

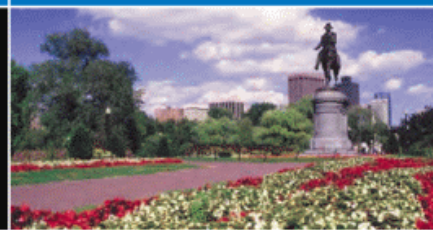
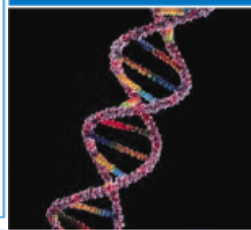


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Boston Area Chapter

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NEWSLETTER

November 2015, Volume XXV, No. 6

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President's Message: Product Show at Gillette Kicks Off a Busy Fall Season

My Fellow Boston Area Chapter Members,

As promised, the Chapter year is off to a tremendous start, thanks to the efforts of our amazing volunteers. September started off strong with the Young Professionals Annual Boat Cruise around Boston Harbor. We could not have asked for a better evening to enjoy the chance to network with the future leaders of our industry. Then in mid-September, we held a ground breaking program with the PDA New England Chapter. Over 150 attended this wildly successful event. The evening was such a success, we are already looking ahead to another joint educational event with the PDA next September.

Our flagship event, the Annual Product Show, broke all records yet again. This year there were over 2700 attendees who visited with the 377 exhibitors plus another 39 companies in the Career Fair for a grand total of 416 exhibits. There was so much going on, it was hard to decide what to see. Starting with the plenary session in the morning, there were four educational events, eight vendor showcases on the Innovation Stage, the Student Development Program, the Champions for Charity pavilion, the Young Professionals Networking Hour, and our ever-popular After-Party, this year topping out at over 800. Our keynote speakers and special guests were John Bournas, CEO and President of ISPE and Andy Skibo, Chair of the ISPE Board of Directors and Head of Global Biologics Operations & Global Engineering at AstraZeneca. Both were floored by the scope and scale of the Product Show and congratulated the Chapter on its accomplishment.

Next year's Show is already being planned and since it will be our 25th Anniversary Show, you can bet we have something special in store. Exhibitors are urged to pre-register for the Show to ensure that they don't get shut out as booths are sure to sell out early. Details can be found on our [website](#).

The Society held its Fall Classroom Training in Boston October 19-23. In conjunction with the training session, the Chapter held its Fall Social at the Baseball Tavern on October 20, giving Chapter Members an opportunity to network with the international attendees and show them how Boston has a wicked good time!

On October 25, the ISPE Nephronators team of Young Professionals and seasoned experts participated in the National Kidney Foundation Walk in Cambridge. It was a crisp autumn day and everyone enjoyed the fundraiser designed to call attention to kidney disease and the need for organ donations. Our team, sponsored by the ISPE Boston Area Chapter and The New England Patriots Charitable Foundation, was one of the top five fundraising teams with over \$8,500 donated by our membership and friends at the Product Show and Fall Social. At the Product Show, 175 attendees donated \$20 for an opportunity to have their photo taken with Patriots alumni Steve Grogan and Joe Andruzzi, the Patriots cheerleaders, and the 2015 Vince Lombardi Trophy. And at the Fall Social, 42 people entered the raffle for a chance to win a beautiful necklace donated by Kings Jewelers of Cohasset (congratulations to Ms. Ramsey who had the incredible foresight to let her husband out for the night). Thanks to all who gave so generously for this important cause.

The Chapter's altruism did not stop with just charitable contributions. This past year we had 108 volunteers who gave their time and expertise in many ways from running educational events to manning the information booth at the Product Show. Our Chapter is successful because of the efforts of these volunteers. During my keynote at the Product Show plenary session, I was especially delighted to be able to honor the outstanding contributions of some of our most dedicated volunteers with our [Chapter Awards](#). This year's winners are:

- **The Hank Moes Lifetime Achievement Award - Brian Hagopian** in recognition of his comprehensive body of work and accomplishments that are widely recognized as truly extraordinary and of positive and lasting impact on ISPE, the Boston Area Chapter and the life sciences/biopharmaceutical industry.
- **Volunteer of the Year - Chris Blackwell and Dan Mardirosian** for their work on the development of our Hubs in Providence and Worcester and helping to serve our many members who live and work outside of the Boston area.
- **Outstanding Achievement - Samir Gondalia** for his work in leading the development and deployment of the Show Guide app and other technological improvements for the Chapter.



