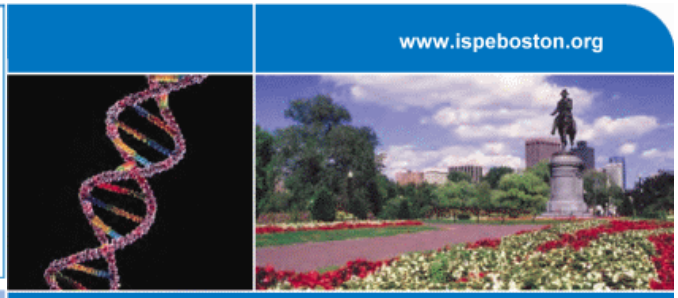
ISPE
Connecting a World of Pharmaceutical Knowledge
Boston Area Chapter
Serving All of New England



NEWSLETTER
January 2015, Volume XXV, No. 1

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President's Message: Exciting Chapter Events Await Members in 2015...

Dear Boston Area Chapter Members,

Happy New Year from the Boston Area Chapter! I hope this past holiday season brought each of you good cheer and happiness.

Looking back, this past year has been an incredibly busy one for the Boston Area Chapter. The Chapter has sponsored and held 85 different events! From educational programs to social events to committee and board meetings to Student Chapter meetings. There has been something for everyone in the industry whether you're from an operating company or a vendor or from one of our great educational institutions. The Chapter has continued to grow and expand our activities so that everyone continues to benefit from Chapter membership.

The Chapter couldn't succeed without the continued support of almost 100 volunteers and all the service and equipment vendors that help to fund our events. Your commitment to this organization has helped make this the most successful ISPE Chapter in the country. We currently have almost 1700 Members and we continue to grow! Additionally, I would like to acknowledge the professional staff at the Center for Association Management (CAMI) for the incredible job they do providing admin support for the Chapter. Amy, Charlotte, Danielle and the rest of the staff: We thank you!

And welcome to the New Year! The Chapter has a lot of events planned for the next few months. For educational opportunities, the January 15 program will explore future trends in the pharmaceutical industry and the February 19 program will focus on facilities. Over the last year, the Chapter has worked hard to expand the geographical reach of our educational programs by offering simulcasts paired with a networking reception at the Crowne Plaza Providence in Warwick, RI. These proved popular in 2014 and will be continued in early 2015 with similar offerings in Worcester, MA. The long term goal is to further expand this effort beginning with the Portsmouth, NH/Portland, ME area.

For those looking to kick back and hang with others in the industry, we will be holding our annual New Year's Social at Flat Top Johnny's in Cambridge on January 22 and March 6 is our annual Ski Trip to a local New Hampshire ski area. And especially for our Student Members, the Student Career Workshop will be held at Northeastern University on February 7 and the Annual Student Poster Competition will be held on April 16 at WPI in Worcester in combination with an educational program. Of special note, the two Poster Competition winners (one graduate and one undergraduate) will each receive a $500 cash prize and a free trip to Philadelphia, PA to compete at the International Student Poster Competition at ISPE's Annual Meeting in November. Winners of the international competition receive cash awards and have the opportunity to publish their research in ISPE's Pharmaceutical Engineering journal, as well as other Chapter/Affiliate publications.

Though October 7 may seem far away, our Product Show Committee is already working hard to make our 2015 Show at Gillette Stadium the best ever. An article later in this newsletter outlines the many changes and improvements planned to enhance the Product Show experience for both exhibitors and attendees. Exhibitor preregistration is now open and provides early access to top booth locations. And if you'd like to help, the committee is still looking for motivated volunteers.

These are only a few of the many exciting events Chapter Members can look forward to in 2015. As we begin our annual trip around the sun, I wish you good luck and prosperity.

Sincerely,

Christopher Opolski
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Pre-register Now for the Product Show and Move to the Head of the Line!

If you're an exhibitor, plan to pre-register now for next year's Show. Pre-registered exhibitors are able to select their booth location a full week before everyone else. So get first shot at your preferred

location and pre-register before January 31. Download a form at http://www.ispeboston.org/ProductShow/index.html or call the Chapter office at 781-647-4773.

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

Want to Become a Chapter Sponsor? It's Easy!

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 www.ISPEBoston.org/Sponsorship/ 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 www.ISPEBoston.org/sponsorship 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 15, 2015

The Future is NOW for Continuous Manufacturing
Biogen Idec, Cambridge, MA

OR

Simulcast to the Crowne Plaza Hotel, Warwick, RI

EVENT INFORMATION: Attend the live program at Biogen Idec in Cambridge, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers.

PROGRAM SUMMARY: If your initial reaction is: Impossible! Can't be done! Not with MY process! You may be surprised to learn that continuous manufacturing is much closer than you think. As our industry evolves and matures, we continue investigating ways to produce biopharmaceutical products more efficiently. Come and learn from three cutting edge speakers working on different areas of this same complex issue as the Chapter presents a "future trends" program to kick off the 2015 educational program year!

Following up on the Lean and Six Sigma concepts covered during the Chapter's December educational program, continuous manufacturing can offer process efficiencies that appeared unimaginable just a short time ago. This program focuses on the science and technology behind different strategies successfully used to continuously manufacture products.

Salvatore Mascia will speak about how integrated continuous manufacturing (ICM) has been implemented at the first ever ICM pilot plant, developed by Novartis and MIT's Center for Continuous Manufacturing to convert raw materials into finished products on a continuous basis.

Maurizio Cattaneo will speak about how to leverage the science behind the design of experiments (DOE) and quality by design (QbD) concepts to create efficiencies in monoclonal antibody production which have increased yields ten-fold by using continuous manufacturing techniques.

Kathleen Mihlbachler will speak about the use of multi-column continuous (MCC) chromatography for the effective separation of chiral (mirror image) compounds on a continuous basis and how this approach can be integrated into a more complex manufacturing strategy.

Register Today:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=465

Thursday, January 22, 2015

New Year's Social

Flat Top Johnny's, Cambridge, MA

EVENT INFORMATION: Come join ISPE Boston Area Chapter and I2SL New England and celebrate the New Year with Friends and Colleagues! Light fare and cash bar will be provided.

This event is geared towards facilitating social and professional networking between people in the pharmaceutical, biotech, and life sciences fields. This is a great opportunity to meet other people from

the industry. Add your personal interests to your badge to facilitate more networking. If you do not indicate an interest, one will be assigned to you!

Register Today:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=541

Sneak Preview of Upcoming Events

Thursday, February 19, 2015
Educational Program

Friday, March 6, 2015
Annual Ski Trip

Enhancements Already Taking Shape for 2015 Product Show at Gillette

by H. Steven Kennedy, Boston Area Chapter Vice President, and Mark Levanites, Chair, Product Show Committee

On behalf of the Product Show Committee and the Boston Area Chapter Board of Directors, we would like to thank our record 355 exhibitors for their support at the 2014 Boston Area Product Show. This year's Show was a huge success with 2458 industry professionals attending (an increase of over 150 from 2013). Their financial support allows the Chapter to provide important services and benefits to our Members and to hold our many top quality educational and social events throughout the year.

We hope you were able to complete our survey following the Product Show and we thank you if you did. We take your responses to heart when we plan future events. Our survey revealed that over 80 percent of exhibitors and attendees want the Show to remain at Gillette Stadium and over 65 percent want it to remain one-day event. So for the next several years at least, the Show will continue to be held on the first Wednesday in October at Gillette.

It is gratifying to know that so many participants think the Show is already the best of its kind. Over 93 percent of exhibitors and attendees were pleased with the Show over every key indicator. But we continue to strive to achieve 100 percent and are making many changes to improve the Show further for 2015. Here is a sneak peak at some of the many improvements already in the planning stages:

Improvements to registration and badging process: You asked and we heard - enhanced registration services and a lead retrieval system are planned for 2015. We are investigating different products and services, including smart phone based solutions that use QR codes and scanners, and will let you know shortly which we have selected.

- To help reduce the length of the lines at registration, we will conduct a raffle for a significant prize to encourage pre-registration. Winners must pre-register and show up to win.
- We are increasing our marketing efforts to operating companies and manufacturing sites to ensure that they send more of their engineering, project management, quality and procurement personnel to the Show. In addition, we will be enhancing our social media marketing efforts to continue to increase traffic to the show.
- The Product Show website will be upgraded and we will be enhancing the mobile app to provide for exhibitor ads, registration, etc. If you have not done so, please download the app now (https://guidebook.com/g/43aiqfn5/).

