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Boston Area Chapter
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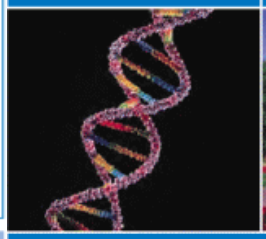

NEWSLETTER
January 2016, Volume XXVI, No. 1

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President's Message: ISPE: Preparing for the Future of Our Industry

My fellow Members,

As I write this, I have recently returned from the ISPE's Annual Meeting in Philadelphia. The meeting was filled with inspiring keynotes, the Global Regulatory Town Hall, six educational tracks, and wonderful networking events. Be sure to check out Jack Campion's wrap up article herein. At the Members breakfast, our own Sydney Shaw of Northeastern University was named winner of the Graduate Student Poster Competition (check out her article in this newsletter about her experience). I participated in productive meetings with my counterparts on the North America and South America Affiliate Council as well as the global Joint Affiliate Council where we discussed the future direction of the Society. There are many interesting initiatives that are coming in the new year, so please keep a lookout for announcements from the Society. It was a great four days meeting with our Chapter's Members as well as Members from around the world that made the trip a success.

But there was one presentation that really got my attention as it was on a subject near and dear to me as a strategic consultant and that was the presentation by Andy Skibo, outgoing Chair of the International Board of Directors and Head of Global Biologics Operations & Global Engineering at AstraZeneca. In his presentation, Andy noted that our industry has come back from the recession in a big way and one of the metrics used to measure that recovery was that there are more than 20 billion dollar projects that will be delivered globally between now and 2021 and the number of projects is projected to increase over the following five years.

While this may sound great initially, it begs the question: Who will be delivering these projects? A decade ago, there were eight global EPC firms serving the cGMP market that an owner could entrust with a billion dollar project on an EPC basis. Now there are two. So that means owners will have to be look at breaking up the projects into smaller components and utilizing multiple engineering and construction management firms to deliver these mega projects. That is okay if the owner has an experienced in house capital projects delivery group to make sure that nothing is falling in between the gaps of the various contracts but the trend during the recession was to downsize and, in some cases, eliminate these groups. So now these firms are trying to rebuild their in house teams and where are they sourcing their candidates? From the very same firms they are looking to for delivery of these projects!

The problem is further exacerbated by the realization that if there are more than 20 billion dollar projects, how many projects are there under a billion? The problem is further complicated when you look around the skyline of Boston or any other major city and you see the amount of development that is occurring beyond our industry. And these projects, while complicated in their own ways, do not have the complexities that a cGMP project brings. So design and construction firms active in these markets may be reluctant to re-enter or enter for the first time into our market. And if they do, where will they find the personnel with the requisite cGMP knowledge to deliver the projects?

Because the other part of this problem is that the cohort with the experience in delivering these projects a decade ago - the Baby Boomers - are leaving the industry at a record pace. In fact, Millennials (adults ages 18 to 34 in 2015) overtook both Baby Boomers and Gen X as the largest generation in the U.S. labor force this year. Boomers now comprise 29 percent of the work force as compared to Gen Xers and Millennials, both at 34 percent. (A decade ago, Boomers were at 49 percent.

When you consider that the Gen X population was significantly smaller than the Boomers and that less of them entered into the engineering and construction fields (those that had aptitude for these fields tended to go into computer-oriented fields), it is not surprising that there is no one for the retiring Boomer to hand the reins to. The issue was made worse by the cyclical nature of the market over the last 20 years and during each of the downturns, experienced individuals left the industry never to return.

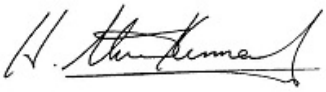
While we are doing a better job attracting Millennials into the industry, they are generally young and unseasoned and years away from being able to take the reins. And that is where ISPE and the Boston Area Chapter can help this critical shortage. With our educational and networking programs, we are here to provide the knowledge and education that our members need. But we need your help. Please contact me and let me know what areas we should focus our efforts on to best address this issue. The problem seems insurmountable, but together we can find solutions. One place you can help: We are always in need of volunteers. If you have the time, get involved with the Chapter and help us solve this problem. We

are looking for support in our Communications Committee, Educational Programs Committee, Geographical Outreach Committee and Product Show Committee.

Speaking of the Product Show, planning for next year's 25th Anniversary Show is well underway. Exhibitors are urged to pre-register for the Show to ensure that they don't get shut out as it is sure to sell out. The show will be starting earlier next year and lots of enhancements are being implemented. Details can be found on our website, so check it often for updates as they are added.

We all have high hopes for the New Year and the Chapter is starting it off with a bang. We have a great educational event this month and our annual Winter Social. Details on both are elsewhere in this newsletter and on our website. I look forward to seeing you at both. Happy New Year!

Warm Regards,



H. Steven Kennedy

Chapter Bulletin Board

Chapter Kicks Off New Mentoring Program

The Chapter is pleased to announce our brand new Mentoring Program, which was officially launched at the Product Show. If you think you could benefit from the experiences of others or if you think you can share your experiences to help a fellow Member, then this is the place for you. Mentoring is a positive experience as well as a growth opportunity for both the mentor and mentee. Check out the new "Mentoring Program" tab on the Chapter website to learn more or click here. All you have to do is register and the Chapter will pair you up.

The mentoring program took about a year to build and was truly a multidisciplinary commitment involving major efforts from Samir Gondalia (Membership Committee Chair), Chris Ciampa (YP Committee Chair) and Brian Hagopian (Student Development Committee Co-Chair) who should all be recognized for their contributions to developing and launching the program.

Pre-register for 2016 Product Show - Be First in Line for Prime Booth Locations

October 5, 2016 - that's the date for next year's Product Show & it's not too early to pre-register. Over 50 percent of exhibitors at the 2015 Product Show have already committed, so don't delay. Simply visit the Product Show website at http://productshow.ispeboston.org/reserve-space/, provide the information requested and pay a small deposit. Doing so gives you the chance to pick your location and advertising opportunities early, before exhibitor registration opens next spring. Don't be left out - do it now!

In order to ensure that we are continuing to deliver the best possible Product Show, the Product Show Committee solicited responses from both Exhibitors and Attendees in separate surveys. The results have been tabulated and are laid out in a report written by H. Steven Kennedy that you can access on our website. The report confirms that the Show was a resounding success and offers insight on which drivers the Show attendees and exhibitors found important. We are using the results to make some adjustments to next year's show. You are encouraged to review the report in anticipation of your participation in the 2016 Product Show. This will help ensure that you have a successful event.

eNewsletter Ad Space Expanding - Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at (781) 647-4773 or office@ISPEBoston.org.

Support Your Chapter - Become a Sponsor!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource containing all the information you need to know to become a Chapter Sponsor.

We invite you to visit the sponsorship page at http://www.ispeboston.org/become_a_sponsor.html to explore the full range of sponsorship options available. Using the sponsorship application as your worksheet, you can view your savings as you select various combinations of sponsorship options - the more you choose, the bigger your discount!

So don't delay, visit http://www.ispeboston.org/become_a_sponsor.html and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or, if you'd rather, contact the Chapter office at (781) 647-4773 or office@ISPEBoston.org and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Thursday, January 14, 2016

ISPE Boston New Year's Social

Blazing Paddles, Boston, MA

EVENT SUMMARY

Previous Issues

Start the New Year off by joining ISPE Boston for a night of Ping Pong and Baseball!! There will be prizes awarded for the Ping Pong tournament winners (sign up early to participate). The batting cage at Fenway Park is available for all to take a few swings. Sign up now and show off your skills on the table and in the cage! Cash bar and light fare will be provided.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=630

Thursday, January 21, 2016

ISPE Build A Bio

UMass Lowell Emerging Technology & Innovation Center, Lowell, MA

PROGRAM SUMMARY

Join ISPE Boston Chapter at the UMass Lowell for an eventful Town Hall discussion covering the ins and outs of manufacturing strategies. The program will include a networking reception including appetizers. As an added bonus, representatives from UMass Lowell are hosting a tour of the Emerging Technologies and Innovation Center. This is an ISPE MEMBER ONLY tour. Tour participation is limited, so register now!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=567

Thursday, January 28, 2016

RE-SHOWING: ISPE Build A Bio

Crowne Plaza Hotel Providence - Warwick, Warwick, RI

WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

PROGRAM SUMMARY

Attend a re-showing at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs will both feature a networking reception including refreshments and appetizers.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=633

Saturday, January 30, 2016

ISPE Student Career Workshop

Northeastern University, Boston, MA

PROGRAM SUMMARY

If you will be graduating in 2016-2019, come to a workshop specifically designed to help you refine your skills and improve your chances of getting that internship, co-op, or full time position in the Life Science Industry.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=600

Sneak Preview of Upcoming Events

Thursday, February 18, 2016
ISPE This Old Plant
Genzyme Center, Cambridge, MA

Thursday, March 24, 2016
ISPE Role of the Pilot Plant in the Product Lifecycle
Shire, Lexington, MA

Thursday, March 31, 2016
Re-Showing: ISPE Role of the Pilot Plant in the Product Lifecycle
Crowne Plaza Hotel Providence - Warwick, Warwick, RI and
WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

Chapter Hosts Japan Affiliate Members

by H. Steven Kennedy, Kennedy Strategic Consulting

In what has become a biannual tradition, the Chapter welcomed a group of 21 delegates from the Japan Affiliate to Boston as they passed through on their way to the ISPE Annual Meeting. This year's activities were coordinated by Michael Lucey for the Japanese Affiliate and by H. Steven Kennedy on behalf of the Board of Directors.