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- **Student Chapter of the Year - Northeastern University** for bringing significant value to its Student Members and actively participating in Boston Area Chapter student-related activities.

Events like the Product Show and the educational programs do not happen without help from our membership. The Chapter needs you to volunteer your time and expertise so that we can continue to be the best Chapter in the Society. There are a couple of new ways to get involved this year. We are looking for marketing experts to join our Communications Committee. This committee is responsible for the Newsletter, the Chapter website, our weekly email blasts, and our presence on social media. If you are knowledgeable in any of these areas, we want to hear from you. We are also looking for people with an expertise in simulcasting to help us bring our educational programs live to our Hubs. And we are looking for people who are interested in starting new Hubs outside the Boston metro area so that we can expand the Chapter's reach into the rest of New England and upstate New York. Please contact the Chapter office if you can help in any of these areas. Who knows? You might be honored with one of our Chapter Awards at a future Product Show!

By the time this issue is published, a couple of Chapter events will have occurred. The first week of November, the Chapter will be hosting the Japan Affiliate as they make their way to the Annual Meeting. While here in Boston, they will be touring some of the area's newest, most innovative facilities at Shire, Biogen, AstraZeneca, and Pfizer and will join the Board for dinner and sake. Next newsletter, we will report on how that visit went as well as the proceedings from the Society's Annual Meeting in Philadelphia including our Chapter's annual social event at the Hard Rock Café.

Our next educational program will take place on November 12 at Genzyme Framingham: "Avoiding Death by PowerPoint (and Other Critical Career Skills Your Professors Forgot to Mention)." In addition to "Avoiding Death by PowerPoint," this dual-track soft skills program will also include "Leadership Lessons" which will offer tips for students and YPs on making their first job change and the more advanced "Managing Multi-Generational Staff" for seasoned professionals. The entire event will be recorded and reshown on November 18 at our Providence and Worcester Hubs in conjunction with a networking reception and light refreshments. Then on December 10, we will present an educational program on Information Systems. Be sure to get all the details and register on our [website](#).

The Board's focus continues to be the long term health of our Chapter. Toward this end we are continually working to update our policies, improve our procedures, streamline our infrastructure, and expand the many benefits we provide to our membership. One of the areas that we are working on is the establishment of an Industry Advisory Board to help provide direction on where the organization should go over the next 25 years. We have also updated our bylaws and SOPs to reflect how we are actually operating as an organization. The Chapter continues to be financially strong and remains the largest in the Society.

Since our next newsletter will be in January, I want to wish everyone a happy Thanksgiving and I hope you have a wonderful holiday season.

Warm Regards,

H. Steven Kennedy

President
ISPE Boston Area Chapter

Chapter Bulletin Board

Chapter Kicks Off New Mentoring Program

The Chapter is pleased to announce the kick off of its 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 really positive experience as well as a growth opportunity for both the mentor and the 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 getting this program built and launched.

Exhibitors! Pre-register for 2016 Product Show to Select Prime Table and Booth Locations Early

October 5, 2016 - that's the date for next year's Product Show & it's not too early to pre-register. Over 50% 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/>, complete the information requested, and pay a small deposit. Doing so gives you the opportunity of picking your location and advertising opportunities early before exhibitor registration opens next spring. Don't be left out - do it now!

Newsletter 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

Sunday, November 8, 2015

ISPE Boston Area Chapter Social at the ISPE Annual Meeting

Hard Rock Cafe, Philadelphia, PA

EVENT SUMMARY

Headed to the ISPE Annual Meeting in Philadelphia, PA? Stop by for cocktails and hors d'oeuvres at The Hard Rock Cafe for a great opportunity for networking, catching up with old friends, and striking up conversations with new colleagues. The Hard Rock Cafe is conveniently located across the street from the Marriott, in the historic Reading terminal train station! This event is for ISPE Boston Area Chapter members only and there is no cost to attend, though in order to provide a count to the venue, we ask that you pre-register.

To register:

Please email your RSVP to office@ISPEBoston.org or call the office at 781-647-4773 by **Friday, November 6**. Walk-ins will be accepted onsite.