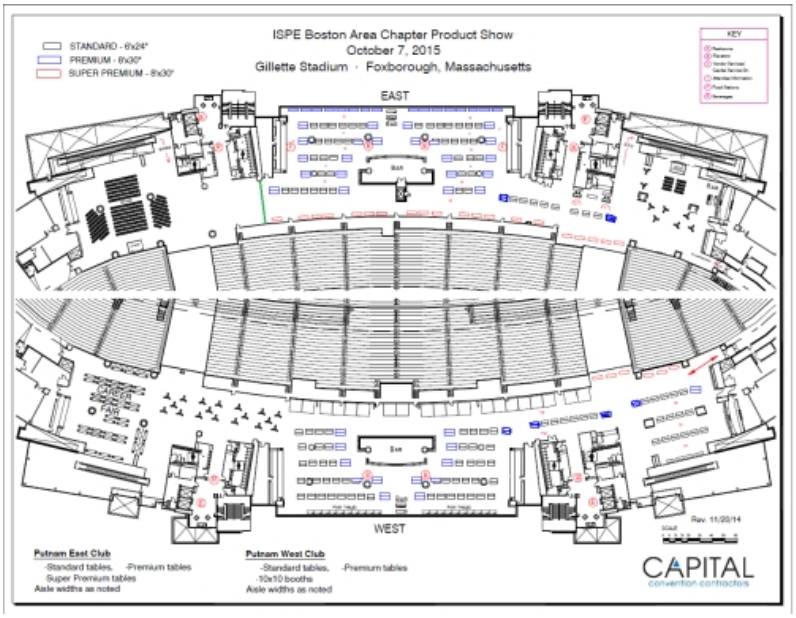
- Both the plenary and educational sessions will be recorded and available for viewing on the Chapter website following the Show.
- Changes are planned for both the Show schedule and layout based on the input received in the surveys.

These include:

- The plenary session will take place in the morning, from10:30am to noon, and will be held in the NE Lounge – same as 2014.
- The four educational sessions will move to the NE Lounge from the suites to allow for larger audiences and will run sequentially (instead of concurrently) beginning at 12:30pm.
- Show hours will be noon to 6:30pm immediately followed by the after-party.
- We will be discussing with Gillette the possibility of allowing exhibitors to set up the night before the Show, most likely from 5 to 8 pm. Set up would also be available the morning of the Show between 8 and 11am.
- A 2-foot space will be added between adjacent tables to improve traffic flow and prevent visitors to one exhibit from "spilling" over into neighboring exhibits. To accommodate the expanded layout, tables will expand into the SW Lounge.
- The Career Fair will move from the SE Lounge to the NW lounge.
- The Vendor Showcase and Entertainment Zone will move to the SE lounge.
- The proposed changes are shown below:

Previous Issues

Newsletter Archive



Additional changes include:

- More food stations and bartenders will reduce waiting times.
- Signage will be improved. Overhead signs with table numbers will be added and signs at the food stations will display the food schedule to make it easier for you to plan your day.
- A professionally-produced "Product Show Instructions" video will be available on our website to assist exhibitors with pre-Show planning.
- Career Fair tables will be free to all companies and increased to about 40.
- Student Members will enjoy a formal, day-long program created for them by the Student Development Committee.

So, as you can see, we have already been hard at work preparing for 2015. We hope you are as excited as we are about these new initiatives.
If you're an exhibitor, plan to pre-register for next year's Show. Pre-registered exhibitors are able to select their booth location a full week before everyone else. So get first shot at your preferred location and pre-register using the online form found here: http://www.ispeboston.org/ProductShow or call the Chapter office at +1-781-647-4773. Pre-registration closes January 31, so don't delay.

A Show like this does not happen without a lot of help from many people. Our volunteers are the backbone of this organization and we're looking for more of them. So join the Product Show Committee and help work to make the 24th edition of the Product Show a reality. This is your chance to influence the direction of the Show and implement the many improvements we have outlined for 2015. If you're interested, contact the Chapter office at +1-781-647-4773.

We would like to wish you a very happy and safe holiday and thank you once again for your continued support. And we look forward to seeing you October 7, 2015 in Foxborough!

"How Do You Validate the Cloud" a Big Hit at Cubist in Lexington

by Heather Longden Waters Corporation, with photos by Joyce Chiu, Honeywell Safety Products

The Boston Area Chapter educational program entitled "Cloud Computing: New Challenges in Data Integrity and Security" was held on Thursday, November 13 at Cubist Pharmaceuticals in Lexington with a simulcast planned for the Crowne Plaza in Providence, Rhode Island. This topic attracted over 60 attendees in Lexington and another 25 attendees in Rhode Island, including a number of nonmembers whom we may have convinced to become ISPE Members.

Attendees chatted with peers while enjoying a light dinner at the opening reception.

(The Chapter extends its apologies to the Rhode Island attendees for the technical issues which could not be resolved that night. Plans are underway to make a video of the presentation available for these attendees. For more information, contact the Chapter office at office@ispeboston.org.)

Following an excellent networking reception with a very impressive spread supplied through Cubist's Cubistro, the program began with opening remarks by Boston Area Chapter President Christopher Opolski who welcomed the guests to Cubist and thanked our generous host for providing a first-class venue. He also made sure to promote a number of upcoming Chapter events including the "Future Trends" educational program on January 15 and the New Year's Social on January 22 at Flat Top Johnny's in Cambridge.

Binesh Prabhakar, founding partner and manager of Cambridge IT Compliance, was then introduced as the program manager and moderator for the panel discussion. Binesh introduced the four panelists and thanked them for providing their insights on cloud hosting technologies in a regulated environment. Each has in-depth, real world experience in leveraging, deploying or validating cloud-hosted solutions and opened the discussion with a short series of slides designed to inspire questions from the audience.

An extended Q&A session allowed attendees to get one-on-one feedback from the panelists.

First up was Tracy Lampula, Associate Director of GIS Compliance, Vertex Pharmaceuticals. Tracy has been deploying GxP IT solutions for a number of years and has experience leveraging cloud-based solutions for Vertex. She believes the short step from application provider, through shared resources to "security as a service" and then to the cloud should not prevent regulated companies from making a risk-based assessment of the new services, provided they take care of those risks as they would for any new deployment model.

Tracy went on to say that cloud models can offer great benefits over traditional deployment models, including an agile approach to changed requirements, exceptional disaster recovery and redundancy (something traditional deployment struggles to provide both practically and with financial justification) and has excellent elasticity which can be critical for high-powered research computing.

But she warned that companies should not be complacent about the cost. Cloud is rarely a cost effective solution, when you need compliance, validation and security to be guaranteed. Vendor management and setting expectations early will ensure you are not paying for controls you don't need while being sure that all your needs really are met, including, "How do I get my data back should I need it or want to change my cloud vendor?" Testing out a cloud vendor with smaller, less critical projects is a good way to accurately gauge what they really can provide.

William Sanborn, Director of Information Technology, LFB-USA, followed Tracy's talk. He highlighted the different elements in the "cloud technology stack" that make up the clients (normally through a browser), the application layer, platform layer and infrastructure layer, then walked us though how these layers have spawned the IaaS, PaaS, and SaaS terms for services that cloud vendors can provide. Despite Tracy's practical advice on the relative costs, William pointed out that the birth of these services was based on the goal of reducing costs to the end user community, enabling them to focus on their core business.

Next up, Robert Streit, Sr. Manager, Q&C Architecture and Design for IT Systems, Johnson & Johnson, covered the particular concerns involved with hosting an application containing data regulated by health authorities. Bob was specifically asked to join our panel as a representative of the ISPE GAMP Special Interest Group on cloud computing. His opening slide addressed the key question in the minds of audience members, "If you build a virtual environment in your own data center, FDA expects validation and qualification of the system. How does this expectation change by putting that system in somebody else's building?"

His answer to this question is that a cloud-based GxP system requires exactly the same validation approach (such as that found in GAMP 5) and validation documentation as any other internal system but care should be taken to look at the risks and risk mitigation with the cloud architecture in mind and pay particular attention to roles, responsibilities and where critical validation documents are managed. Key is the vendor's understanding of life science predicate rules and expected qualification and validation efforts, specifically backup and restore expectations.

And what other "services" are they including in the package you are paying for? When you are using an application as a service, not only your specific data but the entire application and configuration requires protection.