Newsletter Archive

Following a tour of the Cambridge biotech hub with Chapter volunteers as guides, visitors from the Japan Affiliate joined Chapter officers and board members for a family-style dinner in Boston.

The delegation arrived in Boston on Tuesday, November 3, and were taken to the Hyatt Regency Cambridge on the banks of the Charles. Bright and early the next day, Chapter tour guides Board Member Kevin Chronley and Young Professionals Committee Chair Chris Ciampa met the delegation and commenced the start of their 2-day tour. They started with a tour of Shire where hosts Lois Perry, head of the Lexington Manufacturing Site, Shawn Fitzpatrick, and Chapter Board Member Eric Felz showed off 400 Shire Way — Shire's state-of-the-art, single-use manufacturing facility.

After the tour, the delegation headed back to Cambridge for lunch at Legal Sea Foods in Kendall Square. After lunch, they walked across the street to Biogen where host and former Board Member Tom Choyce conducted a tour of the bio2 production facility where Biogen is manufacturing three of their flagship products: Avonex®, Plegridy®, and Eloctate®. After the Biogen tour, the group boarded their bus and were given a tour of the Cambridge biohub by Kevin and Chris as they made their way back to the hotel. Later that evening, the Chapter Board of Directors hosted a reception and dinner for the visitors at Maggiano's Little Italy in Park Plaza where everyone shared an array of Italian specialties served family style.

The next morning, the delegation traveled to Waltham for a tour of the AstraZeneca Research Campus where they were greeted by hosts Paul Joyce, Director Engineering & Site Services; Stephen Shea, Associate Director Facilities & Lab Operations; and Ken Sutton, Director Facilities Management. Escorting them for the Chapter was Chapter President, H. Steven Kennedy and Immediate Past President Chris Opolski. After an excellent lunch, they headed to Connecticut to visit Pfizer Groton. Here they were met by their hosts, Chapter Board Member Darren Wolter and International Board of Directors Vice Chair Michael Arnold, who gave them a tour of their new PCMM - Pharmaceutical Continuous Manufacturing Module. After refreshments, the delegation continued on their journey to the Annual Meeting where they attended the Chapter's Annual Meeting reception at the Hard Rock Café in downtown Philadelphia on Sunday evening.

The delegation has written the Chapter to tell us they appreciate our hospitality and the time spent with the Chapter was the best part of their trip. They have extended an invitation to the Chapter to send a delegation to Japan to attend their 25th Annual Meeting in the spring of 2017. The Chapter will be coordinating a group to visit our "sister" Chapter, so if you are interested in making the trip, keep an eye out for details over the coming year.

The Chapter would like to thank the tour organizers, our hosts at Shire, Biogen, AstraZeneca and Pfizer, and the Chapter volunteers who acted as guides during the two-day tour for making this a great experience for our colleagues from Japan.

Annual Meeting 2015 – A Renewed and Vibrant ISPE

by Jack Campion, The Hart Companies, with photos by Chris Opolski, SPEC Process Engineering, and Brian Hagopian, Clear Water Consulting

There was a new "vibe" at the 2015 Annual Meeting of the ISPE. Both the organization and the industry that its members serve are feeling healthy, strong and growing. Chapter officers and Members traveled to Philadelphia on November 8-11 to learn, share and celebrate. We were joined by thousands of professionals from across the globe in a great conclave themed "New Paradigms for Manufacturing Excellence."

Philadelphia provided a photogenic backdrop for this year's ISPE Annual Meeting.

The "learning" took the form of numerous educational sessions that stretched over 3 days. Broad subject matter categories included Facilities and Equipment; Product Development and Production Systems; Supply Chain Management; Regulatory Compliance and Quality Systems; and Information Systems.

Sessions were led by several Boston Area Chapter Members. Pietro Perrone (EMD Millipore) led a session called "Single-Use Technology: The Advances of a Flexible Technology in a Structured Environment" featuring case studies of risk management associated with SUTs, including extractables and leachables, and reduction of operator errors. Jim Vogel (BioProcess Institute) led a panel called "Single-Use Standardization Update" that included Pietro.

Other members were also featured as speakers and panelists: Chapter Past President Andre Walker spoke on "Emerging Standards and Practices in Continued Process Verification." Andre Gill participated in "Critical Utilities Maintenance Program and Operational Optimization." David Krantz (Shire) and Rob Snow (Genzyme) both presented in a session covering the convergence of continuous processing and single-use technologies. David's talk was "upstream," describing a single-use perfusion bioreactor application. Rob tackled "Chromatography Column Sterilization Needs and Challenges for Continuous Operation." In all it was a great display of the expertise and technical leadership embodied in the Boston Area Chapter membership!

New this year was the "Innovation Forum." This series covered topics such as new strategies to turn piles of data into usable information and assure data integrity; the challenges of implementing new technologies in China; and new thought processes for efficient capital appropriation decisions. "The Future of Pharma" session went beyond the limits of standard topic categories. Ideas discussed included the development of medicines in outer space, the "internet of things," using "Big Data" tools, and the "Maker" movement.

The Forum challenged notions that ideas like those above don't apply or are tangential to pharma manufacturing. Conclusion from the sessions: Not for long! Next year's Forum could have speakers with a different perspective from "unrelated" industries such as aerospace or from companies such as Google.

Plenary sessions featured outstanding speakers and panelists. Notably, John Cox, EVP of Operations and Technology for Biogen, emphasized the need to "transform" biologics manufacturing in order to meet the coming challenge presented by a huge biopharma drug pipeline. A highlight was the introduction of Dr. Theodora (Dora) Kourti, ISPE's new SVP of Global Regulatory Affairs. She has a distinguished and truly global background in industry and academia and will serve as a resource to facilitate the Society's many

technical initiatives.

The "sharing" took place in many forums including the vendor exhibition with numerous Chapter Members promoting their companies prominently. Chapter Manager Amy Poole, along with the Chapter officers led by Chapter President H. Steven Kennedy, participated in the Joint Affiliate Council - a roundtable of Chapter and Affiliate representatives from around the world. Separately the North America/South America Affiliate Council met to discuss collaborations and exchange ideas and best practices. As a result, the Boston Area Chapter leaders are exploring collaborations with the New Jersey Chapter and the Australia Affiliate for truly global education sessions. Separately, we met with the Brazil Affiliate to exchange ideas for event topics and volunteer management - a truly intercontinental learning experience!

Last but not least, "celebrations" included the annual Boston Area Chapter reception held at the nearby Hard Rock Café. About 75 attendees, including our colleagues from the Japan Affiliate, enjoyed the classic rock visuals, sounds, food, drink and each other's company. Boston Area Chapter Members also were out in force at the Society's Tuesday Night Party at the Reading Terminal Market. A highlight of the week occurred at the Annual Awards Breakfast where recent Northeastern grad and Chapter Member Sydney Shaw took the top prize in the international poster contest graduate category. A grand moment for the Chapter!

The Chapter's Sunday evening reception provided a warm welcome to Phillie for Chapter Members and guests.

The Tuesday Night Party provided a great way to unwind after three days of meetings and educational sessions.

Boston Area Chapter members share their congratulations (and a few laughs) with International Poster Contest winner Sydney Shaw (center) at Annual Meeting.

The 2015 Annual Meeting was a delight to attend for so many reasons. Great learning, great connections and a positive "long view" of our important and prosperous industry. See you there next year!