Thursday, November 12, 2015

ISPE Avoiding Death by Powerpoint (and Other Critical Career Skills Your Professors Forgot to Mention)

Genzyme, Framingham, MA

PROGRAM SUMMARY

Join ISPE at Genzyme Framingham for an evening of soft skills presentations that have something for everyone. After a networking reception (including appetizers), the program will begin with a plenary session and will then break into a dual track format for advanced and introductory individuals in the industry.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=478

Wednesday, November 18, 2015

RE-SHOWING: ISPE Avoiding Death by PowerPoint (and Other Critical Career Skills Your Professors Forgot to Mention)

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. Dr. Wulf will also be in attendance at the re-broadcast in Worcester, MA to answer questions from both Crowne Plaza and WPI BETC attendees.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=599

Sneak Preview of Upcoming Events

Thursday, December 3, 2015



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Newsletter Archive

Young Professional's Brewery Tour
Aeronaut Brewing Co., Somerville, MA

Thursday, December 10, 2015

ISPE Information Systems
Pfizer, Andover, MA

Thursday, December 17, 2015

Re-Showing: ISPE Information Systems
Crowne Plaza Hotel Providence - Warwick, Warwick, RI and
WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

Thursday, January 21, 2016

New Facility Design for Single Use Systems
University of Massachusetts-Lowell, Lowell, MA

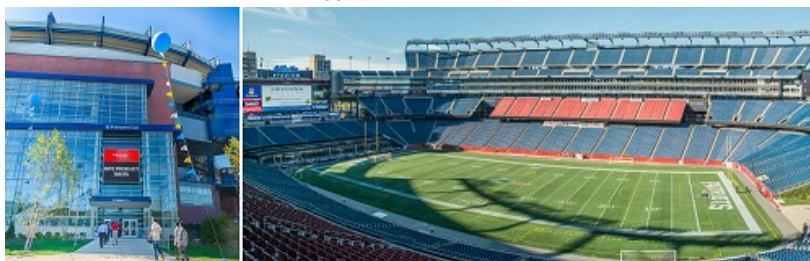
Saturday, January 30, 2016

ISPE Student Career Workshop
Northeastern University, Boston, MA

24th Annual Product Show Breaks All Records!

by Mark Levanites, Sequence Quality and Compliance Services, Chair Product Show Committee with photos by Alastair Battson Photography

What started as an incredible year in New England with a Patriot Super Bowl championship, wrapped up on October 7 at Gillette Stadium with the best ISPE Boston Area Chapter Product Show to date. Spurred by the beautiful fall weather and a full day of exciting activities, a record number of area professionals travelled to Gillette Stadium to attend our biggest Product Show ever.



The Plenary Session opened with Chapter President H. Steven Kennedy who welcomed attendees and reported that the Chapter is financially sound, continues to be the largest ISPE Chapter in the world and has an array of exciting programs and initiatives planned for the upcoming year. He concluded by presenting the 2015 Chapter Awards recognizing the outstanding efforts and accomplishments of Chapter volunteers. Award winners included:

- Hank Moes Lifetime Achievement Award: Brian Hagopian
- Volunteers of the Year: Chris Blackwell and Dan Mardirosian
- Outstanding Achievement: Samir Gondalia
- Student Chapter of the Year: Northeastern University



Chapter Award winners (clockwise, beginning at top left) Brian Hagopian, Chris Blackwell, Dan Mardirosian and Samir Gondalia accept their plaques from Chapter President H. Steven Kennedy.

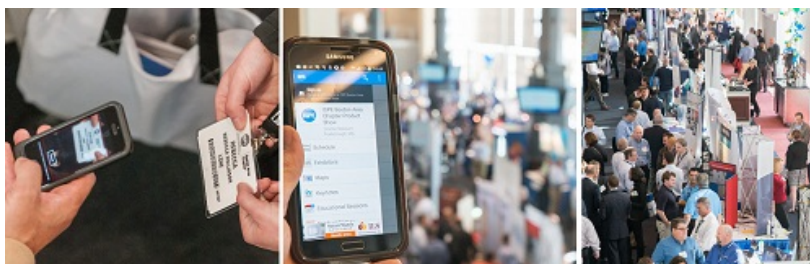
Following Steve's opening comments was special guest speaker, ISPE President & CEO John Bournas, who gave an insightful speech on the ISPE Blueprint for the Future. He laid out the Society's exciting strategy and direction for the next four years as well as providing a sneak preview of the upcoming Annual Meeting next month in Philadelphia.