Finally, Robert Wherry, CPIP, Principal Consultant, Strategic Compliance Services, PAREXEL International, turned our attention to the current challenge of demonstrating data integrity to

regulators, ensuring that they trust that data created or managed in the cloud is as truthful as any other data produced. Having a third party manage the security and access to the data opens risks about the integrity of that data. The tricky part is how to assess how well they are achieving that.

For a normal third party arrangement, a key aspect of supplier assessment is to conduct on-site audits into their procedures and processes but cloud vendors rarely permit that level of access. And what if a regulator insists on that same level of access? This is where a company can use their validation of the application and their data review to show that the data is secure. Just as you would run validation testing for critical data integrity processes (such as security, audit trails and backup and restore) in your own hosted solutions, you should do exactly the same for a vendor-hosted solution or have your vendor do that for you.

Equally, data integrity can be assured much more easily if you can demonstrate control over the environment and manage change appropriately. Ensure you have purchased and manage test/development and validation environments as well as production environments, especially for cloud-based applications.

How do companies prepare for a detailed data integrity focused audit when the application is in the cloud? The key is to know and understand what causes regulators to lose trust in the company's data and make sure to address any new risks that the cloud deployment might be introducing. Remember, the FDA itself stores critical records in the cloud!

A lively and extended question and answer session followed as the audience raised their specific concerns about moving regulated life science data into a cloud environment.

- How to get quality agreements set up that include details of how the vendor would implement software and hardware changes? What kinds of notification should a company expect (ideally, before the changes occur and in time to evaluate those changes)?
- How to prepare for a regulator who may insist on visiting a cloud provider?
- What kind of cloud vendors are out there? Is it better to look to a large provider with broad experience across many different applications; or focus on smaller, niche companies who have specific experience hosting life science applications for pharmaceutical or medical device companies?
- What about access to the backups of critical data? Those also contain proprietary information. Where are they kept? How secure are they and who "owns" the information the backups contain? Most cloud vendors have no interest in having responsibility for your data, so perhaps sending you the backups to store locally is a good solution especially since then you do not need to pay the vendor to store the backups as well as the live data.
- When a hosted solution is solely for security verification or if security is a part of the hosted solution, who is responsible for the updating such as removing access for ex- users?
- When is it cost effective to use cloud services? Is there a "sweet spot?" Should we avoid use of the cloud for regulated data and simply use it for non-regulated data?
- What about the security of the vendor's data centers? Even though the cloud is private and secure, there is still physical security to consider.
- And speaking of physical security, where IS my data? For most regulated pharmaceutical data, it seems key to ensure that the data stays in the US for a US-based company. This ensures compliance with local laws and regulations. Data that resides outside the US could become subject to the laws and regulations of the hosting country which would seriously add to costs.
- Bob Streit had talked about certifications for vendors, but what does that mean? In reality, the exact certifications may not guarantee your data is protected but the more quality processes the company has in place that have been verified by a third party, the more confidence you can have that they have the internal quality knowledge and procedures that should protect your data.
- What is a reasonable time to allow in an SLA for retrieval of data if, for example, you wanted to end an agreement and search for an alternative cloud hosting service? This could be a critical aspect when the original vendor holds your data. Accessibility to the data would be simpler for a IaaS or PaaS hosting versus a SaaS service where you might get your data back but would be unable to read it without the original application. Perhaps spinning it up into your own internal virtual environment would give you time to find a new hosting vendor.
- Just as with internal computerized systems, validation and qualification based on risk is the key. A companywide policy for data classification should determine and demonstrate what is permitted to be stored in the cloud and what should never go into a hosted virtual environment. This should include instructing employees (including vendors and subcontractors) about what data should never, unofficially be kept on any cloud service, including the likes of Google Drive and Dropbox.
- Further discussion arose about whether cloud-hosted applications should be considered "open" or "closed" in context of 21 CFR Part 11, with some difference of opinion amongst the attendees. All agreed, however, that transmission of data should use, at a minimum, a VPN link; but that encryption of transmitted data to prevent interception might also be a reasonable mitigation.

The evening's program, as a whole, was a resounding success, delivering quality information on a topic of great interest and relevance to Chapter Members. The Boston Area Chapter and Program Managers Binesh Prabhakar, Christopher Ciampa and Heather Longden would like to thank the panelists and audience members for their valuable contributions to this program and Cubist for providing the venue and catering for the event.

Chapter Members Explore Lean Six Sigma at Lantheus Medical Imaging

by Juan Espinal, Lantheus Medical Imaging

The ISPE Boston Area Chapter educational program entitled "Lean Six Sigma - Theory, Applications and Lessons Learned in the Biopharma Industry" was held Thursday, December 11 at Lantheus Medical Imaging headquarters in north Billerica and was offered via simulcast at the Crowne Plaza Providence in Warwick, RI. The goal of this program was to present an overview of the Lean Six

Sigma tools and techniques and illustrate how they can be successfully applied to biopharmaceutical operations using actual case studies.

The opening networking reception gave attendees the opportunity to introduces themselves and interact with the speakers while enjoying a light dinner. The program began with opening remarks by Boston Area Chapter President Christopher Opolski who welcomed the attendees, followed by Lantheus Manufacturing and Operations Vice President William Dawes who gave a brief presentation about Lantheus and its product portfolio. After that, Meeting Manager and Lantheus Validation Specialist Juan Espinal introduced the presentations and the speakers.

Speakers (l to r) Rui Coelho, Dan Fleming and Niranjan Kulkarni joined forces to explain how biopharma can benefit from Lean and Six Sigma methodologies.

The first speaker, Dan Fleming, Continuous Improvement Manager, GBMP, gave an introduction explaining how Lean connects the company, processes, employees and customers. He emphasized how the use of Lean tools like JIT (just in time), Jidoka and standardization can improve product quality and reduce cost and delivery time. Dan mentioned than Lean focuses 10 percent on techniques and 90 percent on people and emphasized that management support plays a big role in its successful implementation.

Next up was Rui Coelho, Associate Director, Operational Excellence, Biogen Idec, who has over 25 years of management experience applying various product and process improvement approaches. Rui presented on several Lean case studies including one at Biogen called the grass roots improvement process (GRIP) which involved training the workforce in Lean methodologies then empowering them to apply the tools. Tools used included 5S, standard work, visual management, employee idea submission/implementation, and Kanban. The results included gains in efficiency and cost savings. He also presented a lab case study where the use of Kanban produced significant savings.

Following the introduction to Lean presented by Dan and Rui, Niranjan Kulkarni, PhD, Sr. Operations Specialist at CRB, followed with the Six Sigma part of the program. Niranjan began with an introduction to Six Sigma describing its philosophy, methodology, metrics and tools and presented several biopharm case studies where applying the Six Sigma model resulted in benefits such as 35 percent reduction in changeover times, 60 percent increase in manufacturing throughput (ie. number of batches) and 43 percent increase in QC lab throughput (ie. number of tests). He pointed out that in spite of successes such as these Six Sigma cannot be used for everything and should only be applied in the areas where is well suited.

The evening's three speakers did a great job of explaining how the industry can benefit from the intersection of these powerful methodologies in combination with employee engagement. Lean and Six Sigma are not competing approaches. Instead they are complimentary and together can have a significant positive impact on efficiency and indirectly on the patients who rely on the industry and its products. Selecting the right tools and techniques for solving the problem at hand is very important. However, even more critical for a successful Lean Six Sigma journey is management support combined with employee involvement and cultural change.

Following the presentations, the audience demonstrated their interest and enthusiasm by asking many fantastic questions including:

- "How do you manage project overload?" Utilize Policy Deployment and set up a PMO.
- "How do I get started?" Get educated through books, webinars, workshops and DVDs but, most important, find an expert in the field who can recommend the best approach and provide coaching while you "learn by doing."

The Boston Area Chapter and Program Managers Juan Espinal and John Sheridan would like to thank the speakers and audience members for their valuable contributions to this program and Lantheus Medical Imaging for providing the venue and great preparation for the event.

Activity was Brewin' at the December YP Social!

by Brian Kennedy, Genzyme

On December 4, the Boston Area Chapter Young Professionals hosted a social event at Night Shift Brewery in Everett. Nearly 40 people representing some 34 companies and universities turned out for an engaging evening of food, networking and craft beer.

An evening filled with fun, laughter, and networking greeted the Chapter's Young Professionals at the Night Shift Brewery in Everett.

