to attendees. From the impressive new location at the Raleigh Convention Center to the dynamic line-up of speakers, this event was one to remember in the life of our Chapter.

The tone of this year’s conference was set prior to stepping through the front door as two sign spinners outfitted in Tyvek suits showed off their best moves while perched on elevated columns along Salisbury Street.



Inside, the action was just as hot. Raleigh Mayor Pro Tem, Eugene Weeks, welcomed conference attendees to the downtown venue and CaSA President Jennifer Clark, CPIP, delivered a powerful message on the impact of life science professionals to patients around the world.

As the morning progressed, attendees enjoyed seminars from industry leading experts, discussions with over 200 corporate, university, and non-profit exhibitors, and product demonstrations featuring cutting edge technology for drug manufacturing.

A scrumptious lunch buffet was followed by what many viewed as the highlight of this year’s conference, the keynote speech by Bob Ingram. As former CEO/Chairman of GlaxoWellcome, General Partner of Hatteras Venture Partners, Board Chairman of the RTP Foundation, board member of numerous major biopharmaceutical manufacturers, and National Cancer Advisory Board appointee by President George W. Bush, Mr. Ingram engaged conference attendees with his address on industry trends, Southeast regional opportunities, and new vision for Research Triangle Park. ISPE CaSA was also pleased to have International President and CEO Nancy Berg address attendees to close out the conference.

Evening events were spiced up with BBQ-stuffed hush puppies pierced with sauce-filled syringes and live entertainment from Adam Pitts, who jammed out on the piano, harmonica, guitar, and microphone (YES, all by himself!). To sum it up, the conference was an event to remember in the life of the ISPE CaSA Chapter.

Thank you goes out to all the Committee Members who worked tirelessly to make the conference a success. A special thanks goes to Bruce Craven, who has done a tremendous job chairing this event over the past two years. For attendees

that made the trip and experienced the 20th Annual ISPE Technology Conference, thank you! For those who didn’t make it, we hope to see you on April 8, 2014, as we promise to deliver yet another unprecedented ISPE CaSA Technology Conference.



Bob Ingram



Nancy Berg, ISPE International President and CEO



Technology Conference Special Feature

ISPE CaSA 2013 Student Poster Competition

By LeAnna Pearson, Student Affairs Committee Chair



The Annual CaSA ISPE Student Poster competition was held in conjunction with the 20th Annual CaSA ISPE Technology Conference. We had a great group of student competitors representing the following schools: Campbell University, North Carolina Central University (NCCU), and North Carolina State University (NCSU).

The 2013 CaSA ISPE Undergraduate poster winner was **Charles Okechukwu** from NCCU with a poster entitled, "Revealing the Role of Cancer Testes Antigens in HIF Signaling."

The 2013 CaSA ISPE winner in the Graduate category was **Oscar Bernal** from NCSU with a poster entitled, "Highly Reactive Microbial Paper and Non-Woven Biophotocomposites for CO₂ recycling and H₂ production."

Both the undergraduate and graduate winners receive a fully funded trip to the 2013 ISPE Annual Meeting in Washington, DC to compete in the International Student Poster Competition.

A big "thank you" goes out to all of our student competitors who proved why CaSA ISPE has some of the best Student Members in the world. We also want to thank all of our poster judges for taking the time to invest part of their Technology Conference experience providing feedback to the future of our industry.

microbial paper is dried prior to rehydration and shows sustained long-term reactivity following rehydration. Hydrogen gas production derived from acetate by the activity of nitrogenase in CGA009 Rps. palustris entrapped in microbial paper can be sustained >1000 hours at a rate of 4.00 ± 0.28 , mmol H₂ m⁻² hr⁻¹ following rehydration. SEM images of composite microstructure reveal the distribution of the bacterial cells in the paper matrix as clusters between paper fibers (in their characteristic rosette morphology) that do not clog the pore space, which allows for perfusive flow through the cellulose fiber matrix. Composite microbial paper provides a beneficial microenvironment for cells to remain viable and reactive for long periods of time after drying and rehydration. This bio-composite materials approach may be promising as an inexpensive photoreactive material for solar energy trapping as a component of a microbial photo fuel cell (MPFC), for advanced biofilters and separation devices and for the production of liquid biofuel precursors where a very high concentration of cellular biomass is maintained metabolically active in a non-growth state for 1,000s of hours. Current efforts are focused on the confirmation of the non-growth state of the cells in the paper, prevention of cell leaching to the liquid phase and adaptation of the paper formation method for immobilization of a high volume fraction of viable cyanobacteria cells for CO₂ recycling and O₂ production.