Soft Skills Educational Program: What Your Professors Never Taught You

by Jillian Willard, Genzyme, with photos by Joyce Chiu, Shire

A group of industry professionals gathered on a rainy Thursday night at Genzyme in Framingham to listen to a discussion of a number of different soft skills topics. First up was "How to Avoid Death by PowerPoint," presented by the Boston Area Chapter Educational Committee's own Michael Levesque and Howard Sneider. The dynamic duo discussed the many ways good presentations can go bad and how to avoid

common pitfalls through better planning and structure. Howard encouraged participants to develop and concentrate on a message and bring all the elements of a presentation together to focus on that message, while Mike highlighted how bad PowerPoint etiquette can tank a presentation and distract from that message.

(I to r) Presenters and Education Program Committee Co-Chairs Michael Levesque and Howard Sneider with Meeting Manager Thomas Vaughan.

Following Mike and Howard, WPI Professor Sharon Wulf presented "Managing Multi-Generational Staff." Sharon discussed the four different generations in today's workforce: Generation Y, Generation X, the Baby Boomers and the Silent Generation, and the key generational differences and similarities. Participants learned how to use this knowledge to build effective teams and effectively mentor others by sharing life experiences, values, and perspectives.

Presenter and WPI Professor Sharon Wulf receives accolades from Past President Andre Walker.

The night concluded with a discussion of leadership skills lead by industry veteran Robert Wherry, who taught us that everything we need to know about leadership can be learned from The Beatles. Who would have thought The Beatles would ever be featured so prominently in an ISPE educational event?! Robert showed the attendees just how The Beatles provide an effective illustration of key leadership skills such as managing work (and stress!), teams and organizations, as well as how they relate to the biotech and pharmaceutical industries.

Pfizer Andover Hosts Plant Tour and Discussion of Industrial Wireless Networks

by Howard Sneider, CRB with photos by the author and Karima Erriahi, Thermo Fisher Scientific

The last educational program of 2015, "An Industrial Wireless Network: What It Is and How It's Done," took place on Thursday, December 10, at Pfizer's Andover manufacturing facility. The 60 attendees joined an opening reception in the atrium outside of F1300 where they enjoyed conversation and appetizers. While the reception was going on, representatives from Pfizer guided attendees through suites A and B to

observe some of the equipment used in processing Prevnar13. This included fermenters, a centrifuge, filtration equipment and UF/DF equipment. The tour guide explained how the automation system controls and records asset, batch and material tracking. The tour also passed through the first floor of suites C and D where an array of process support equipment, including the base of the NPCW and WFI tanks, as well as the WFI pumps, was visible. The guide then demonstrated how whiteboards located in the corridor outside of central parts storage are used to communicate production status, safety metrics, quality review and other operational metrics to the facility staff in huddles at the start of each shift.

Attendees enjoyed the networking reception while waiting their turn to tour Pfizer's Andover manufacturing facility.

Following the reception and tour, Kristen Scharf of New England Controls opened the program by discussing the different types of wireless networks likely to be used in manufacturing environments and the difference between these networks and the networks used in consumer electronics. She emphasized that the goal of industrial wireless networks is to facilitate improving processes and assets. To that end, wireless is being used everywhere to make big improvements. The application examples she described ranged from installing automation to getting people out of hazardous areas, to monitoring assets to prevent downtime, to improving efficiency of processes and environmental and safety monitoring.

Presentations by Kristen Scharf and Erik Westberg combined for a timely and comprehensive overview of wireless networks used in manufacturing.

Kristen next described some of the particular aspects and challenges of field networks including the use of wireless networks for backhaul, RFID tracking, mobile workstation environments, and security cameras. She also discussed how wireless field networks provide pervasive wireless and analytics. As data volume and complexity increase over time, and trends indicate they will, the access wireless devices provide will become more important. Two examples that Kristen focused on were vibration monitoring and steam trap ultrasonic measurement.

Kristen concluded her presentation with a discussion of the Industrial Internet of Things (IIoT). This emerging technology allows pervasive data sensing to be analyzed in real time and provides real-time control recommendations. Wireless systems have enabled IIoT by lowering the cost of installing the sensors required for this technology.

Next up was Erik Westberg of Pfizer whose presentation described the design, implementation, and validation of the wireless Ethernet network used in Pfizer's Andover manufacturing suites. He began with an overview of the control system network layers, components and functionality, then explained that the decision to explore wireless was based on production requirements and challenges with the in-place wired connections. One benefit to implementing the selected system was that the validated programming could be reused with the new hardware. After implementing the change, risk assessments on security, throughput, and robustness were conducted. Once Pfizer had determined that the wireless system

performed as well as the wired predecessor, there were additional challenges that needed to be met. These included wireless signal overlap, malfunctions caused by duplicate addressing, and loss of data caused by dropped connections.

A question-and-answer session followed each presentation. The audience had many excellent questions for each presenter, attesting to the high level of interest in the subject matter. The Chapter would like to thank each of our speakers for their wonderful presentations, the staff at Pfizer who coordinated the event and tour, event sponsor Acentech, and everyone who helped make this event a great success!

"Orangutan Skies" at Aeronaut Brewing in Somerville

by Brian Kennedy, Genzyme, with photos by Christopher Ciampa, Thermo Fisher Scientific

On December 3rd, the Boston Area Chapter Young Professionals hosted a social event at Aeronaut Brewing in Somerville. This is the second time the Chapter has hosted a networking event at a Boston-area microbrewery after a very successful event at Night Shift Brewery last year in Everett. This year followed suit with nearly 30 people, representing some 22 companies and universities, turning out for an engaging evening of barbeque-style food, networking, and craft beer.

Chapter YPs hosted a networking social, brewery tour and craft beer tasting at Aeronaut Brewing in Somerville. Orangutan Skies, anyone?

Aeronaut Brewing was started in 2013 by a group of MIT graduates who began brewing craft beers in a Somerville backyard. In the summer of 2014 they opened their current location on Tyler Street, creating Somerville's first craft brewery in more than a century. Co-owner Ben Holmes provided ISPE Members with tours of the in-house laboratory as well as the large-scale brewing area as he guided us through the process of making beer. He provided a great overview of the purpose of each of the vessels as well as the precautions and practices they adopted to successfully manufacture in an aseptic manner. The similarities to the biotech industry were stark, both in the lab-scale culture of yeast lines and in the large-scale production of the beer.

Attendees got the chance to try several of the 8 tasty and uniquely-named craft beers that Aeronaut currently offers on tap, with the "Orangutan Skies" and "Saison of the Western Ghats" being two of the more popular selections. The fare for the evening included jerk chicken, Texas BBQ beef, and mac 'n' cheese from Redbones BBQ in Davis Square.

The event at Aeronaut was a big success, filled with opportunities to meet new people, build connections, and learn a bit about how craft beer is made. Given the popularity of this and the previous brewery event, we look forward to holding similar events at other Boston-area microbreweries in the future!

2016 Shaping Up as Another Great Year for the YPs

by Christopher Ciampa, Thermo Fisher Scientific

Hello everyone! Now that 2015 has come to a close, I wanted to provide a look at what we have to offer for 2016. 2015 was an amazing year for the Young Professionals and we look forward to serving the Chapter again this year! Our December social and tour at Aeronaut Brewery in Somerville was a big success as you can see from the accompanying article and we have a full schedule of equally great social and educational events for you to look forward to in the upcoming 12 months.

Currently we are in the process of planning the social and educational events for the winter and spring seasons. While we used to host the popular Medieval Manor Social in February each year, we just discovered Medieval Manor closed their doors on December 31, so we are looking at a roller skate themed event at Roller World in Saugus instead. The timing will be around the first week of February and the theme will be "90s Throwback Thursday." Since most millennials grew up in the 90s, the theme should be perfect!

In March, we will be hosting our first "roundtable" session. This will be good timing for an event geared toward graduating students who will soon be entering the industry. The topic is still to be determined but we will keep you posted. In April, we will host a dual-track educational program with the students at WPI. This time the topic will be "Science and Technology: What Will the Next Ten Years Bring?" In addition, the Chapter's Annual Student Poster Contest will be judged the same evening - with the posters on display during the networking reception - so plan to be there to show your support for the student participants!