Night Shift Brewery was started in 2012 by a group of friends who began brewing craft beers in a 5-gallon pot in their apartment. They experimented with unorthodox brewing ingredients and yeasts, creating some very unique and flavorful beers. After some success in brewing competitions, the friends decided to commercialize their products and have had great success providing the greater Boston area with unique beers.

The company moved to a new Everett location within the past year. We were fortunate enough to get an up-close tour of the brewing facility where all of Night Shift's beers are brewed, fermented and bottled. We saw the vessels where different types of malts are crushed and mixed with hot water to release the fermentable sugars within. The resulting liquid, known as wort, is separated and combined with hops prior to fermentation in large airtight tanks. Once fermentation is complete, the beer is aged and bottled by hand on site.

Each attendee got the chance to sample a handful of the seven beers on tap before choosing their favorite to enjoy with the food provided, a very hearty spread including chicken Caesar salad wraps, pasta salad, and buffalo chicken fingers. The event spanned two rooms: the taproom, with the bar and sitting area, and the barrel room, where you can see dozens of barrels of aging beers as well as play a few rounds of Cornhole!

The evening was filled with fun, laughter and networking. Overall the event was a big success, offering many opportunities to meet new people and build connections, and we look forward to holding similar events at other Boston-area microbreweries in the future!

Looking Forward to a Great 2015

Looking back, 2014 was a great year for the Boston Area Chapter Young Professionals. The membership of the YPs grew as we were able to promote the YP group at various events, including the Product Show as well as on the Chapter website. The last few YP events were extremely successful, with maximum registration (including some walk-ins the night of the event) for the Night Shift event in December and the Harbor Cruise in September.

The Boston Area Chapter Young Professionals organization is widely recognized as a very successful YP group. The Boston Area Chapter YP Committee co-chairs now have the opportunity to interface with the international ISPE organization and YP leaders from other Chapters and Affiliates via conference call on a monthly basis. This is an excellent opportunity to discuss best practices and we believe it will advance our organization and the Boston Area Chapter, both in the US and internationally.

We are expecting 2015 to be our best year yet. With your help, we are hoping to attract new YP Members from within the Chapter and increase the participation of current YP Members by continuing to offer a full calendar of exciting educational and social events. We also hope to attract new Chapter Members from outside ISPE and engage current and prospective Members across social media platforms (e.g., LinkedIn, Facebook). We feel that this will be the best way to keep in touch with YPs, who already have a very large presence on these platforms.

We are also looking to partner with several Student Chapters. For example, we are planning a joint educational event with the Mass College of Pharmacy in early 2015 and a dual-track educational program at WPI in April. We are also hoping to partner with the Educational Program Committee and have planned a "soft skills" workshop in November. Lastly, we are looking for volunteers to help develop and run a mentorship program. This is an excellent opportunity to get more involved in ISPE and interact with YP's and other Boston Area Chapter Members. If you are interested in volunteering, please contact YP Committee Co-Chairs Chris Ciampa (christopher.ciampa@gmail.com) and Jared Marshall (Jared.Marshall@genzyme.com)

In the next few months, we have scheduled numerous social events that we hope you will attend. In the spring, we will be heading to Sacco Bowling/Flatbreads in Davis Square for pizza, craft beer, and bowling. We will also be returning to Medieval Manor, a venue that was very popular in the past with both YP and seasoned Chapter Members. Due to the success of the Night Shift event in early December, there are plans to visit another local micro-brewery, such as Aeronaut Brewing in Somerville, for a night of beer and networking. Please stay tuned as these events will be a great forum for the YPs, as well as the more seasoned Members of the Boston Area Chapter.

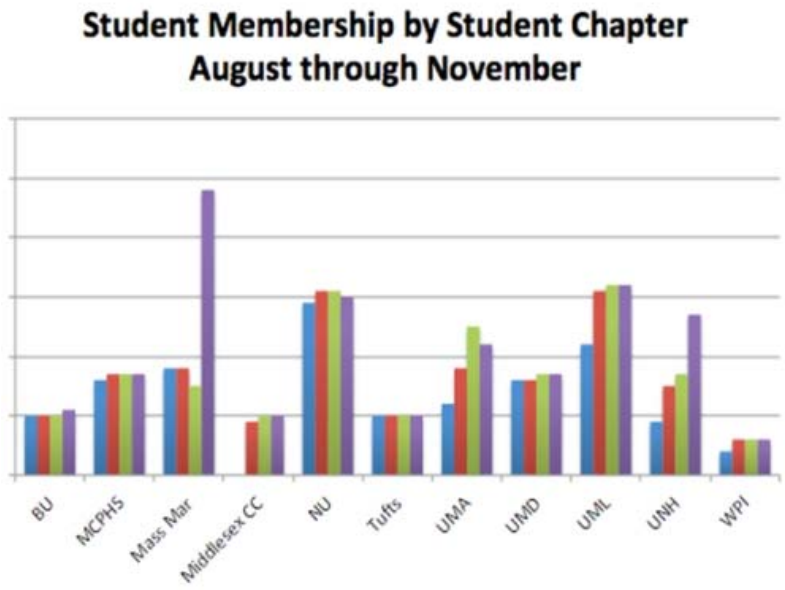
As a final thought, please remember that the YPs are always happy to hear your ideas, whether

you're a new YP or a more experienced Member of the Boston Area Chapter. If you have any suggestions or are interested in attending a YP Committee meeting, please feel free to contact YP Committee Co-Chairs Chris Ciampa (christopher.ciampa@gmail.com) and Jared Marshall (jared.marshall@genzyme.com).

Student Chapter Update

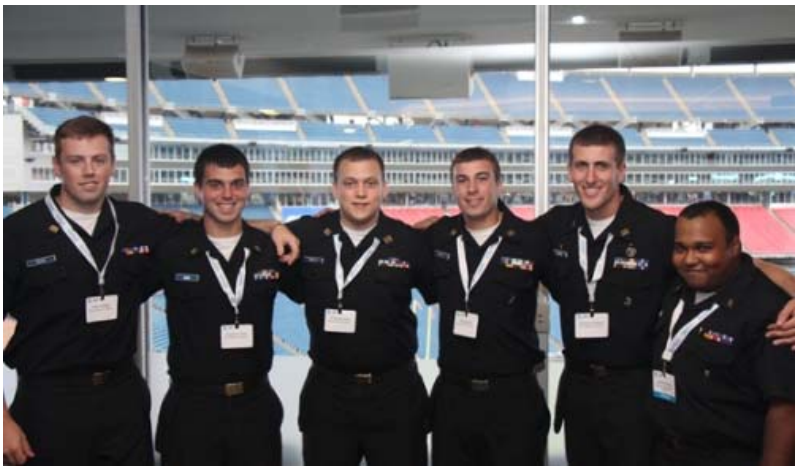
by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer

Student Chapters Hit New Membership High
The Chapter has been very active on campuses this year, with 11 Student Chapters and a 35 percent increase in student membership since the beginning of the semester! The Boston Area Chapter now has the most Student Members of any ISPE Chapter! The graph below provides a breakdown of student membership by Student Chapter from August through November.



Special recognition goes to students at Mass Maritime Academy, University of New Hampshire, UMass Amherst and UMass Lowell who have had the greatest increases in student membership since the beginning of the semester.

Scholarship Program Reaches New High
The Chapter's Joel Goldenberg Scholarship Program awards $12,500 to its Student Members twice a year, with the latest application period concluding November 15. The Chapter has a track record of awarding scholarships to an unfathomable 50 percent of applicants. Look for the winners in the next newsletter. And remember, you can't win a scholarship if you don't apply! For more information visit the Chapter website at [insert link to scholarship page].



Mass Maritime students (l-r) Jack Radke, Steven Scire, Aristides Ortiz, Tyler Smith, Gordon Stillwell, and Jackie Gomes at the Product Show.