Graduate Winner: Oscar Bernal

Highly reactive microbial paper and non-woven biophotocomposites for CO₂ recycling and H₂ production

Whole living photosynthetic cells have significant stability advantages over isolated chloroplasts, photosynthetic proteins and artificial photocatalysts for engineering photoreactive composite materials. Cells have all the necessary molecular machinery to carry out photosynthesis in a stable chemical environment and produce useful metabolites capable of generating more energy. Microbial latex paper coatings have the potential to stabilize photosynthetic reactivity by providing a porous support that keeps the cells hydrated and acts as a transport network that nourishes the cells, eliminates waste material and separates products. Here we report a novel extension of engineering cellular composite materials in which we use a paper matrix for long-term stabilization of photoreactive microbial biomass as an integral part of the bio-composite microstructure. This reactive

Undergraduate Winner: Charles Okechukwu

Revealing the Role of Cancer Testes Antigens in HIF Signaling

The hypoxia-inducible factor-1 (HIF-1 α), is a transcription factor that responds to changes in oxygen homeostasis¹. Furthermore, the HIF pathway has been observed to contribute to tumor aggressiveness. The overexpression of HIF proteins has been observed to increase malignancy in tumor cells. Identifying the mechanisms that regulate HIF is essential to developing therapeutic strategies to inhibit its function. Here, we asked whether any members of the cancer-testes (CT)- antigen (CTA) family support HIF signaling. We combined a siRNA mediated loss of function approach with a luciferase reporter fused to a HIF Response Element (HRE), to determine consequences on HIF signaling following individual depletion of 120 CTAs. This screen revealed that a subset of CT-antigens played a role in Hif1 α protein binding to HRE. It was then shown, by western blot, that depletion of this subset of CTAs, MAGEA3/6 and IGF2BP3, lead to decreased Hif1 α protein. These findings suggest that CTAs may support stress signaling, particularly under hypoxic conditions, and further demonstrate that CTAs may be playing functional roles in supporting tumor cell survival.



Technology Conference Special Feature

ISPE Tech Conference Career Fair

By Karin Cleary, Technology Conference Committee Career Fair Co-Chair

Job highlights, company overviews, and technical skills surrounded the room at the 2013 ISPE Tech Conference Career Fair. Thanks to the many company representatives and talented participants who made successful connections that day!

Participating companies included:

- Biogen Idec
 - Catalent
 - Eisai
 - Novartis
 - Merck
 - Grifols
 - Hospira
 - Belcan
 - Sequence Validation
 - PCI
 - Mangan BioPharm
 - NNE PharmaPlan
 - Professional Project Services
 - Novo Nordisk
 - Kelly Scientific
- And more!

"We received many potential and qualified applicants this year, providing the hiring managers with a better technical selection than the years previously. The location also made it easier for one on one discussions and informal interviews."