Next up was the much-anticipated keynote address delivered by Andrew D. Skibo, Head of Global Biologics Operations & Global Engineering at Medimmune/AstraZeneca, and current Chairman of the ISPE Board of Directors. His talk focused on the Pharma Industry Outlook and the role of ISPE in helping to build necessary flexibility and agility back into the industry and was both insightful and well received. In case you missed them, all three Plenary Session presentations were recorded and are now available on the Product Show website at <http://productshow.ispeboston.org/attendees/show-schedule/plenary-session/>.



ISPE President & CEO John Bournas (l) and ISPE International Board of Directors Chair Andrew Skibo (r) addressed members during the Plenary Session.

Once the doors officially opened at noon, 2650 attendees (a new record high) began to filter in to visit with the 377 exhibitors on the Show floor. This year we added space between the tables and more booths and both attendees and exhibitors were happy with the new layout. Other changes included the new electronic registration/lead retrieval system and updates to the Show Guide mobile app. The new Show Guide app got rave reviews - especially since it made it a lot easier to find all the free food we added this year!



Exhibitors loved the Show's added amenities including the automated lead retrieval system, updated Show Guide mobile app and roomier exhibit space.

A full slate of training sessions was offered throughout the day and this year, for the first time, the four flagship sessions were all conveniently located in the plenary session area and held one after the other with a 30-minute break in between. This meant attendees could attend all the sessions and still be able to visit the exhibits. Topics covered were: "Keeping Up with Single-Use: An Introduction to Single-Use Manufacturing Systems" led by Geoffrey Hodge; "Implementing Innovative Technologies" led by Jorg Thommes; "Oral Solid Dosage Baseline Guide Preview" led by Jack Chu; and "Bioprocessing Intensification: Strategies for handling High-Titer Mammalian-Based Bioprocess Systems" led by John Romero. All four sessions were very well attended but if you were not able to catch them all, you can view them on the Product Show website at <http://productshow.ispeboston.org/attendees/educational-sessions/>.



Educational sessions, conveniently located adjacent to the exhibit area, drew a record turnout this year.

Throughout the afternoon on the Innovation Stage, eight exhibitors showcased their latest breakthrough technologies and techniques, including Parker dominick hunter, PTI Inspection Systems, Pressure Biosciences, Harrington Pure/E&S Technologies, ILC Dover, Clark-Reliance, Cimetrics and King Gage Engineering. Meanwhile, the Student Development Program attracted over 160 students with two sessions: "How to Network Successfully" led by Laura Poisson, Senior Vice President of Business Development and Client Services at ClearRock, Inc., and "An Introduction to Quality Systems" led by Theresa McCarthy, Pharmaceutical Sciences Audit Inspection Compliance Effectiveness Manager at Pfizer, and Byron Mattingly, Director of Systems Quality Engineering at Pathfinder Software. There were plenty of opportunities to learn something new at every level.

The Career Fair, a show within a show, was expanded this year to 39 hiring companies eager to meet with potential new employees. We partnered with Career Builder to help source talent and over 650 of the Show's attendees visited the Fair this year. Many of the visitors - 150 to be exact - took advantage of our complimentary professional photographer to get a new headshot. Feedback on the Career Fair was overwhelmingly positive all around, so if you are a hiring company, contact us and be sure to sign up early for next year's Fair.



Forty hiring companies and professional head shots drew over 650 visitors to the Career Fair.

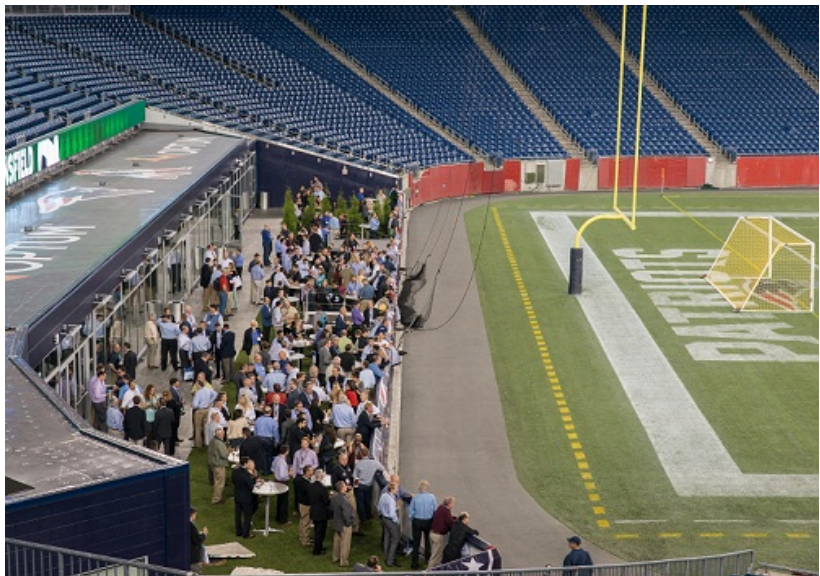
We are really excited that our Champions for Charity pavilion was a huge success. Over 175 visitors