Spring Will Be Busy for ISPE Student Members
In addition to their busy workloads on campus, ISPE will provide opportunities for Student Members to get ready to enter the life sciences industry. This spring, the Chapter is organizing an excellent activity every month for our Student Members:

- February - Career Workshop at Northeastern in Boston
- March – Genzyme Plant Tour in Framingham
- April – Annual Poster Contest at WPI in Worcester

On Saturday, February 7, the Chapter is holding its third annual Career Workshop at Northeastern's Alumni Center. Get your resume in order and learn the secrets to success in the life sciences industry at this event. In late March, the Chapter is hosting a Plant Tour at Genzyme in Framingham. And Thursday, April 16 is the date for the Student Poster Competition. This year's event will be held at WPI's Biomanufacturing Education and Training Center in Worcester right before a monthly educational program. Students will compete in graduate and undergraduate categories and have the opportunity to meet and network with industry professionals and attend an educational program. Winners get an expenses-paid trip to compete in the International Poster Competition at the ISPE Annual Meeting in the fall of 2015 plus a $500 cash prize. For more details on any of these events, check out the Chapter event calendar at http://www.ispeboston.org/eventcal/calendar.html
Remember, Students Attend ISPE Educational Events for Free

Remember, once you join ISPE as a Student Member (visit www.ispe.org/join-or-renew), you can attend all Chapter educational and related events for free! Membership in the Boston Area Chapter truly does have its privileges!

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.

Broad Institute Founder Altshuler Joins Vertex
Vertex Pharmaceuticals has announced that David Altshuler, M.D., Ph.D., will join the company as Executive Vice President, Global Research and Chief Scientific Officer. Dr. Altshuler was one of the four founding members of the Broad Institute of Harvard University and the Massachusetts Institute of Technology, where he has served as Deputy Director and Chief Academic Officer since 2009. Dr. Altshuler is also currently a Professor of Genetics and Medicine at Harvard Medical School and an Adjunct Professor of Biology at the Massachusetts Institute of Technology and has been an attending physician at the Massachusetts General Hospital.

Dr. Altshuler's scientific research has been focused on the discovery of new pathophysiological processes underlying the risk of developing type 2 diabetes to identify and validate new drug targets. At Vertex, Dr. Altshuler will lead the company's research efforts aimed at discovering new medicines for the treatment of serious diseases, overseeing activities across the company's five research sites in the United States, Canada and Europe.

Dr. Altshuler has received numerous awards for his research and clinical activities related to human genetics, including, most recently, the Champion of Change: Open Science Award from the White House, the Outstanding Scientific Achievement Award from the American Diabetes Association and the Curt Stern Award from the American Society of Human Genetics. He is a member of the Institute of Medicine of the National Academy of Sciences, the American Academy of Arts and Sciences, the American Society for Clinical Investigation and the Association of American Physicians, among other organizations. He has served on advisory boards for many leading institutions, government organizations and nonprofit foundations, including The National Institutes of Health, The Wellcome Trust, The American Society of Human Genetics, Eisai Pharmaceuticals and Pfizer.

Dr. Altshuler received his B.S. from the Massachusetts Institute of Technology, a Ph.D. from Harvard University and his M.D. from Harvard Medical School. He completed his internship, residency and clinical fellowship training at Massachusetts General Hospital. Dr. Altshuler has resigned from his position as a Vertex Director and will begin his new role at Vertex in early 2015. (Source: Vertex Pharmaceuticals Website, 15 December, 2014)

Voyager Therapeutics Opens New Headquarters in Cambridge
Voyager Therapeutics, a gene therapy company developing life-changing treatments for fatal and debilitating diseases of the central nervous system (CNS), celebrated the opening of its new headquarters on October 21. Voyager's new headquarters, located at 75 Sidney Street in Cambridge, contains research and process development laboratories.

Voyager is working to advance the field of AAV (adeno-associated virus) gene therapy through vector optimization and engineering, dosing and delivery techniques, and process development and production. The company's initial pipeline is focused on CNS diseases including Parkinson's disease, a monogenic form of amyotrophic lateral sclerosis (ALS), and Friedreich's ataxia. Voyager Therapeutics was launched in 2014 with funding from life sciences investor Third Rock Ventures. (Source: Voyager Therapeutics Website, 21 October, 2014)

Astrazeneca to Close Westborough Plant
In a move that is a major economic blow for the town and region, pharmaceutical giant AstraZeneca will close its manufacturing plant in Westborough in late 2015. The Westborough plant, familiar for its distinctive glass pyramid building on Otis Street, is currently one of three producers of the company's Pulmicort Respules. AstraZeneca will consolidate manufacture of the medicine to two sites in Sweden and Australia. The drug, which is inhaled, is used to control and prevent asthma symptoms in young children.

The company said some of the 180 jobs affected may be eliminated in March, while other positions will continue through the decommissioning of the site at the end of 2015. The company said it will work one-on-one with workers to help them assess opportunities and needs.

Karen J. Chapman, president of the Corridor Nine Area Chamber of Commerce, said in an email Thursday morning, "We consider it a loss to the local business community to have AstraZeneca close their doors. They were a great corporate citizen and partner to the Corridor Nine Chamber. We have complete faith in Westborough's ability to attract someone to that property and will provide our energetic abilities to help support its next tenant." (Source: Carol Mcdonald, Worcester Business Journal, 11 December, 2014)

FDA Requests Additional Data Be Included in Serepta's New Drug Application for Eteplirsen
Sarepta Therapeutics, developer of RNA-based therapeutics, has been asked by the FDA to include additional data in the company's planned New Drug Application (NDA) submission for the approval of Eteplirsen for the treatment of Duchenne muscular dystrophy (DMD). The FDA requested specific additional data be included as part of or at the time of Sarepta's NDA submission.

The guidance requests more specific data including a minimum duration of safety in new patients exposed to Eteplirsen, patient-level natural history data to be obtained by Sarepta from independent academic institutions, and MRI data from a recent study conducted by an independent academic group. The FDA indicated that further discussion with Sarepta regarding its NDA will be required. Based on these requests, Sarepta plans to submit an NDA by mid-year 2015, pending any additional requests from further discussions with the FDA.

DMD is a rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. DMD affects approximately one in every 3,500 boys born worldwide. The condition is universally fatal, and death usually occurs before the age of 30. Eteplirsen is Sarepta's lead drug candidate and is designed to address the underlying cause of DMD. Eteplirsen uses Sarepta's proprietary technology to skip a genetic mutation that is known to impact some DMD patients. (Source: Serepta Website. 27 October, 2014)

Biogen Idec Third Quarter 2014 Revenues Increase 37 Percent to $2.5 Billion
Biogen Idec reported third quarter 2014 results, including revenue of $2.5 billion, a 37 percent increase compared to the third quarter of 2013. The company stated that revenue growth for the full year of 2014 is expected to be approximately 38 percent to 41 percent compared to 2013, which is unchanged from prior guidance. The company attributed the increase over 2013 to a number of products, including:

- Tecfidera revenues were $787 million, consisting of $638 million in U.S. sales and $149 million in sales outside the U.S.
- Interferon revenues, including Avonex and Plegridy, were $745 million, consisting of $482 million in U.S. sales and $263 million in sales outside the U.S.
- Tysabri revenues were $501 million, consisting of $275 million in U.S. sales and $226 million in sales outside the U.S.
- Net revenues relating to Rituxan and Gazyva from Biogen Idec's unconsolidated joint business arrangement were $291 million.
- Alprolix revenues were $25 million, and Eloctate revenues were $22 million. (Source: Biogen Idec Website, 22 October, 2014)

Bristol-Myers Squibb Drug Opdivo Approved by FDA for Advanced Melanoma
The FDA has granted accelerated approval to Opdivo (nivolumab), a new treatment for patients with unresectable or metastatic melanoma who no longer respond to other drugs. Opdivo is marketed by Princeton, New Jersey-based Bristol-Myers Squibb.

Melanoma is the fifth most common type of cancer in the U.S. It forms in the body's melanocyte cells, which develop the skin's pigment. The National Cancer Institute estimates that 76,100 Americans will be diagnosed with melanoma and 9,710 will die from the disease this year.

Opdivo works by inhibiting the PD-1 protein on cells, which blocks the body's immune system from attacking melanoma tumors. Opdivo is intended for patients who have been previously treated with ipilimumab and, for melanoma patients whose tumors express a gene mutation called BRAF V600, for use after treatment with ipilimumab and a BRAF inhibitor.

"Opdivo is the seventh new melanoma drug approved by the FDA since 2011," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "The continued development and approval of novel therapies based on our increasing understanding of tumor immunology and molecular pathways are changing the treatment paradigm for serious and life-threatening diseases."

The FDA granted Opvido breakthrough therapy designation, priority review and orphan product designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies; the drug had the potential, at the time of the application was submitted, to be a significant improvement in safety or effectiveness in the treatment of a serious condition; and the drug is intended to treat a rare disease, respectively.