—Bruce Craven, Mangan BioPharm



Technology Conference Special Feature

Photo Gallery: Education Sessions

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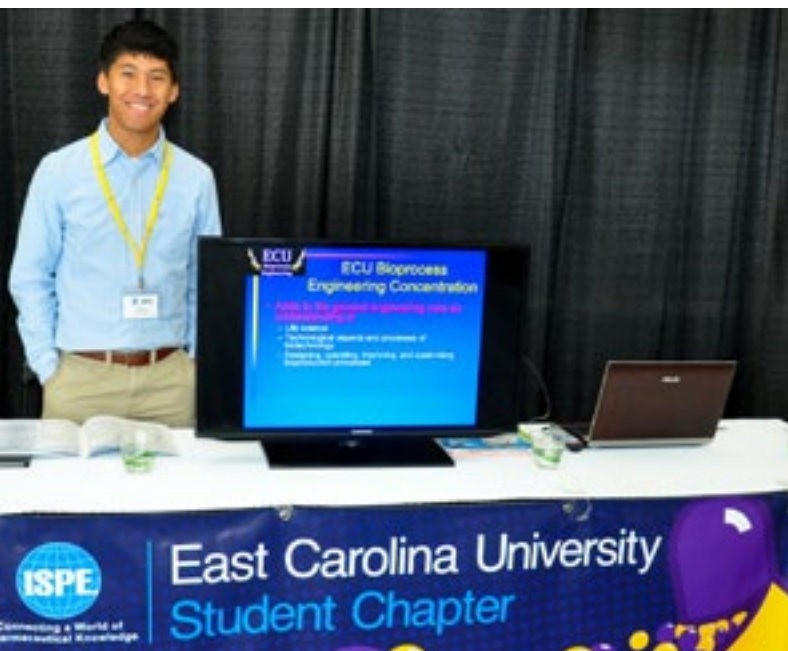
Technology Conference Special Feature

Photo Gallery: Networking Reception



Technology Conference Special Feature

Photo Gallery: University Booths



Technology Conference Special Feature

Photo Gallery: Scenes from the day

Welcome
to the
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(above) Mike Putnam (left), Co-Chair of Conference and Bruce Craven (right), Chair of Tech Conference

(below) CaSA Chapter President, Jennifer Lauria Clark, CPIP presenting the 20th Annual Tech Conference Cake to Bruce & Mike.



(above) Mayor Protem, Eugene Weeks, welcoming conference attendees to the downtown venue

(below) Jennifer Lauria Clark, CPIP, ISPE CaSA President



Technology Conference Special Feature

Technical Topic Featured at the Tech Conference

Exploiting the Not-So-Best Practices of the Pharma Supply Chain

By Ron Guido, VP of global brand protection and supply chain integrity, Johnson & Johnson



This article is republished with permission from Pharmaceutical Online.
Original publication date was 1 Mar. 2013

I want to thank the honest and hard-working members of the global pharmaceuticals supply chain for being naive, uninformed, or apathetic to the lucrative and growing business opportunities I enjoy at their expense. To the IP owners of those products affected, I am equally indebted for creating “trust” in those brand names among the user community, thereby establishing a healthy base of business for me to exploit. You see, I am actually honoring you by copying your products.

You may not know me, but I certainly know you very well. In fact, it is easy to become acquainted with you by simply observing your predictable routines and trusting behaviors. I am amused by your preoccupation with service levels, fill rates, global sourcing networks, and speed of delivery. Ah yes, I enjoy the way you process countless transactions and inventory transfers without that verification part — my fortune is built upon your trust-sans-verification habits.