April will bring a return to Sacco's Bowl Haven/The Flatbread Company in Davis Square for another bowling social. In June, we'll continue the momentum with our Annual Red Sox Social, and after a brief summer siesta, we'll be back in September with our annual harbor cruise. This year we're going to shake things up and do a joint event with the PDA - based on the success of the Chapter's joint educational program with the PDA in September, this should be another blockbuster. Given the success of the Kidney Walk this year, we are planning to participate again in 2016 and may branch out with other charitable events this year as well.

In terms of communication and social media, we now have grown our online presence significantly. There are now 3 ways to stay in touch with the YPs. The first is through email distribution (if you want to be added to the list, let me know). Second, we have both a LinkedIn and a Facebook YP page. Both the LinkedIn and Facebook groups are called ISPE Boston Area Chapter Young Professionals. In 2016 we will be using all of these means to communicate YP updates and push events.

As always, we want to hear from you! If you have any suggestions or would like to attend one of the regularly scheduled Young Professionals Committee (YPC) meetings, please don't hesitate to reach out to me (christopher.ciampa@gmail.com). Hope to see you at lots of our events this year!

Chapter Student Members Win International Poster Competition, Scholarships...

by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer, with photo by Brian Hagopian

The Boston Area Chapter is proud to congratulate D. Ezra Aurian-Blajeni and Sydney Shaw, winners of the Chapter's 2015 Student Poster Competition winners, both of whom competed in the international-level Poster Competition at the ISPE Annual Meeting in November. And extra-special congratulations to Sydney Shaw for winning the top award in the graduate category! This year's local Poster Competition is on April 20, giving you the chance to share your work, polish your presentation skills and compete for one of two $500 cash awards and more! Read Sydney's article below for an "up close and personal" look at her experience, then check out the program flyer for everything you need to know about entering the local competition: http://www.ispeboston.org/boston_area_student_chapters_postercontest.html.

International Poster Contest winner Sydney Shaw happily accepts her plaque and congratulations from Joe Famulare, Chair of the ISPE International Board of Directors.

The Chapter Scholarship Committee has been busy this semester, sifting through applications and awarding $13K in scholarships as part of the Chapter's commitment to giving back and "investing in the future" of our industry. This brings our 2015 scholarship award total to more than $25K. Congratulations to the following Student Members (listed alphabetically):

Oluwatosin Adedokun, New Jersey Institute of Technology
John de la Parra, Northeastern University
Victoria Drake, University of Connecticut
Margaret Grace, Temple University
James Hughes, Tufts University
Diego Leonardo, Middlesex Community College
Anton Malin, Brown University
Steven Rodriguez, University of Connecticut
Brody Stara, University of Massachusetts Amherst
Ryan Sullivan, University of Massachusetts Amherst
Peter Trearchis, Tufts University

We want to welcome to the ISPE community our two newest Student Chapters: the University of Connecticut and the Community College of Rhode Island. This brings the number of Student Chapters up to an even "baker's dozen." Students from each of these institutions were highly motivated to start Student Chapters, with efforts on both campuses dating back to last year. Look for them to be active in the coming year and please extend a warm welcome when you see them at ISPE events!

We're very excited to have just released a promotional video to highlight the benefits of belonging to ISPE. While it's geared toward students, it's a great commentary on the value that the ISPE network can deliver to all of our Members. Check it out at https://vimeo.com/148636910. We're sure you will be impressed!

The next big event for students is the Career Workshop on January 30 which is filled with practical "tricks of the trade" from industry experts designed to help students build resumes, make great first impressions, win interviews and land that dream job, internship or co-op position. The workshop's popularity has grown so much that we've had to expand to a bigger venue. Registration is open to ISPE Student Members and it's free to attend but we'd really appreciate it if everyone would register in advance so we can have enough food, drink, etc. for everyone. Here's the link: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=600. We're also planning a tour for students at Shire in March. Final details are being worked out now, so stay tuned.

Annual Meeting Poster Competition Provides Winning Experience

by Sydney Shaw, Genzyme, with photo by Katie Darby Photography

In April 2015, I was in the middle of wrapping up my master's degree in chemical engineering at Northeastern University and job searching at the same time. Although I made a rather late decision to participate in the Boston Area Chapter's Annual Poster Competition because of my impending thesis deadlines, the event was ultimately a great experience. It not only gave me a chance to practice presenting a part of my work to a non-academic audience but provided me with the opportunity to network with local ISPE Members in the process.

My poster was titled, "The effect of light, jasmonate, and tissue organization on the expression of the vindoline pathway genes in Catharanthus roseus." The work focused on comparing gene expression levels of certain genes in the alkaloid metabolic pathway of the flowering plant C. roseus (common name

Madagascar periwinkle). Catharanthus alkaloids are used in medicinal applications, including chemotherapy treatments but they are very expensive and difficult to produce synthetically or in a cell culture system. My goal was to better understand the plant system's native metabolic regulation with the ultimate aim of being able to genetically manipulate the metabolism to upregulate production of these unique compounds. It was particularly fun to present my work at the competition because the judges showed genuine interest in my research and their questions led to engaging discussion with a more practical focus than what I was used to when presenting to an academic group.

International Poster Competition Winner Sydney Shaw of Northeastern (center) with local winner D. Ezra Aurian-Blajeni of UMass Amherst (far right) surrounded by Boston Area Chapter well-wishers (l to r) Jack Campion, Andre Walker, Chris Opolski, H. Steven Kennedy and Brian Hagopian.

In the seven months between winning the local poster competition and traveling to Philadelphia for the ISPE Annual Meeting, I had graduated from Northeastern and started a full-time position at Genzyme - giving me even more of a reason to take full advantage of the opportunity to attend. As a newcomer to the industry, it was almost overwhelming to walk through the exhibitor hall and talk to some of the vendors who supply or support every need imaginable in the manufacturing process. The educational sessions I attended also allowed me to see more of the industry than I experience in my day-to-day process engineer job - including discussions on quality control and applications of single-use bioprocess technologies.

For me, the biggest challenge of the poster competition process was planning how to emphasize the importance of the work, show my technical knowledge and cover the critical findings, all within the 5-minute time limit. At ISPE's Annual Meeting, I was happy with how my talk went but knew I had some stiff competition after spending time getting to know the other student participants. At the awards breakfast the next morning, I was genuinely surprised to be named the winner - but was also very excited to know that all my preparation had paid off.

If you are a student interested in getting more involved in ISPE, or if you want an interesting opportunity to present your research outside of the typical university setting, I would highly recommend participating in the Boston Area Chapter's Annual Poster Competition this spring. Judging will be taking place at WPI on April 20 so it's not too early to start thinking about your poster. It was a great experience for me and the Chapter is always eager to get more students actively involved.

Remember: winners in each category, undergrad and graduate, receive $500 and a trip to the ISPE Annual Meeting to participate in the international level competition. Since I'll be one of the judges this year, I'll plan to see you at WPI in April!

Industry News In Brief

by Jillian Willard, Genzyme, a Sanofi Company

Industry News In Brief, a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to our readers. Please submit news items for consideration to office@ispeboston.org.

Vertex and CRISPR Therapeutics to Collaborate on Genetic Diseases

Vertex Pharmaceuticals and CRISPR Therapeutics announced that the two companies have entered into a research collaboration focused on the use of CRISPR's gene editing technology, known as CRISPR-Cas9, to discover and develop potential new treatments aimed at the underlying genetic causes of human disease. The CRISPR-Cas9 technology may be able to correct defects in specific gene targets known to cause or contribute to diseases. The collaboration will evaluate the use of CRISPR-Cas9 across multiple diseases where targets have been validated through human genetics.

The initial focus of the collaboration will be on the use of CRISPR-Cas9 to potentially correct the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene known to result in the defective protein that causes CF and to edit other genes that contribute to the disease. Additionally, the companies will seek to discover and develop gene-based treatments for hemoglobinopathies, including sickle cell disease. Vertex and CRISPR will also evaluate other genetic targets as part of the collaboration.

Discovery activities will be conducted primarily by CRISPR, and the related expenses will be fully funded by Vertex. Vertex will have exclusive rights to license up to 6 new CRISPR-Cas9-based treatments that emerge from the collaboration. As part of the collaboration, Vertex made an up-front commitment of $105 million to CRISPR, including $75 million in cash and a $30 million investment in CRISPR, which is a private company. Vertex will fund 100 percent of the development expenses of licensed treatments. For each of the up to six treatments in-licensed for development, Vertex will pay future development, regulatory and sales milestones of up to $420 million as well as royalty payments on future sales.