Opvido is being approved under the FDA's accelerated approval program, which allows 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. This program provides earlier patient access to promising new drugs while the company conducts additional clinical trials to confirm the drug's benefit. (Source: FDA Website, 22 December 19, 2014)

Mass Life Sciences Center Announces Grant Program to Fund Early-Stage Companies
The Massachusetts Life Sciences Center (MLSC) announced the launch of a new grant program in November. The Life Sciences Milestone Achievement Program (MAP) will award early-stage life sciences companies in Massachusetts with funding necessary to perform and complete milestones. The program application will be available on the MLSC's website starting on December 8, 2014 and applications will be due on February 2, 2015.

The Life Sciences MAP was created in response to feedback from industry stakeholders, strongly reinforced by the Impact 2020 Report released by MassBio and Health Advances in April 2014. The MLSC sought and received input from the funding, technology, and mentoring community to identify key areas in which early-stage companies would benefit from additional financial support. The program's goals include filling a gap in the funding environment and empowering companies to attract additional outside funding. The MLSC's Board of Directors has approved up to $2 million in funding.

Final awards for this initial round will be determined by the MLSC's Board of Directors and are projected to be announced in May 2015. Information sessions for potential applicants will be held from now into January 2015 in various locations around Massachusetts. Dates and locations are

listed on the MLSC's website. (Source: Mass Bio Website, 07 November, 2014)

AMAG Pharmaceuticals Acquires Lumara Health's Maternal Health Business
AMAG Pharmaceuticals announced that it has completed the acquisition of Lumara Health, a specialty pharmaceutical company with a particular focus on maternal health. The transaction was announced on September 29, 2014 and included upfront consideration of $600 million in cash and 3,209,971 shares of AMAG common stock, and additional contingent consideration of up to $350 million based on the achievement of sales milestones.

Lumara Health markets Makena (hydroxyprogesterone caproate injection), the only FDA-approved product indicated to reduce the risk of preterm birth in women who are pregnant with one baby and who have delivered one preterm baby spontaneously in the past. (Source: AMAG Pharmaceuticals Website, 12 November, 2014)

Merck to Acquire Lexington-Based Cubist Pharmaceuticals
Merck and Cubist Pharmaceuticals have announced that the companies have entered into a definitive agreement under which Merck will acquire Cubist for $102 per share in cash, which represents a 35 percent premium to Cubist's average stock price for the most recent five trading days. The companies expect the transaction to close in the first quarter of 2015.

Unanimously approved by the boards of directors of both companies, the transaction has an equity valuation of $8.4 billion and will also include $1.1 billion in net debt (based on projected cash balances) and other considerations for a total transaction value of approximately $9.5 billion. Merck expects the acquisition to add more than $1 billion of revenue to its 2015 base.

Cubist develops and supplies antibiotics to treat infections caused by a broad range of increasingly drug-resistant bacteria. Cubist's antibiotic Cubicin, the only approved once-a-day therapy for both s. Aureus bacteremia and complicated skin and skin structure infections (csssi), has been used to treat more than two million patients. Cubist's in-line and late-stage pipeline of anti-infective medicines, including Zerbaxa which is pending approval from the FDA, will enhance Merck's hospital acute care business in a variety of therapeutic areas, including gram-positive and gram-negative multi-drug resistant infections. (Source: Cubist Pharmaceuticals Website, 08 December, 2014)

Shire to Relocate Over 500 Jobs to Massachusetts
Shire has announced plans to relocate over 500 positions to Massachusetts from its Chesterbrook, Pennsylvania site and establish Lexington, Massachusetts as the company's U.S. operational headquarters. The transition is a continuation of the Company's "One Shire" efficiency program and will streamline business globally through two principal locations – Massachusetts and Switzerland – with support from a limited number of regional and country-based offices around the world.

Simplifying operations in two principal locations will increase efficiencies and Shire expects to realize approximately $25 million in annual savings beginning in 2016. This site strategy will also enable greater alignment and execution of priorities between the company's commercial and research and development teams to more effectively bring innovative products to patients, as well as strengthen collaboration and cross-development of employees.

Shire plans to move employees in several phases beginning in the first quarter of 2015 and targets completion by the first quarter of 2016. All directly impacted employees who do not relocate will be offered severance, outplacement service and other employee assistance. (Source: Shire Website, 09 November, 2014)

Genzyme's Lemtrada Approved by the FDA
Genzyme, a Sanofi company, has announced that the FDA approved Lemtrada (alemtuzumab) for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. First approved in September 2013 in the European Union, Lemtrada is approved in more than 40 countries. Multiple sclerosis is estimated to affect more than 2.3 million people globally. There are approximately 400,000 people living with MS in the United States.

The Lemtrada label includes a boxed warning noting a risk of serious, sometimes fatal autoimmune conditions, serious and life-threatening infusion reactions and also noting Lemtrada may cause an increased risk of malignancies including thyroid cancer, melanoma and lymphoproliferative disorders. Lemtrada is only available through a restricted distribution program, the Lemtrada REMS (Risk Evaluation and Mitigation Strategy). This program has been developed to ensure that access to Lemtrada in the U.S. is only through certified prescribers, healthcare facilities and specialty pharmacies and to also ensure that patients are enrolled in the REMS program. The program is intended to help educate healthcare providers and patients on the serious risks associated with Lemtrada and the appropriate periodic monitoring required to support the detection of these risks for 48 months after the last infusion. (Source: Genzyme Website, 14 November, 2014)

Bristol-Myers Squibb and Lonza Expand Manufacturing Agreement
Bristol-Myers Squibb Company and Lonza announced a multi-year expansion of their existing biologics manufacturing agreement. The contract expansion will include the production of commercial quantities of a second Bristol-Myers Squibb biologic medicine at Lonza's mammalian manufacturing facility in Portsmouth, New Hampshire. Financial terms were not disclosed.

Bristol-Myers Squibb and Lonza have been collaborating since 2003 to produce commercial supplies of a biologics medicine marketed by Bristol-Myers Squibb worldwide. Currently, Lonza also produces clinical supplies of an investigational biologics medicine for Bristol-Myers Squibb. (Source: Bristol-Myers Squibb Website, 30 October, 2014)

Agios Announces New Data from Trial of AG-221 in Patients with Advanced Hematologic Malignancies
Agios Pharmaceuticals has announced new data from the ongoing Phase 1 dose escalation study of AG-221 as a single agent in patients with IDH2-mutant positive advanced hematologic malignancies. With additional patient enrollment and longer follow-up, the data continue to show a favorable safety profile as well as durable clinical activity for AG-221, with an overall response rate of 56 percent in

advanced hematologic malignancies.

As of the data cut-off on October 1, 2014, the ongoing Phase 1 study of AG-221 had enrolled 73 patients, with a documented IDH2 mutation, in a broad range of advanced hematologic malignancies. Patients enrolled included those with relapsed or refractory acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), chronic myelomonocytic leukemia (CMML) and untreated AML who decline intensive chemotherapy. At the time of the data cut-off, the data showed that 25 out of 45 evaluable patients achieved investigator-assessed objective responses, including six complete remissions, nine complete remissions with various degrees of hematologic recovery and ten partial remissions. (Source: Agios Website, 07 December, 2014)

bluebird bio Announces Promising Early Results for Gene Therapy Treatment for Beta-Thalassemia Major
At the 56th Annual Meeting of the American Society of Hematology (ASH) in San Francisco in December, bluebird bio announced data from eight subjects treated with LentiGlobin BB305 drug product. In the first four subjects, treatment resulted in sufficient hemoglobin production to reduce or eliminate the need for transfusion support among patients with beta-thalassemia major who would otherwise require chronic blood transfusions.

LentiGlobin BB305 drug product aims to treat beta-thalassemia major and severe sickle cell disease by inserting a fully functional human beta-globin gene into the patient's own hematopoietic stem cells ex vivo and then transplanting those modified cells into the patient through infusion, also known as autologous stem cell transplantation.

Beta-thalassemia is an inherited blood disease that can cause severe anemia. Patients with beta-thalassemia cannot make enough of the beta-globin part of hemoglobin, the protein used by red blood cells to carry oxygen throughout the body. Approximately 40,000 children are born with a serious form of the disease every year, making it one of the most common genetic diseases in the world. In its most severe form, beta-thalassemia is fatal if not treated.