donated over \$2000 to the National Kidney Foundation and had the opportunity to have their photo taken with New England Patriots alumni Steve Grogan and Joe Andruzzi, Pats cheerleaders and the 2015 Vince Lombardi trophy. Their donations will go toward supporting our team of walkers, the ISPE Nephronators, participating in the Boston Kidney Walk on October 25.



Pats Cheerleader Dance Team members Kayla Brunson (l) and Brittany Dickie (r) join (l to r) Andrew Skibo, Chair of the ISPE International Board of Directors; Steve Grogan, Pats Quarterback 1975-90; John Bourmas, ISPE President & CEO; Mike Arnold, Treasurer of the ISPE International Board of Directors; H. Steven Kennedy, ISPE Boston Area Chapter President; Joe Andruzzi, Pats Offensive Guard, 2000-04; and the Vince Lombardi Trophy awarded to the New England Patriots for winning Super Bowl XLIX.

And if that wasn't enough, the Young Professionals held a Networking Social Hour where students and YPs met and mingled with music provided by "industry" band Wolfpack. Later, when the exhibitor floor closed at 6:30pm, 800 attendees and exhibitors flooded into Gillette's new Optum Field Lounge in the stadium end zone to unwind, enjoy some more great food, listen to the jams of Keytar Bear, and grab a picture and autograph from Super Bowl hero, New England Patriot Malcolm Butler. A great end to a tremendous day!



Eight hundred After-Party attendees got an exciting, up close & personal view of the end zone from the brand new Optum Field Lounge.

The ISPE Boston Area Chapter is pleased that this event continues to be offered free of charge, supported in full by our generous exhibitors. This includes free parking, free admission, free food, free soft drinks, free educational seminars and free After-Party autographs. The Product Show is our Chapter's flagship event and the revenue generated funds the Chapter, allowing us to provide many worthwhile benefits for our membership. So, on behalf of the Chapter, thanks to all of our exhibitors for your continued support. We look forward to your participation next year and encourage you to pre-register. To make it easy, you can pre-register and pay your deposit online on our Product Show website at <http://productshow.ispeboston.org/reserve-space/>. Doing so will allow you to pick your booth location early once registration opens.



Lucky member David Saxner shares a photo with After-Party special guest Malcolm Butler while Mass Maritime students happily wait their turn.

Next year will be the 25th anniversary of the Product Show - our silver jubilee! It goes without saying that a Show like ours does not happen without a lot of help from many people. Our volunteers are the backbone of this organization and we are grateful for their help in making the Show a continuing success. The Product Show Committee is already hard at work planning how to top this year's extravaganza and we are always looking for enthusiastic, imaginative and fun people to help us design and run this event. If that is you and you would like to join us, please contact the Product Show Committee at office@ispeboston.org.

So mark your calendars for October 5, 2016 at Gillette Stadium and watch this space through the coming year to learn what we have planned. Thank you for your support and see you at the Product Show in 2016!

Outstanding Contributors Win Chapter Awards at Product Show

by Janet Tice, GMP Piping, with photos by Alastair Battson Photography

Well on its way to becoming an annual tradition, Chapter President H. Steven Kennedy presented this year's Annual Chapter Awards during the Product Show Plenary Session. The awards were introduced in 2013 as a way to honor the exceptional contributions of the Chapter's volunteers.



Chapter Award winners (clockwise, beginning at top left) Brian Hagopian, Chris Blackwell, Dan Mardirosian and Samir Gondalia accept their plaques from Chapter President H. Steven Kennedy.

The **Volunteer of the Year Award** recognizes Chapter Members who have demonstrated an exceptional level of dedication to the Chapter's goals and who, through their dedicated effort and involvement over the past year, have enabled the Chapter to accomplish these goals. This year's winners are **Chris Blackwell** of Hargrove Controls + Automation and **Dan Mardirosian** of WPI's Biomanufacturing Education and Training Center for their efforts on the Geographic Outreach (GO) Committee.