Vertex and CRISPR will collaborate on the research, development and commercialization of treatments for hemoglobinopathies that emerge from the collaboration. Specifically for hemoglobinopathies, including treatments for sickle cell disease, Vertex and CRISPR will equally share all research and development costs and sales, with CRISPR Therapeutics leading commercialization efforts in the U.S. For all other diseases, Vertex will lead all development and global commercialization activities. (Source: Vertex Website, 26 October, 2015)

Biogen Will Cut Jobs, Restructure

Biogen recently announced a corporate restructuring, which includes the termination of a number of pipeline programs and an 11 percent reduction in workforce. These changes are expected to reduce the current annual run rate of operating expenses by approximately $250 million. The Company plans to reinvest these savings to support key commercial initiatives, including increased sales and marketing activities behind Tecfiders, and the advancement of high potential pipeline candidates in areas such as Alzheimer's disease, multiple sclerosis, and spinal muscular atrophy.

The company plans to complete the majority of the 11 percent reduction of its global workforce by the end of 2015. The company is in the process of notifying employees affected by the restructuring, and has initiated the required consultation processes in European countries where employees may be impacted. Biogen has also discontinued several programs, including its Phase 3 program for Tecfidera in secondary progressive MS, the development of anti-TWEAK in lupus nephritis, and certain activities in immunology and fibrosis research. (Source: Biogen Website, 21 October, 2015)

FDA Approves Two Alexion Products, Issues Company Two Valuable Priority Review Vouchers

In October, Alexion Pharmaceuticals announced that the FDA has approved Strensiq™ (asfotase alfa) for the treatment of patients with perinatal-, infantile- and juvenile-onset hypophosphatasia (HPP). Strensiq, is an enzyme replacement therapy (ERT), and is the first therapy approved in the U.S. for the treatment of patients with HPP, a genetic, chronic, and progressive ultra-rare metabolic disease in which patients experience devastating effects on multiple systems of the body, leading to debilitating or life-threatening complications.

In December, the FDA approved Alexion's Kanuma™ (sebelipase alfa) for the treatment of patients of all ages with a diagnosis of lysosomal acid lipase deficiency (LAL-D). Kanuma, is another enzyme replacement therapy (ERT), and is the first therapy approved in the U.S. for the treatment of patients with LAL-D, a genetic and progressive ultra-rare metabolic disease in which patients suffer multi-organ damage and premature death.

Both Alexion products treat ultra-rare diseases, which is defined as a disease that affects fewer than 20 patients per one million in the general population. The FDA approved both Strensiq and Kanuma under Priority Review and had granted Breakthrough Therapy designation for both as well. The FDA also issued a Rare Pediatric Disease Priority Review Voucher for each of the approvals, which confers priority review to two subsequent drug applications that would not otherwise qualify for priority review. The rare pediatric disease review voucher program is designed to encourage development of new drugs and biologics for the prevention or treatment of rare pediatric diseases. Strensiq and Kanuma are also approved in the European Union. (Source: Alexion Website, 23 October and 08 December, 2015)

Merrimack Pharmaceuticals Wins FDA Approval for Onivyde for Pancreatic Cancer

Cambridge-based Merrimack Pharmaceuticals has won FDA has approval for Onivyde (irinotecan liposome injection), in combination with fluorouracil and leucovorin, to treat patients with advanced (metastatic) pancreatic cancer who have been previously treated with gemcitabine-based chemotherapy. The FDA granted Priority Review and orphan drug designations for Onivyde.

Patients receiving Onivyde plus fluorouracil/leucovorin had a delay in the amount of time to tumor growth compared to those who received fluorouracil/leucovorin. The average time for those receiving Onivyde plus fluorouracil/leucovorin was 3.1 months compared to 1.5 months for those receiving fluorouracil/leucovorin.

The labeling for Onivyde includes a boxed warning to alert health care professionals about the risks of severe neutropenia and diarrhea. Onivyde is not approved for use as a single agent for the treatment of patients with metastatic pancreatic cancer. (Source: FDA Website, 22 October, 2015)

Shire to Acquire Burlington-based Dyax Corp

Shire has announced that it will acquire Dyax, a publicly traded, Burlington, Massachusetts-based biotech company primarily focused on the development of plasma kallikrein (pKal) inhibitors for the treatment of HAE, a debilitating and sometimes life-threatening rare genetic disease. Dyax has already successfully developed and commercialized Kalbitor, which is approved for HAE acute treatment in patients 12 years of age and older, and represented an early innovation in HAE treatment.

Dyax's most advanced clinical program is DX-2930, a Phase 3-ready, fully humanized monoclonal antibody targeting pKal with proof-of-concept Phase 1B efficacy data. DX-2930 has received Fast Track, Breakthrough Therapy, and Orphan Drug designations by the FDA and has also received Orphan Drug status in the EU. It is expected to enter Phase 3 clinical trials by year-end 2015. If approved for the

prevention of Type 1 and Type 2 HAE, DX-2930 could generate estimated annual global sales of up to $2.0 billion.

Shire will acquire Dyax for $37.30 in cash per Dyax share, for aggregate upfront consideration of approximately $5.9 billion. Dyax shareholders may receive additional value through a non-tradable contingent value right (CVR) that will pay $4.00 in cash per Dyax share upon approval of DX-2930 in HAE, representing a potential additional $646 million in aggregate contingent consideration. The transaction has been unanimously approved by the Boards of Directors of both Shire and Dyax and is expected to close in the first half of 2016. The transaction is subject to approval by Dyax shareholders and customary closing conditions and regulatory approvals. (Source: Shire Website, 02 November, 2015)

Spark Therapeutics Opens New Office in Waltham

Spark Therapeutics announced that it has expanded into Waltham, MA, where the company has opened a new satellite office. The new office will support the growth of several departments, including the commercial, medical, patient advocacy and business development groups. There are currently job openings in Spark's quality assurance, regulatory affairs, technical operations and commercial groups.

Spark is a company focusing in gene therapies. The company's most advanced product candidate, SPK-RPE65, has received both breakthrough therapy and orphan product designation, and also recently reported positive top-line results from a pivotal Phase 3 clinical trial for the treatment of rare blinding conditions. Spark's validated gene therapy platform is being applied to a range of clinical and preclinical programs addressing serious genetic diseases, including inherited retinal dystrophies, hematologic disorders and neurodegenerative diseases. (Source: Spark Therapeutics Website, 04 November, 2015)

Voyager Therapeutics Closes $80 Million IPO

Voyager Therapeutics, a clinical-stage gene therapy company developing life-changing treatments for severe diseases of the central nervous system (CNS), announced the closing of its initial public offering of 5,750,000 shares of its common stock at a public offering price of $14.00 per share, including 750,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares. All of the shares were offered by Voyager Therapeutics. The gross proceeds from the initial public offering were $80,500,000, before underwriting discounts and commissions and estimated offering expenses. (Source: Voyager Therapeutics Website, 16 November, 2015)

Pfizer and Allergan to Combine in $160 Billion Merger

Pfizer and Allergan announced that their boards of directors have unanimously approved, and the companies have entered into, a definitive merger agreement under which Pfizer will combine with Allergan in a stock transaction currently valued at $363.63 per Allergan share, for a total enterprise value of approximately $160 billion, based on the closing price of Pfizer common stock of $32.18 on November 20, 2015. The transaction represents more than a 30 percent premium based on Pfizer's and Allergan's unaffected share prices as of October 28, 2015. Allergan shareholders will receive 11.3 shares of the combined company for each of their Allergan shares, and Pfizer stockholders will receive one share of the combined company for each of their Pfizer shares. The completion of the transaction is expected in the second half of 2016.

Under the terms of the proposed transaction, the businesses of Pfizer and Allergan will be combined under Allergan plc, which will be renamed "Pfizer plc." The companies expect that shares of the combined company will be listed on the New York Stock Exchange and trade under the "PFE" ticker. Upon the closing of the transaction, the combined company is expected to maintain Allergan's Irish legal domicile. Pfizer plc will have its global operational headquarters in New York and its principal executive offices in Ireland.

Pfizer's current businesses will be supplemented with the revenue stream from Allergan's flagship brands in areas such as Aesthetics and Dermatology, Eye Care, Gastrointestinal, Neuroscience and Urology. The combined company is expected to generate annual operating cash flow in excess of $25 billion beginning in 2018. The new company will also have a combined pipeline of more than 100 mid-to-late stage programs in development. As a result of the combination with Allergan and subsequent integration of the two companies, Pfizer now expects to make a decision about a potential separation of the combined company's innovative and established businesses by no later than the end of 2018. (Source: Pfizer Website, 23 November, 2015)

AstraZeneca and Sanofi Exchange Over 200,000 Chemical Compounds

AstraZeneca and Sanofi have announced a direct exchange of 210,000 compounds from their respective proprietary compound libraries, enhancing the diversity of the compound collections of both companies and allowing each to screen a broader, more diverse chemical space as the starting point in the search for new small-molecule medicines.