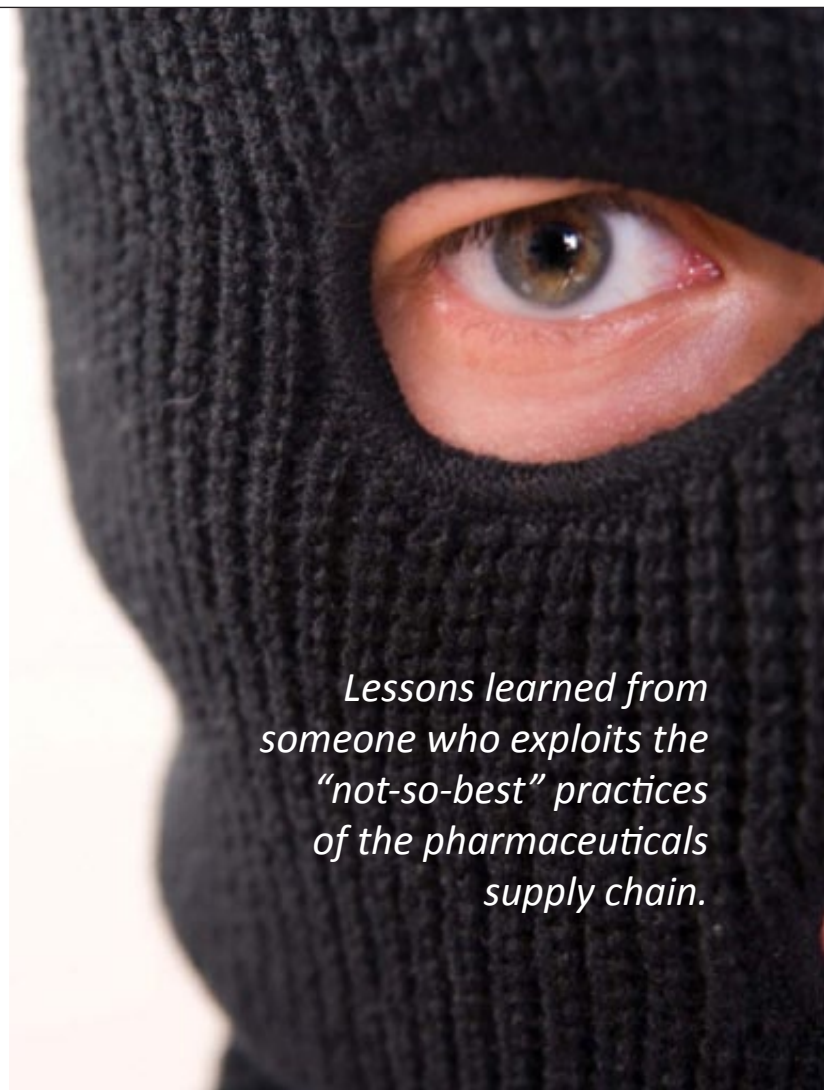
Nevertheless, I do feel obligated to share some of my practices with you, because I get the feeling you think that counterfeiters cannot be stopped or even deterred away from dangerous medicines to other more benign product categories. And you pathetically believe that you, the legitimate trade masters of the pharmaceutical industry, are simply victims of my success rather than accomplices. As you will learn, all you have to do to render me powerless is to get your collective acts together, share control of the supply chain with each other, and add visibility to information you feel you must hide from each other.

What I am offering you is a chance to see how you unknowingly contribute to a not-so-secure pharmaceuticals supply chain ... from the vantage point of a business opportunist. So let's get started with my confessions.

Confession #1: My Market Space is the Facility of Global Commerce

The global market for prescription medicines is rapidly approaching \$1 trillion according to recent IMS data. The key is cross-border trade facilitated by a growing percentage of production taking place in a country in which those goods are not consumed. This is the case with pharmaceuticals.

Stimulated by free trade agreements and geopolitical will



Lessons learned from someone who exploits the “not-so-best” practices of the pharmaceuticals supply chain.

for a single global economy, Asia, in particular, has become the “factory” for the world. The growth and capitalization of emerging markets, combined with a relative lack of respect for and protection of IP in some countries, has created a cornucopia of opportunity for those of us who understand international trade. And if the situation wasn't easy enough to exploit, there is a perpetual shortage of regulatory and enforcement resources around the world. In the unlikely event

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Technology Conference Special Feature

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that my goods are confiscated in transit, the risk of prosecution is much lower than the reward. In fact, I can't think of any form of commerce that has a more attractive risk/reward profile than sending branded drugs across borders. If such illicit endeavors still appear risky, the safe haven of e-commerce is always available to me. With the lack of international regulations and oversight policing Internet sales, taking Internet orders and sending the goods through parcel services is perhaps the easiest and least risky trade route available to those of us in this profession.

Confession #2: My Targets Are Multinational Brands in High Demand

Why spend time and money falsifying obscure brands with limited demand when you can exploit reputable, highly recognizable brands which are registered for trade virtually everywhere? My experience tells me that price is a plus, but not as important as volume, particularly considering my low cost of goods. Areas of prime interest in counterfeit trade include branded apparel, media products, software, electronics, and healthcare products. All are money-makers for the same reason — high-volume, popular brands attract less scrutiny than specialty items and are easier to move throughout their respective supply chains.