The **Outstanding Achievement Award** is awarded to a Chapter Member, group of Members or committee that has accomplished a specific task or completed a discrete project during the past year that has significantly contributed to the Chapter's success. This year's winner is **Samir Gondalia** of Pfizer for leading the development of the Product Show mobile app.

The **Student Chapter of the Year Award** is presented to a Student Chapter that has distinguished itself during the previous year by bringing significant value to its Student Members and participating in Boston Area Chapter student-related activities to the greatest extent possible. This year's winner is **Northeastern University**.

Named for the Chapter's founder, the **Hank Moes Achievement Award** is presented to a Chapter Member in recognition of a comprehensive body of work and specific accomplishments that are widely recognized as truly extraordinary and of positive and lasting impact on ISPE, the Boston Area Chapter and the life sciences/biopharmaceutical industry. The award is presented to **Brian Hagopian** of Clear Water Consulting for his many years of service to the Society and the Chapter in a broad range of roles including Chapter President; and for his outstanding contributions in several areas, including the Product Show, student development and the CPIP program.

The Chapter would like to extend its thanks and congratulations to this year's winners and to all the volunteers whose efforts ensure the Chapter's success.

Closing Out the Summer at Pier 6 with a Thank You to Our Volunteers

by Dan Kenny, Northeast Engineering, with photos by Joyce Chiu, Shire, and Brian Hagopian, Clear Water Consulting



With its prime location on the waterfront in Charlestown, Pier 6 provides a perfect spot for the Chapter's summertime thank you to volunteers.

With the summer coming to an end, the Chapter hosted our annual Summer Social at Pier 6 on August 27. This is the second consecutive year we have held this event at Pier 6, as its great location in the Charlestown Navy Yard and roomy outdoor space make it a perfect choice for a summer get together. This year we also used the event to thank our many Chapter volunteers who were invited to attend at no charge and turned out in force.



Volunteers (l to r) Howard Sneider, Dan Kenny & Eva Price enjoy the Chapter's recognition for their many contributions.

Members in attendance were welcomed with a gorgeous view, superb weather and an awesome spread of food. The turnout was excellent: a diverse gathering of long-time Members, Young Professionals and new Members alike. The event gave Members the opportunity to meet incoming Chapter President H. Steven Kennedy, who began his term in early August and took a few moments to thank the Chapter's many volunteers for its success. After all, the Chapter depends on the dedicated efforts of our many hard working volunteers for its success. This past year over 100 Members gave their time and expertise in many different ways, from running educational events to manning the information booth at the Product Show. In addition, Steve thanked Immediate Past President Chris Opolski and retiring Board Members Tulsa Scott, James Stout and Jillian Willard for their valuable contributions to the Chapter.



Past President Sylvia Beaulieu (r) joins Eva Price (l) and fellow members for the evening's celebration.

A special thank you to our event sponsors: Albireo Energy (formerly GxP Automation), Boston Analytical, Commissioning Agents, Festo Corporation, New England Lab, Northeast Engineering, Sentrol, Superior Controls and The Richmond Group who helped make the evening's event a success. And to Past President Jim Grunwald, Eva Price and the Social Committee for their hard work coordinating this and all of the Chapter's social events.



Outgoing President Chris Opolski displays his "silver gavel award" for Past Presidents Rick Pierro (l) and Dave Novak (r).

At the end of the evening it was clear that all who attended had had a great time and were looking forward to the next networking get together, the Fall Social at the Baseball Tavern in Boston on October 20.



Long time volunteers Joyce Chiu and Jared Marshall have earned the Chapter's thank you with years of dedicated service.

Chapter Joins Forces with New England PDA for Joint Educational Program

by Brian Hagopian, Clear Water Consulting, with photo by Shauna Barnum-Gouette, Boston Analytical

The Boston Area Chapter held its "first ever in the history of the world" joint educational program with the New England Chapter of the Parenteral Drug Association (PDA) on September 16. Turnout was record-breaking with over 150 in attendance. The program was re-aired in video format for Chapter Members in our Providence and Worcester "hubs" a week later, at the Crowne Plaza Hotel in Warwick and WPI's Biomanufacturing Education and Training Center in Worcester, with accompanying networking reception at each location.

The program focused on "Process Validation Lifecycle Approaches: A Return to Science" and featured two distinguished speakers: Hal Baseman, COO of Valsource, and Rusty Morrison, Principal Consultant at CAI Consulting, who led us through thought provoking presentations that touched on topics as diverse as the pressures faced by regulators by the US Department of Public Health, to challenging the "3 batch" rule, and the science behind taking a risk-based approach to establish how many batches are actually required.