AstraZeneca and Sanofi have each selected the compounds to exchange based on differences from those in their own libraries. Chemical structures and synthetic procedures will be shared to facilitate the use of these compounds. The compounds will be exchanged in sufficient quantity to enable the receiving company to carry out high throughput screening for several years to determine whether they are active against specific biological targets. If a compound matches a target, it will go through several modifications to optimize its structure before being classified as a ‘lead compound' to be taken forward to development.

There are no payments associated with the compound exchange. Each company can investigate the compounds it receives without restrictions on disease areas. (Source: AstraZeneca Website, 20 November, 2015)

Bristol-Myers Squibb to Acquire Cardioxyl Pharmaceuticals

Bristol-Myers Squibb (BMS) and Cardioxyl Pharmaceuticals have announced that BMS will acquire all of the issued and outstanding capital stock of Cardioxyl, a private biotechnology company focused on the discovery and development of therapeutic agents for the treatment of cardiovascular disease. The acquisition will give BMS full rights to Cardioxyl's lead asset CXL-1427, a nitroxyl (HNO) donor (prodrug) in Phase 2 clinical development as an intravenous treatment for acute decompensated heart failure (ADHF).

The transaction includes upfront and near-term milestone payments of up to $300 million and potential additional consideration of up to $1.775 billion upon the achievement of certain development, regulatory and sales milestones. The transaction, which is expected to be dilutive to 2015 GAAP EPS by approximately $0.12, with minimal dilution to non-GAAP EPS in both 2015 and 2016, has been approved by the boards of directors of both companies.

CXL-1427 releases nitroxyl, a molecule that has demonstrated beneficial effects on heart muscle and vascular function. Pre-clinical and early clinical data indicate that CXL-1427 improves how the heart muscle contracts and relaxes without increasing heart rate or the demand for oxygen. Current therapies for ADHF that improve heart muscle function produce an increase in heart rate and/or oxygen consumption, and are associated with an increased risk for ischemia, arrhythmias and increased mortality.

Cardioxyl Pharmaceuticals is focused on the discovery and development of new classes of therapeutic agents for the treatment of cardiovascular disease. Cardioxyl has developed expertise in the chemistry, biology and clinical applications of nitroxyl (HNO) technology. The company's core HNO platform has generated several pre-clinical and clinical candidates. Cardioxyl is a privately held company. Bristol-Myers Squibb and Cardioxyl anticipate the transaction will close during the fourth quarter of 2015. (Source: Bristol-Myers Squibb Website, 02 November, 2015)

BMS and AbbVie Receive FDA Approval of Empliciti for Multiple Myeloma

Bristol-Myers Squibb Company (BMS) and AbbVie have announced that the FDA has approved Empliciti (elotuzumab) for the treatment of multiple myeloma as combination therapy with Revlimid (lenalidomide) and dexamethasone (ERd) in patients who have received one to three prior therapies. The approval of this first and only immunostimulatory antibody for multiple myeloma is based on data from a Phase 3 clinical study which demonstrated that the ERd regimen resulted in a 30 percent reduction in the risk of disease progression or death compared to Rd alone.

Bristol-Myers Squibb and AbbVie are co-developing Empliciti, with BMS solely responsible for commercial activities. Prior to approval, Empliciti was granted Breakthrough Therapy Designation by the FDA for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one to three prior therapies.

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. Empliciti is also under review by the European Medicines Agency and has been granted accelerated assessment. (Source: Bristol-Myers Squibb Website, 30 November, 2015)

FDA Approves Newton-based Alcresta Pharmaceuticals' Relizorb

Alcresta Pharmaceuticals, a specialty pharmaceutical company focused on developing enzyme-based products for gastrointestinal and rare disease, has announced it received approval from the FDA to market Relizorb^{TM} (immobilized lipase). Relizorb is a digestive enzyme cartridge designed to mimic the normal pancreatic function by breaking down fats in enteral tube feeding formula. By breaking down these fats from enteral tube feeding formulas prior to ingestion, Relizorb allows for the delivery of increased absorbable calories from fatty acids and monoglycerides to adults who are partially or completely unable to breakdown and absorb fats.

Many patients face the challenge of attaining proper nutrition, which is required as a critical part of maintaining overall health and disease recovery. According to the Cystic Fibrosis Foundation's patient data report, a relationship has been established in cystic fibrosis (CF) between good health outcomes and patients' nutritional levels, reinforcing the need for individuals to maintain adequate weight gain. Specifically, low levels of certain fatty acids contribute inflammatory characteristics of CF, and negatively affect a person's ability to maintain or gain weight and absorb critical fatty acids and other nutrients.

It is estimated that more than 344,000 people of all ages in the U.S. are receiving enteral nutrition at home. There are an additional 613,000 patients in intensive care units that use enteral feeding. Based on market survey data, 10-20 percent of people with CF and 20-40 percent of people with pancreatic and stomach cancer use enteral tube feeding on a daily basis. (Source: Alcresta Pharmaceuticals Website, 15 December, 2015)

Cambridge-based Idera Pharmaceuticals to Collaborate with GSK on Renal Disease

Idera Pharmaceuticals, a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with cancer and rare diseases, announced it has entered into an exclusive worldwide collaboration and license agreement with Glaxo Smith Kline (GSK) to research, develop and commercialize selected molecules from Idera's third-generation antisense platform for the treatment of selected targets in renal disease.

Under the terms of the agreement, Idera is eligible to receive approximately $100 million in development and regulatory milestone payments, including a $2.5 million upfront payment. Additionally, Idera is eligible to receive royalties on all sales upon commercialization at varying rates up to five percent on annual net sales in excess of $500 million. (Source: Idera Pharmaceuticals Website, 23 November, 2015)

Marlboro-based Ocata Therapeutics to be Acquired Astellas Pharma

Astellas Pharma of Tokyo, Japan and Ocata Therapeutics of Marlboro, MA have entered into a definitive agreement under which Astellas will acquire Ocata. The boards of directors of both Astellas and Ocata have unanimously approved the agreement.

Ocata Therapeutics is a biotechnology company focused on the research and development of new therapies in the field of regenerative medicine, primarily cell therapy addressing unmet medical needs in ophthalmology patients. Ocata's most advanced products are in clinical trials for the treatment of Stargardt's macular degeneration, dry age-related macular degeneration, and myopic macular degeneration. Ocata's intellectual property portfolio includes pluripotent stem cell platforms - hESC and induced pluripotent stem cell (iPSC) - and other cell therapy research programs.

The acquisition of Ocata represents the coming together of two companies with significant

accomplishments and a shared commitment to develop innovative therapies that address the unmet medical needs of patients suffering from severe ophthalmic diseases. Further, acquiring Ocata will enable Astellas to establish a presence in ophthalmology and a leading position in cell therapy. (Source: Astellas Pharma Website, 09 November, 2015)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights, a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech and device industries, and related fields.

FDA Approves New Therapy for Certain Types of Advanced Soft Tissue Sarcoma

The FDA has approved chemotherapy drug Yondelis (trabectedin) for the treatment of specific soft tissue sarcomas (STS) - liposarcoma and leiomyosarcoma - that cannot be removed by surgery (unresectable) or is advanced (metastatic). This treatment is approved for patients who previously received chemotherapy that contained anthracycline.

Yondelis carries a warning alerting health care providers of the risk of severe and fatal blood infections (neutropenic sepsis), muscle tissue breakdown (rhabdomyolysis), liver damage (hepatotoxicity), leakage around the vein or catheter (extravasation), tissue necrosis (breakdown) and heart failure (cardiomyopathy). Patients with known hypersensitivity to trabectedin, a drug used to treat cancer, should not take Yondelis. Further, health care providers are encouraged to advise women of potential risks to a developing fetus when taking Yondelis. Women who are taking Yondelis should not breastfeed. Yondelis is marketed by Janssen Products of Raritan, New Jersey. (Source: FDA Website, 23 October, 2015)

FDA Approves First Oncolytic Viral Therapy in the US

Amgen has announced that the FDA has approved the Biologics License Application for Imlygic™ (talimogene laherparepvec), a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. Imlygic has not been shown to improve overall survival or have an effect on visceral metastases. Imlygic is the first oncolytic viral therapy approved by the FDA based on therapeutic benefit demonstrated in a pivotal study. Amgen anticipates the average cost of Imlygic therapy to be approximately $65,000.