Confession #3: As a Rule, Never Be Seen With the Goods

My success in remaining undetected as a counterfeiter is largely attributable to ensuring that my manufacturing site not be visible to the legitimate supply chain. Once I manufacture my goods, I want to cross a border as soon as possible. In so doing, I am able to utilize gray-market diverters to "dilute" fake products among genuine goods. In addition, I always ship my goods across borders in multiple small quantities rather than bulk so that, in the unlikely event that they are intercepted by the authorities, my investment is not totally lost. For added protection, I use my friends and family for import/export operations, regularly "transplanting" trusted colleagues to port cities to serve as trading brokers.

Confession #4: My Technology Investments Are Largely in Packaging

I spend at least 80% of my operating budget on packaging. I always begin by purchasing genuine products to use as a template and utilize the latest Web-based printing tools to replicate packaging. Even better, I try to secure discarded genuine packaging to encase my fakes. I am not admitting to the art of "dumpster-diving" as a means of procuring spent packaging, but I do know colleagues who enjoy the fruits of such practices. Whenever possible, I source containers, caps, inks, and labels from the same suppliers used by my targeted brands, unless of course the legitimate rights holders are prudent enough to track inventories of such supplies into and out of their providers.

I'm most amused by the term "anticounterfeiting technologies." Do you really believe that just because you bury some secret foo-foo dust deep into your printing inks, I will be deterred? If no one can find such authentication markings because the required high-tech scanners are located halfway around the world, or if no one even knows what to look for, I thank you for investing in such a false sense of security. Remember, my objective is to fool the inspectors, not the users of the product or the company's security ink brigade.

More broadly, when it comes to technology, I have been fortunate to be in practice at a time when excess capacity exists across the pharmaceuticals industry. Plant closings offer me a plethora of equipment, from printing plates to dies to pill-making equipment. Online auction sites routinely offer the equipment I need to reproduce anything, usually at a fraction of the original cost. Oddly, the legitimate drug manufacturing industry is ostensibly handing me the know-how, supplies, and hardware I need to become a so-called third-party manufacturer of their most cherished brands. Regardless of how I choose to make a fake, I always check for mistakes using sound quality control practices. Most arrests begin with someone identifying subtle packaging flaws.

Confession #5: My Favorite Supply Chain Category Is Reverse Logistics

People in my line of work know that famous brands have liberal returns policies. Perhaps the easiest way to make money in counterfeit trade is to sell the fakes to the company whose brands you are falsifying! I know this seems absurd, but consider this: Returned prescription medicines aren't generally restocked and resold. There is no need to worry about such fakes reaching the patient. Furthermore, the administrative tasks involved are usually too overwhelming to include any significant authentication, particularly when returned drugs are quarantined for destruction anyway. Typically, my returned goods are sent back to the company through enterprising returns processors or aggregators, providing a natural fence between me and the IP rights holders.

Lastly, I want to point out a major deficiency in the way

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"Do you really believe that just because you bury some secret foo-foo dust deep into your printing inks, I will be deterred?"

returned goods are processed by legitimate supply chain managers. Destruction of damaged, expired, or obsolete pharmaceuticals is typically orchestrated through a third-party contractor which picks up the inventory and brings it to a re-

mote site for destruction, burial, or incineration. Yet many of your company's practices simply require the driver to sign for the load or, more securely, photograph the act of destruction. I have found it relatively easy to repurchase such inventory from your third-party contractors for a fraction of the market value and reintroduce those products into the reverse logistics network. I often wonder if such drugs are ever returned for a second trip to the dump.

Confession #6: I Am Inspired by the Lack of Pharma Supply Chain Visibility

I am almost embarrassed to share my observations about how the lack of visibility to transactions in the downstream supply network allows me to become wealthy. First, as long as those within pharmaceutical supply operations continue to call it a "chain," instead of recognizing it as the "network" it really has become, transparency of transactions will remain an aspiration but never a reality. The history of pharmaceutical trade explains the lack of visibility. Manufacturers are motivated to rapidly sell and distribute their remarkable innovations in medical science to all dispensing outlets utilizing all reasonable means to do so. Consequently, the "chain of custody" or pedigree of a given inventory unit is lost among a sea of transactions with little coordination of events across trading entities. Authentic products visit wholesalers, second-