Treating beta-thalassemia includes frequent and lifelong blood transfusions, which deliver red blood cells to the body to correct the anemia. However, blood transfusions also cause excess iron to build up in the body, which can damage organs and cause additional issues, such as abdominal pain, weakness, fatigue, joint pain, endocrine dysfunction, liver cirrhosis and heart failure. Patients who receive ongoing blood transfusions must also receive treatment to remove the excess iron.

The only currently available curative treatment option for beta-thalassemia is allogeneic hematopoietic stem cell transplant. However, these transplants are only offered to pediatric patients with matched sibling donors (occurring in less than 25 percent of all cases), due to the significant risk of transplant-related morbidity and mortality. (Source: bluebird bio Website, 08 December, 2014)

Cubist Wins FDA Approval for New Antibacterial Drug Zerbaxa
The FDA has approved Zerbaxa (ceftolozane/tazobactam), a new antibacterial drug product from Lexington-based Cubist Pharmaceuticals, to treat adults with complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI). Zerbaxa is a combination product containing ceftolozane, a cephalosporin antibacterial drug, and tazobactam, a beta-lactamase inhibitor. Zerbaxa is used to treat cUTI, including kidney infection. It is used in combination with metronidazole to treat cIAI.

Zerbaxa is the fourth new antibacterial drug approved by the FDA this year. In June, the agency approved Cubist's Sivextro (tedizolid). Dalvance (dalbavancin) was approved in May and Orbactiv (oritavancin) in August. Dalvance is marketed by Chicago-based Durata Therapeutics, and Orbactiv is marketed by Parsippany, New Jersey-based The Medicines Company.

Zerbaxa is the fourth new antibacterial drug product designated as a Qualified Infectious Disease Product (QIDP) to receive FDA approval. Under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act, Zerbaxa was granted QIDP designation because it is an antibacterial or antifungal human drug intended to treat a serious or life-threatening infection.

As part of its QIDP designation, Zerbaxa was given priority review, which provides an expedited review of the drug's application. The QIDP designation also qualifies Zerbaxa for an additional five years of marketing exclusivity to be added to certain exclusivity periods already provided by the Food, Drug and Cosmetic Act. (Source: FDA Website, 19 December 19, 2014)

Regulatory & Legislative Highlights

by Janet Tice, GMP Piping

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 Two Drugs to Treat Idiopathic Pulmonary Fibrosis
The FDA has approved Esbriet (pirfenidone) and Ofev (nintedanib) for the treatment of idiopathic pulmonary fibrosis (IPF). Esbriet is manufactured for InterMune of Brisbane, California. Ofev is distributed by Boehringer Ingelheim Pharmaceuticals of Ridgefield, Connecticut.

Idiopathic pulmonary fibrosis is a condition in which the lungs become progressively scarred over time. As a result, patients with IPF experience shortness of breath, cough, and have difficulty participating in everyday physical activities. Current treatments for IPF include oxygen therapy, pulmonary rehabilitation, and lung transplant.

The FDA granted both drugs fast track, priority review, orphan product, and breakthrough designations. (Source: FDA Website, 15 October, 2014)

FDA Approves New Treatment for Rare Form of Hemophilia

The FDA has approved Obizur [Antihemophilic Factor (Recombinant), Porcine Sequence] for the treatment of bleeding episodes in adults with acquired hemophilia A (acquired Factor VIII [FVIII] deficiency). Obizur is manufactured by Baxter Healthcare of Westlake Village, California.

Acquired hemophilia A is a rare, but potentially life threatening, bleeding disorder caused by the development of antibodies (immune system proteins) directed against the body's own FVIII, a protein important for blood clotting. When FVIII is inactivated by these autoantibodies, a person's blood doesn't clot normally, resulting in excessive bleeding that can occur spontaneously or following an event such as injury or surgery.

Unlike inherited hemophilia, acquired hemophilia A is not a genetic disorder and affects both males and females.

The development of acquired hemophilia A has been related to other medical conditions or health states, such as pregnancy, cancer, or the use of certain medications. However, in about half of the cases, no underlying cause can be found. Diagnosis of this condition can be difficult and the severity of the bleeding can make treatment challenging.

Obizur contains a recombinant analogue of porcine (pig) FVIII. Porcine FVIII is used because it is similar enough to human FVIII to be effective in blood clotting, but is less likely to be affected by the antibodies against human FVIII that are present in people with acquired hemophilia A.

Obizur received orphan drug designation by the FDA because the drug is intended for use in treatment of a rare disease or condition. (Source: FDA Website, 24 October, 2014)

First Vaccine Approved by FDA to Prevent Serogroup B Meningococcal Disease
The FDA has announced the approval of Trumenba, the first vaccine licensed in the United States to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B in individuals 10 through 25 years of age. Trumenba is manufactured by Wyeth Pharmaceuticals, a subsidiary of Pfizer.

Meningococcal disease is a life-threatening illness caused by bacteria that infect the bloodstream (sepsis) and the lining that surrounds the brain and spinal cord (meningitis). N. meningitidis is a leading cause of bacterial meningitis. The bacteria are transmitted from person to person through respiratory or throat secretions (e.g., by coughing, kissing, or sharing eating utensils). According to the Centers for Disease Control and Prevention, about 500 total cases of meningococcal disease were reported in the United States in 2012; of those cases, 160 were caused by serogroup B.

"Recent outbreaks of serogroup B Meningococcal disease on a few college campuses have heightened concerns for this potentially deadly disease," said Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research. "The FDA's approval of Trumenba provides a safe and effective way to help prevent this disease in the United States."

Meningococcal disease can be treated with antibiotics to reduce the risk of death or serious long-term problems, but immediate medical attention is extremely important. Vaccination is the most effective way to prevent meningococcal disease. Until today, meningococcal vaccines approved for use in the United States have only covered four of the five main serogroups of N. meningitidis bacteria that cause meningococcal disease: A, C, Y, and W.

The FDA used the accelerated approval regulatory pathway to approve Trumenba. Accelerated approval allows the agency to approve products for serious or life-threatening diseases based on evidence of a product's effectiveness that is reasonably likely to predict clinical benefit, reducing the time it takes for needed medical products to become available to the public.

Trumenba was granted breakthrough therapy status, which is intended to expedite the development and review of medical products that address a serious or life-threatening condition. Working closely with the company, the FDA was able to evaluate Trumenba's safety and effectiveness and approve it in well under six months, the usual timeframe for a priority review. (Source: FDA Website, 29 October, 2014)

FDA Approves Blincyto to Treat Rare Form of Acute Lymphoblastic Leukemia
The FDA has approved Blincyto (blinatumomab) to treat patients with Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL), an uncommon form of ALL. Blincyto is marketed by Thousand Oaks, California-based Amgen.

Precursor B-cell ALL is a rapidly growing type of cancer in which the bone marrow makes too many B-cell lymphoblasts, an immature type of white blood cell. The Philadelphia chromosome is an abnormality that sometimes occurs in the bone marrow cells of leukemia patients. The National Cancer Institute estimates that 6,020 Americans will be diagnosed with ALL and 1,440 will die from the disease in 2014.

Blincyto is an example of immunotherapy, a treatment that uses certain parts of a person's immune system to fight diseases such as cancer. Blincyto is the first approved drug that engages the body's T-cells, a type of white blood cell or lymphocyte, to destroy leukemia cells. The drug acts as a connector between a protein called CD19, which is found on the surface of most B-cell lymphoblasts, and CD3, a protein on T-cell lymphocytes. It is intended for patients whose cancer returned after treatment (relapsed) or did not respond to previous treatment (refractory).

The FDA granted Blincyto breakthrough therapy designation, priority review and orphan product designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies; the drug had the potential, at the time the application was submitted, to be a significant improvement in safety or effectiveness in the treatment of a serious condition; and the drug is intended to treat a rare disease, respectively. Blincyto is being approved more than five months ahead of the prescription drug user fee goal date of May 19, 2015, the date the agency was scheduled to complete review of the application.

Blincyto carries a boxed warning alerting patients and health care professionals that some clinical trial participants had problems with low blood pressure and difficulty breathing (cytokine release

syndrome) at the start of the first treatment, experienced a short period of difficulty with thinking (encephalopathy) or other side effects in the nervous system.