PDA New England Chapter President Jonathan Morse (second from left) and ISPE Boston Area Chapter President H. Steven Kennedy (far right) share the limelight with presenters Hal Baseman (far left) and Rusty Morrison.

Hal opened the session by providing some history and background on the link between quality issues and drug shortages in the past, reviewed the evolution of the concept of process validation, and stressed the importance of identifying potential sources of variation and establishing controls during the process development stage of a product.

Rusty followed with a discussion of how manufacturing history and process knowledge can be leveraged to identify risks and establish levels of confidence in a particular process. Each process is different and risk analysis tools can be employed to arrive at the correct number of batches required. Rusty indicated that the number of batches should not be used as a way to check if a process is under control but rather as proof that the process is under control.

Both speakers cited the complimentary missions of ISPE and PDA and cited references to materials published by each society on this topic. The audience came away with the clear message that process validation is an ongoing process and data generated during manufacturing should be reviewed continuously and integrated to establish the robustness (or lack thereof) of a process.

With over 150 professionals in attendance, the program clearly demonstrated the advantages of pooling knowledge and collaborating. With all the positive feedback generated by the event, this type of collaborative program will surely be repeated. Congratulations to meeting managers Laurie Masiello and Mary Griffin from PDA and Brian Hagopian and Mallory Duquesne from ISPE for the success of this "first of its kind" educational program.

Chapter Hosts ISPE Trainees at Fall Social

by Dan Kenny, Northeast Engineering

A beautiful autumn evening greeted attendees at the Chapter's Annual Fall Social held at the Baseball Tavern near Fenway Park on October 20. The Social Committee scheduled the event to coincide with the ISPE Fall Classroom Training being held in the Fenway area October 19-23 and the turnout was great. The event enabled Chapter Members to network and socialize with ISPE trainees from all over the world in addition to their peers from the Boston area. The Baseball Tavern was a great host for the group and the spread they put out did not disappoint.



The Chapter hosted an international group of ISPE members at the Baseball Tavern for this year's Fall Social.

In keeping with Chapter tradition, the social had an altruistic side as well, as it featured a raffle designed to raise money for the National Kidney Foundation and the Chapter's ISPE Nephronators taking part in the Boston Kidney Walk the following Sunday. Forty-two people entered the raffle for a chance to win a beautiful necklace donated by Kings Jewelers of Cohasset and added their donations to the almost \$7000 already raised by the Chapter for the NKF. Thanks to all who gave so generously for this important cause.



President Steve Kennedy presented the raffle prize to lucky winner & new Chapter member Kyle Roberts of CAI.

Lastly, a special thanks to the Social Committee for organizing another great networking event. Including the ISPE trainees made it unique and gave Chapter Members a chance to show they know how to party!

It's not too early to start looking forward to our next networking get together: the Holiday Social in January 2016. See you there!

Chapter Members

by Christopher Ciampa, Thermo Fisher Scientific

On Sunday, October 25, the Boston Area Chapter took part in a two-mile walk organized as a fundraiser by the National Kidney Foundation. The event took place at Canal Park, which is connected to the Cambridgeside Galleria area in Cambridge. In addition to fundraising, the Walk strives to raise awareness, educate the public and promote organ donation.



YP Committee Chair & Kidney Walk coordinator Chris Ciampa (r) with Chapter members (l to r) Tom Struble and Jared Marshall.

The name of our team was the "ISPE Nephronators" which combined a play on words from the Terminator movie franchise with "nephros," the Greek word for "kidney." Over 20 Chapter Members signed up to walk and some folks even brought their families with them! This event had special meaning for the Chapter since the wife of Past President and Chapter Founder Richard Priester has developed kidney disease. Luckily, her story is positive as she will be receiving a transplant on December 1, however, not everyone suffering from the disease has as fortunate an outcome.



Congratulations to the "ISPE Nephronators" and Chapter members who raised over \$8500 for the National Kidney Foundation!

The two-mile walk started at 10:30am and wound around the Cambridge area, beginning at Canal Park, continuing through the Lechmere area, looping around near the Museum of Science and eventually returning to Canal Park. As of that day, the Chapter ranked fifth for top team donations, with total donations of over \$8,500! The Nephronators had a goal of \$3,000 and was able to beat that goal by over 150 percent! Great job, everyone!