ary distributors, repackagers, and third-party logistics parties across many boundaries and regulatory jurisdictions before arriving at the patient's side. Separately, financial records are generated and processed by some of the same entities as well as by importers, exporters, retailers, clinics, and brokers along the way. In short, records of trade are asynchronous to money and inventory flows, leaving a myriad of opportunities to insert falsified product into such a web of unregulated trade. Each legitimate player in the network contributes to the problem by acting independently of others. IP rights holders quickly "sell out" their brands to intermediaries in order to register revenue, but this creates attractive gray zones outside their purview. Intermediaries are reluctant to share trade data for fear of being disintermediated from the network. External manufacturing sites require separate flow lanes for legitimate trade while opening the door for shadow operations to arise. Suppliers of legitimate components and services openly seek new customers to leverage available capacity. Trivial checks by government agents create a false sense of security. Trusting retailers and consumers don't worry about integrity of supply. Lastly, Internet purchasing is attractive to consumers, yet the most difficult to regulate. With so many opportunities to insert fake goods into what is perhaps the most complex of all global supply networks, the only logical way to illuminate the supply chain is to implement and enforce a realtime track-and-trace system.

Confession #7: Laissez Faire Provides a Supportive Business Environment for Counterfeiters

Controls, regulations, audits, certifications, and intellectual property rights all impede free commerce, and therefore, they will usually be denied or minimized in favor of allowing business success to drive economic growth. There is a natural bias of local authorities to favor their own economic development over international trade rules. Inbound customs inspections, for example, are more rigorous than scrutiny of exported goods.

Some governments actually endorse local production of unauthorized generics in the interest of jobs creation. An



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argument can be made for the value of knockoffs in stimulating local economies and generating new tax revenue. In most industries, while genuine brands establish demand for a product category, “generics” will usually suffice. Consumers tend to be trusting and/or apathetic about the dangers of fake goods. Although this is not necessarily the case for pharmaceuticals, given a choice, the public tends to favor economic stimuli over concerns for supply integrity.

So there you have it — my true confessions! I do feel bad about all of you honest people trying to figure out how to safeguard the supply chain. Maybe I can take a pill for that.

10 Best Practices to Counter the Counterfeiter

Since I like making money at my job as a drug counterfeiter, I’m hoping you don’t follow these guidelines, which demonstrate some of the countermeasures currently in place or under development to help pharmaceuticals manufacturers prevent counterfeits from entering the legitimate supply chain.

1. Establish a companywide business culture of trust with verification.
2. Respond aggressively to all reported incidents.
3. Rewrite agreements with intermediaries to assure your branded products are only purchased from your authorized sources.

4. Enlist the support of government agencies in authenticating your brands as they cross borders.
5. Utilize authentication technologies interoperably with track-and-trace systems to identify where and when counterfeits enter the supply chain.
6. Apply stringent reverse logistics procedures to assure that returned goods are genuine and destruction is witnessed and documented.
7. Market monitoring and supply/demand analytics can identify potential brand attacks.
8. Ensure suppliers and contract manufacturers are not supporting shadow operations.
9. Protect your facilities and cargo from pilferage, theft, and other security breaches.
10. Prevent your excess and retired equipment from being acquired by counterfeiters.

Ron Guido spoke on this topic at the 2013 ISPE Technology Conference.

Upcoming Events

DATE	DETAILS
June 27, 2013	Therapeutic Thursday at Carolina Ale House, Cary, NC sponsored by CleanSeal Door Systems
August 21, 2013	Summer Social at Durham Bulls Athletic Park
August 26-28, 2013	ISPE Durham Training: Join ISPE in Durham, North Carolina Learn how to improve manufacturing efficiency, maintain product quality and improve GMP compliance.
August 27-28, 2013	Biotechnology 2013 - Looking Ahead to the 4th Decade, Durham, NC The dynamics of the modern Biotechnology industry are changing on many fronts. Next-generation manufacturing systems, advances in bioprocessing, streamlined compliance programs and the introduction of new products can have significant impact on how engineers develop and validate projects.



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