The FDA approved Blincyto with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a communication plan to inform health care providers about the serious risks and the potential for preparation and administration errors. (Source: FDA Website, 03 December, 2014)

FDA Approves Jakafi to Treat Chronic Type of Bone Marrow Disease
The FDA has approved a new use for Jakafi (ruxolitinib) to treat patients with polycythemia vera, a chronic type of bone marrow disease. Jakafi is the first drug approved by the FDA for this condition. Jakafi is marketed by Wilmington, Delaware-based Incyte.

Polycythemia vera occurs when too many red blood cells are made in the bone marrow. Patients may also experience an increase in white blood cells and platelets. An overabundance of blood cells can cause the spleen to swell, bleeding problems and blood clots in the veins near the skin surface (phlebitis). In addition, it puts patients at increased risk of stroke or heart attack.

Jakafi's new use is intended to treat polycythemia vera patients who have an inadequate response to or cannot tolerate hydroxyurea, another medicine often prescribed to reduce the number of red blood cells and platelets in the blood. Jakafi works by inhibiting enzymes called Janus Associated Kinase (JAK) 1 and 2 that are involved in regulating blood and immunological functioning.

The FDA reviewed Jakafi's use for polycythemia vera under the agency's priority review program because, at the time the application was submitted, the drug demonstrated the potential to be a significant improvement in safety or effectiveness over available therapy in the treatment of a serious condition. Priority review provides an expedited review of a drug's application. Jakafi also received orphan product designation because it is intended to treat a rare disease.

In 2011, the FDA approved Jakafi for treatment of patients with another bone marrow disorder, intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. (Source: FDA Website, 04 December, 2014)

FDA Approves Gardasil 9 for Prevention of Certain Cancers Caused by HPV
The FDA has approved Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV). Covering nine HPV types, five more HPV types than Gardasil (previously approved by the FDA), Gardasil 9 has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers. Gardasil 9 is manufactured by Merck Sharp & Dohme, a subsidiary of Merck & Co., based in Whitehouse Station, New Jersey.

Gardasil 9 is a vaccine approved for use in females ages 9 through 26 and males ages 9 through 15. It is approved for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the prevention of genital warts caused by HPV types 6 or 11. Gardasil 9 adds protection against five additional HPV types—31, 33, 45, 52 and 58— which cause approximately 20 percent of cervical cancers and are not covered by previously FDA-approved HPV vaccines.
(Source: FDA Website, 10 December, 2014)

FDA Expands Use of Cyramza to Treat Aggressive Non-Small Cell Lung Cancer
The FDA has expanded the approved use of Cyramza (ramucirumab) to treat patients with metastatic non-small cell lung cancer (NSCLC). The most common type of lung cancer, NSCLC occurs when cancer cells form in the tissues of the lung. The National Cancer Institute estimates that 224,210 Americans will be diagnosed and 159,260 will die from lung cancer in 2014. Cyramza is marketed by Indianapolis-based Eli Lilly.

Cyramza works by blocking the blood supply that fuels tumor growth. The drug is intended for patients whose tumor has grown (progressed) during or following treatment with platinum-based chemotherapy, and it is to be used in combination with docetaxel, another type of chemotherapy.

On April 21, the FDA approved Cyramza as a single agent to treat patients with advanced stomach cancer or gastroesophageal junction (GEJ) adenocarcinoma, a form of cancer located in the region where the esophagus joins the stomach. On November 5, the FDA expanded Cyramza's use to treat patients with advanced gastric or GEJ adenocarcinoma to include paclitaxel, another chemotherapy drug.

The FDA reviewed Cyramza's application for this new use under the agency's priority review program, which provides for an expedited review of drugs that are intended to treat a serious disease or condition and, if approved, would offer significant improvement compared to marketed products.
(Source: FDA Website, 12 December, 2014)

Astrazeneca's Ovarian Cancer Drug Wins FDA Approval
The FDA has granted accelerated approval to AstraZeneca's Lynparza (olaparib), a new drug treatment for women with advanced ovarian cancer associated with defective BRCA genes, as detected by an FDA-approved test. The National Cancer Institute estimates that 21,980 American women will be diagnosed with and 14,270 will die from ovarian cancer in 2014. Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. It is intended for women with heavily pretreated ovarian cancer that is associated with defective BRCA genes.

"Today's approval constitutes the first of a new class of drugs for treating ovarian cancer," said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Lynparza is approved for patients with specific abnormalities in the BRCA gene and is an example of how a greater understanding of the underlying mechanisms of disease can lead to targeted, more personalized treatment."

The FDA approved Lynparza with a genetic test called BRACAnalysis CDx, a companion diagnostic that will detect the presence of mutations in the BRCA genes (gBRCAm) in blood samples from

patients with ovarian cancer. The BRCA genes are involved with repairing damaged DNA and normally work to suppress tumor growth. Women with mutations resulting in defective BRCA genes are more likely to get ovarian cancer, and it is estimated that 10 to 15 percent of all ovarian cancer is associated with these hereditary BRCA mutations. BRACAnalysis CDx is manufactured by and performed at Salt Lake City, Utah-based Myriad Genetic Laboratories.

The FDA evaluated the BRACAnalysis CDx's safety and efficacy under the agency's premarket approval pathway used for high-risk medical devices. Until now, the manufacturer, a clinical laboratory, had been marketing this test, although not specifically for use as a companion diagnostic, without FDA approval as a laboratory developed test (LDT), which is a test that is designed, manufactured and used in a single laboratory. The new test is approved as a companion diagnostic, specifically to identify patients with advanced ovarian cancer who may be candidates for treatment with Lynparza.

"The approval of safe and effective companion diagnostic tests and drugs continue to be important developments in oncology," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "We are very excited that the BRACAnalysis CDx is the FDA's first approval of an LDT under a premarket approval application and is the first approval of an LDT companion diagnostic. The use of companion diagnostics helps bring to market safe and effective treatments specific to a patient's needs."

In June, Lynparza was reviewed by the FDA's Oncologic Drugs Advisory Committee for potential use as maintenance therapy (treatment given to keep cancer from returning). The committee advised the agency in a vote of 11 to 2 that the data did not support Lynparza's accelerated approval for this use. After the meeting, the company submitted additional information supporting Lynparza's use for a different use: in patients with gBRCAm-associated ovarian cancer who have received three or more chemotherapy treatments.

The FDA is approving Lynparza under the agency's accelerated approval program, which allows 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. This program provides earlier patient access to promising new drugs while the company conducts confirmatory clinical trials. Lynparza's application was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that are intended to treat a serious disease or condition and, if approved, would offer significant improvement compared to marketed products.

BRACAnalysis CDx's application was reviewed under the FDA's priority review program for devices, which provides for priority review of devices that meet certain criteria, including that the devices are intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition and, if approved, would offer significant, clinically meaningful advantages compared to marketed products. (Source: FDA Website, 19 December 19, 2014)

AbbVie Wins FDA Approval for Viekira Pak to Treat Hepatitis C
The FDA has approved Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets) to treat patients with chronic hepatitis C virus (HCV) genotype 1 infection, including those with a type of advanced liver disease called cirrhosis. Viekira Pak is marketed by AbbVie based in North Chicago, Illinois.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to reduced liver function, liver failure or liver cancer. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take decades. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with HCV, and without proper treatment, 15-30 percent of these people will go on to develop cirrhosis.

Viekira Pak contains three new drugs—ombitasvir, paritaprevir and dasabuvir—that work together to inhibit the growth of HCV. It also contains ritonavir, a previously approved drug, which is used to increase blood levels of paritaprevir. Viekira Pak can be used with or without ribavirin, but it is not recommended for patients whose liver is unable to function properly.

"The new generation of therapeutics for hepatitis C virus is changing the treatment paradigm for Americans living with the disease," said Edward Cox, M.D., M.P.H., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. "We continue to see the development of new all-oral treatments with very high virologic response rates and improved safety profiles compared to some of the older interferon-based drug regimens."
Viekira Pak is the fourth drug product approved by the FDA in the past year to treat chronic HCV infection. The FDA approved Olysio (simeprevir) in November 2013, Sovaldi (sofosbuvir) in December 2013 and Harvoni (ledipasvir and sofosbuvir) in October 2014. Olysio is marketed by Raritan, New Jersey-based Janssen Pharmaceuticals. Sovaldi and Harvoni are marketed by Gilead Sciences, based in Foster City, California.

Viekira Pak is the eleventh new drug product with breakthrough therapy designation to receive FDA approval. The FDA can designate a drug as a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients with serious or life-threatening diseases. Viekira Pak was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness. (Source: FDA Website, 19 December 19, 2014)

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