Imlygic is a genetically modified herpes simplex virus type 1 designed to replicate within tumors and produce an immunostimulatory protein called granulocyte-macrophage colony-stimulating factor (GM-CSF). Imlygic causes cell lysis, or death, which ruptures tumors, releasing tumor-derived antigens, which along with GM-CSF, may promote an anti-tumor immune response. However, the exact mechanism of action is unknown.

Amgen is currently studying Imlygic in combination with other immunotherapies in advanced melanoma and other solid tumors. Metastatic melanoma continues to be one of the most difficult-to-treat cancers because it is often insensitive to chemotherapy, can be highly aggressive and can require several different types of treatment depending on the stage and location of the disease and health of the patient. (Source: Amgen Website, 27 October, 2015)

BMS Melanoma Drug Yervoy Approved for Expanded Use

The FDA has expanded the approved use of Yervoy (ipilimumab) to include a new use as adjuvant therapy for patients with stage III melanoma, to lower the risk that the melanoma will return following surgery. Melanoma, the most aggressive type of skin cancer, is the leading cause of death from skin cancer. It is more likely to spread to other parts of the body than other forms of skin cancer and has been on the rise over the past several decades according to the National Cancer Institute, with an estimated 73,870 new cases and 9,940 deaths from the disease this year. In stage III melanoma, the cancer has reached one or more lymph nodes. Patients with stage III melanoma are generally treated by surgery to remove the melanoma skin lesions and the nearby lymph nodes.

Yervoy, administered intravenously, was originally approved in 2011 to treat late-stage melanoma that cannot be removed by surgery. Due to the potential for fatal immune-mediated adverse reactions and unusual severe side effects with Yervoy, the label includes a Boxed Warning. A Medication Guide will also be provided to patients to inform them about the therapy's potential side effects. Yervoy is manufactured by Bristol-Myers Squibb in Princeton, New Jersey. (Source: FDA Website, 28 October, 2015)

Genentech Receives FDA Approval for Cotellic for Advanced Melanoma

The FDA has approved Cotellic (cobimetinib) to be used in combination with vemurafenib to treat advanced melanoma that has spread to other parts of the body or cannot be removed by surgery, and that has a certain type of abnormal gene (BRAF V600E or V600K mutation).

Cotellic was reviewed under the FDA's priority review program that provides for an expedited six-month review of drugs that, at the time the application was submitted, have the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. Cotellic also received orphan drug designation, which provides incentives such as tax credits, user fee waivers and eligibility for orphan drug exclusivity to assist and encourage the development of drugs for rare diseases. Cotellic and Zelboraf are both marketed by Genentech of San Francisco, California. (Source: FDA Website, 10 November, 2015)

FDA Approves AstraZeneca's Tagrisso for Non-Small Cell Lung Cancer

The FDA has granted accelerated approval for an oral medication to treat patients with advanced non-small cell lung cancer (NSCLC). Tagrisso (osimertinib) is now approved for patients whose tumors have a specific epidermal growth factor receptor (EGFR) mutation (T790M) and whose disease has gotten worse after treatment with other EGFR-blocking therapy.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new diagnoses and 158,040 deaths in 2015, according to the National Cancer Institute. The most common type of lung cancer, NSCLC occurs when cancer cells form in the tissues of the lung. EGFR is a protein involved in the growth and spread of cancer cells.

The FDA also approved the first companion diagnostic test (cobas EGFR Mutation Test v2) to detect the type of EGFR resistance mutation that Tagrisso is known to target. The newly approved version (v2) of the test adds the T790M mutation to the clinically relevant mutations detected by the original cobas EGFR Mutation Test (v1).

Tagrisso was approved under the agency's accelerated approval program, which allows the approval of a drug to treat a serious or life-threatening disease based on clinical data showing the drug has an effect on a surrogate endpoint reasonably likely to predict clinical benefit to patients.

Tagrisso is marketed by AstraZeneca Pharmaceuticals based in Wilmington, Delaware. The cobas EGFR Mutation Test v2 is marketed by Roche Molecular Systems of Pleasanton, California. (Source: FDA Website, 13 November, 2015)

Baxalta Wins FDA Approval for Adynovate for Hemophilia A

The FDA has approved Adynovate, Antihemophilic Factor (Recombinant), PEGylated for use in adults and adolescents, aged 12 years and older, who have Hemophilia A. Adynovate is modified to last longer in the blood and potentially require less frequent injections than unmodified Antihemophilic Factor when used to reduce the frequency of bleeding.

Adynovate is approved for on-demand (as needed) treatment and control of bleeding episodes and to reduce the frequency of bleeding episodes (prophylaxis) in patients with Hemophilia A. Adynovate consists of the full-length Coagulation Factor VIII molecule (historically known as Antihemophilic Factor) linked to other molecules, known as polyethylene glycol (PEGylated). This link makes the product last longer in the patient's blood.

Hemophilia A is an inherited, sex-linked, blood-clotting disorder that primarily affects males, which is caused by defects found in the Factor VIII gene. According to the Centers for Disease Control and Prevention, Hemophilia A affects one in every 5,000 male births in the United States. Patients with hemophilia A may experience repeated episodes of serious bleeding, primarily into the joints, which can be severely damaged as a result. Adynovate is manufactured by Baxalta US, based in Westlake Village, California. (Source: FDA Website, 13 November, 2015)

FDA Approves First Monoclonal Antibody for Treating Multiple Myeloma

The FDA has granted accelerated approval for Darzalex (daratumumab) to treat patients with multiple myeloma who have received at least three prior treatments. Darzalex is the first monoclonal antibody approved for treating multiple myeloma. It is marketed by Janssen Biotech of Horsham, Pennsylvania.

Multiple myeloma is a form of blood cancer that occurs in infection-fighting plasma cells (a type of white blood cell) found in the bone marrow. These cancerous cells multiply, produce an abnormal protein and push out other healthy blood cells from the bone marrow. The disease may result in a weakened immune system and cause other bone or kidney problems. Darzalex injection, given as an infusion, is a monoclonal antibody that works by helping certain cells in the immune system attack cancer cells.

Darzalex was approved under the agency's accelerated approval program, which allows the approval of a drug to treat a serious or life-threatening disease based on clinical data showing the drug has an effect on a surrogate endpoint reasonably likely to predict clinical benefit to patients. (Source: FDA Website, 16 November, 2015)

FDA Approves Bristol-Myers Squibb's Opdivo for Advanced Renal Cell Carcinoma

The FDA has approved Opdivo (nivolumab) to treat patients with advanced (metastatic) renal cell carcinoma, a form of kidney cancer, who have received a certain type of prior therapy. Renal cell carcinoma is the most common form of kidney cancer in adults and forms in the tissues of the kidney that make urine. The National Cancer Institute estimates 61,560 new cases and 14,080 deaths from kidney and renal pelvis cancer in the United States this year.

Opdivo works by targeting the cellular pathway known as PD-1/PD-L1 (proteins found on the body's immune cells and some cancer cells). By blocking this pathway, Opdivo may help the body's immune system fight cancer cells. Opdivo is intended for use in renal cell carcinoma in patients who have received prior anti-angiogenic therapy (treatments that interfere with the blood vessels that contribute to the growth of cancerous cells).

"Opdivo provides an important therapy option for patients with renal cell carcinoma," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "It is one of few therapies that have demonstrated the ability to extend patients' survival in treating this disease."

"Additionally, Opdivo's extended indication, from melanoma and non-small cell lung cancer to renal cell cancer, demonstrates how immune therapies can benefit patients across a wide range of tumors," continued Dr. Pazdur.

Opdivo has the potential to cause serious side effects that result from the immune system effect of Opdivo (known as "immune-mediated side effects"). These severe immune-mediated side effects involve healthy organs, including the lung, colon, liver, kidneys, hormone-producing glands and the brain.

The FDA granted the Opdivo application a breakthrough therapy designation, fast track designation, and priority review status. These are distinct programs intended to facilitate and expedite the development and review of certain new drugs in light of their potential to benefit patients with serious or life-threatening conditions. Opdivo is marketed by Bristol-Myers Squibb based in Princeton, New Jersey. (Source: FDA Website, 23 November, 2015)

FDA Approves Portrazza to Treat Advanced Squamous Non-Small Cell Lung Cancer

The FDA has approved Eli Lilly's monoclonal antibody drug Portrazza (necitumumab) in combination with

two forms of chemotherapy to treat patients with advanced (metastatic) squamous non-small cell lung cancer (NSCLC) who have not previously received medication specifically for treating their advanced lung cancer.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new diagnoses and 158,040 deaths in 2015. The most common type of lung cancer, non-small cell lung cancer, is further divided into two main types named for the kinds of cells found in the cancer - squamous cell and non-squamous cell (which includes adenocarcinoma). Portrazza is a monoclonal antibody that blocks activity of EGFR, a protein commonly found on squamous NSCLC tumors. (Source: FDA Website, 24 November, 2015)

TRIA Places Second in Toy Drive

TRIA, a new science and technology-focused architecture firm located in Boston's Seaport district, participated in the 7th Annual Toy Drive & Holiday Party hosted by Allsteel and Union Office Interiors. The toy drive focuses on spreading holiday cheer to all children in the community. Several local A/E/C industry companies participate in the event each year. The companies receive an oversized box to decorate and fill with toys, which are then showcased at the holiday party.

The TRIA team took inspiration from their science-based background and constructed a fume hood from Santa's Lab. The fume hood was complete with beakers, petri dishes, and even billowing "smoke fumes" coming out of the exhaust vents. With help from DPS, they were able to provide an overflowing box of toys for a great cause. TRIA placed second in the most creative box decoration competition.

New Members

Christopher J. Anderson, Community College of Rhode Island

Natassia Aravind, Deloitte & Touche LLP

Nathaniel G. Benjamin, Massachusetts Maritime Academy

Dr. Rajesh Beri, Lonza Biologics Inc

Joseph Bertucci, Massachusetts Maritime Academy

Samuel Bessey, DPS Engineering

Liladhar (Dhar) Bharatula, BS, MSIE, MBA, Citra Labs, A Zimmer Biomet Biologics Company

John A. Bishara, Massachusetts Maritime Academy

Elizabeth Bramhall, Massachusetts Maritime Academy

Evan Braun, Massachusetts Maritime Academy

Christina Brennan, Massachusetts Maritime Academy

Janelle R. Carretero, New England Controls Inc.

James M. Casey, LotusWorks

Humberto Castillo, EMD Millipore

Tyler N. Chaisson, Massachusetts Maritime Academy

Anthony Christensen, Massachusetts Maritime Academy

Eliana Clark, PhD, Biogen

Karen Clifford, DPS Engineering

Anthony P. Coletti, Massachusetts Maritime Academy

Lisa Conti, Integrated Commissioning and Quality Corporation

Connor M. Corsi, Massachusetts Maritime Academy

John Courtney, Aircuity, Inc.

Dr. Csilla Csank, Takeda Oncology

Talia June D'Ambrvoso, University of Massachusetts Dartmouth

Kimberly Dinsmore, Softworld, Inc

Matthew Donovan, Massachusetts Maritime Academy

Robert Dries, Massachusetts Maritime Academy

Joey Fababeir, DPS Engineering

Filip Filipov, DPS Engineering

Dan E. Foley, DPS Engineering

William Frederick, Alexion Pharmaceuticals

Leah M. Gionet, Massachusetts Maritime Academy

Brian Haseman, Massachusetts Maritime Academy

Samuel W. Hastings, Massachusetts Maritime Academy

Matthew S. Hayden, Massachusetts Maritime Academy

Jamie E. Hayes, Massachusetts Maritime Academy

Kwame Heyward

Jason Hickey, Bothwell Engineering Inc.

Brandon Hitchings, Massachusetts Maritime Academy

Kevin L. Huska, Massachusetts Maritime Academy

Janessa Jahara, University of Massachusetts Dartmouth

Benjamin J. Joyal, Massachusetts Maritime Academy

Kevin Keating, M.Eng., Minerva Biotechnologies

Brendan T. Kelley, Massachusetts Maritime Academy

Ashkang Kima-Tabong, University of Massachusetts Dartmouth

Christina Lam, University of Massachusetts Dartmouth

Brendan Leary, Massachusetts Maritime Academy

Renee LeClaire, Worcester Polytechnic Institute

Kayla Loycano, University of Massachusetts Dartmouth

Evdokia Mandalou

Joseph Marella, Massachusetts Maritime Academy

Martin C. Markarian, Sunovion Pharmaceuticals Inc

Kyle A. Marobella, Massachusetts Maritime Academy

Thomas J. McEntee, Massachusetts Maritime Academy

Brendan McLaughlin, Emerson Process Management

Chris Mechler, Gerflor USA

Amit Y. Mehta

Kathryn A. Merritt, Worcester Polytechnic Institute

Nicole Moquin, Massachusetts Maritime Academy

Kate Murray, DPS Engineering

Shalini Pallwal, University of Massachusetts Dartmouth

Charles Chase Parker, Rockwell Automation

Carlos Pascoal, BS Ch.E, SPEC Process Engineering and Construction

Luke F. Pascucci, Massachusetts Maritime Academy

Amy Patel, University of Massachusetts Dartmouth

Sherman Peoples, DPS Engineering

Nicholas R. Petrosino, Massachusetts Maritime Academy

Thomas Picotta, Massachusetts Maritime Academy

Amir Raissipour, Massachusetts Maritime Academy

Sarah Ricci, BSChE, Alexion Pharmaceuticals

Catie Riordan, Enterprise Ireland

Matthew M. Rota, Massachusetts Maritime Academy

Raymond J. Russas, Massachusetts Maritime Academy

Renato Salas, DPS Engineering

Danielle Salvadore, Alkermes

Stephen Sanborn, Decco

Antonio Scatena, Accuratus Lab Services

Peter Schultz, Massachusetts Maritime Academy

Garett Scott, Rhodes Technologies

Joseph P. Seaver, Massachusetts Maritime Academy

Ashley Simpson, Community College of Rhode Island

Eddie Skillington, DPS Engineering

Carol Ann Suddy, University of Massachusetts Dartmouth

Terrance M. Sullivan, Massachusetts Maritime Academy

Elizabeth Truman, Johnson & Johnson

Richard Lee Waddell, DPS Engineering

Joanna Walsh

Tony Wang, Amgen, Inc.

John P. Ward, Patheon - Framingham

Ryan P. Wentworth, Massachusetts Maritime Academy

Steve Whyte, DPS Engineering

Connor Williams, University of Massachusetts-Lowell

Greg Witte, BSIE, New England Controls Inc

Yusef Yacouba-Issa, Pharmaligent LLC

Member Anniversaries

Over Twenty Years

- Michael L. Anderson, Total Facility Solutions, Inc (21 years)
- Brian L. Clark, ImmunoGen Inc (22 years)
- Andrew A. Coull (22 years)
- Daniel J. Dumont, Dynamic Systems Inc (23 years)
- Christopher J. Fournier, Mar Cor Purification (22 years)
- Michael S. Giorgetti, Sr., Alkermes Inc (22 years)
- Pauline Jurasinski, Genzyme a Sanofi Company (25 years)
- William C. Lynch (23 years)
- Todd McLaren, Biopharm Etc. (22 years)
- Richard D. Priester, Strategic Facility Planning LLC (25 years)
- Douglas A. Queen, TRG Builders LLC (22 years)
- Michael J. Severino, Festo Corporation (22 years)
- James D. Vogel, PE, The BioProcess Institute (23 years)
- Stephen J. Wiles, Hyde Engineering + Consulting Inc (21 years)

Twenty Years

- Anthony C. Bevilacqua
- Beth M. Wescott, PE, Pfizer

Fifteen Years

- Mario Miele, AbbVie
- Chris S. Shields, Saint-Gobain PPL Corp

Ten Years

- Benjamin Battat, IN USA Inc
- David E. Berardinelli, A/Z Corporation
- Alice Day, Shire
- Matthew F.K. Dorf, Nora Rubber Flooring
- Anil K. Rattan, PhD, Shire
- Carrie Troester, Amgen

Five Years

- Tammy S. Bishop, Caligor Rx, Inc.
- David Gallagher, GxP Automation
- Salvatore LaFauci, Interstate Electrical Services, Inc.
- Bankim R. Patel, ImClone Systems Corporation

Chapter Manager: Amy Poole, CAMI - Tel: 1.781.647.4773 and E-mail: office@ispeboston.org