Still want to donate, but missed the walk? Donations are still being accepted! Donations can be submitted via check, made out to "The National Kidney Foundation" and mailed to National Kidney Foundation, Attn: Boston Kidney Walk, 85 Astor Avenue, Suite 2, Norwood, MA 02062. Put **Team ISPE Nephronators** in the Memo line! The Kidney Walk website will also continue accepting donations via credit card until January 25, 2016 at http://donate.kidney.org/site/TR/Walk/NewEngland?pg=entry&fr_id=7592.

Keeping Up with the YPs...

by Chris Ciampa, Thermo Fisher Scientific, with photos by Joyce Chiu, Shire, and Alastair Battson Photography

Happy fall! The crisp New England air is now upon us - you can already smell the aroma of wood burning. As I wrote this, the Product Show was in full swing and as you may have read elsewhere in this newsletter, it was a very successful event! See below for a Product Show recap from the YP perspective plus comments on other recent events. After that we'll let you know what to expect for the next few months.

Our Annual Boston Harbor Cruise took place during the first week in September on a balmy summer night perfect for sailing the local waters. Sponsored by the YPs, the Harbor Cruise welcomes all Chapter Members and their guests, which numbered close to 50 people this year. Next year, we plan to schedule the event closer to the end of September so that our returning student chapter members can attend. Also, given the success of the joint ISPE/PDA educational event in September, we are looking into partnering with another local organization (such as the PDA) for a YP social event in 2016, which may just be the Harbor Cruise!



The Boston skyline provided a magical backdrop for this year's harbor cruise.

As always, the Product Show was a great event with lots of special activities for Young Professionals. This year's YP Networking Hour took place an hour before the Product Show ended and attracted a record turnout - a mix of students and young working professionals - with food, drink, a gift card raffle and live entertainment. We collected contact information so the attendees can be invited to join the Young Professionals Committee and become even more active in the future.

This year's Product Show Career Fair grew by leaps and bounds over prior years, with a grand total of 39 hiring companies on hand to chat with potential applicants. Both YPs and students took advantage of the opportunity to talk informally with hiring managers & learn what the industry has to offer new grads and YPs moving up the career ladder.



YPs joined students & others at this year's highly successful Career Fair.

On October 25, the Chapter took part in the 2015 Boston Kidney Walk presented by the National Kidney Foundation and the YPs played a lead role in that effort. Our team was called the "ISPE Nephronators" and we had a sizeable group participating. A "Champions for Charity" booth at the Product Show as well as a raffle at the Fall Social were used to raise awareness and donations for the event. All in all, the Chapter raised over \$8,500 for the NKF and its efforts to eradicate kidney disease and promote organ donation. NKF is still taking donations, so help our team continue to raise funds by [clicking here to donate](#).



Chapter founder Tom Moss supported the ISPE Nephronators and the National Kidney Foundation with a donation at the Product Show's "Champions for Charity" pavilion.

On November 12, there will be a dual track educational program held at Genzyme in Framingham with a focus on "soft" skills. The two-part program is geared for both Young Professionals/Students and also more seasoned members and has been designed to facilitate networking opportunities. The speaker for the YP event is Larry Elle who will discuss "Making Your First Job Change." His talk is intended to help young professionals understand what is needed to move beyond the entry level and take that first step up the industry career ladder. This will be a great opportunity for students and YPs to network with other Members. Who knows? They may even create connections leading to that first job change!

Last December the YPs tried a new type of event: a tour at a local microbrewery. Given the success of that event, we have decided to host another one during the first week of December and we are targeting Aeronaut Brewery in Somerville. The event will include a brewery tour as well as appetizers, networking, and of course a great craft beer selection. Keep an eye out for more information - this is one event you don't want to miss!

As you may have heard, a Chapter-wide Mentoring Program is currently in the works. This program will be designed to connect like-minded Young Professionals/students with seasoned Members in a year-long partnership that will help mentees achieve their career objectives. Details on the program are on the Chapter Bulletin Board section of the newsletter and is also posted on the Chapter website at <http://www.ispeboston.org/mentoringdescription.html>.

As always, we want to hear from you! If you have any suggestions or would like to attend one of the regularly scheduled YP meetings, please don't hesitate to reach out to me at christopher.ciampa@gmail.com. Thank you for tuning in and I hope you all enjoy the rest of your fall season!

Annual Product Show Wows Students

by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer with photos by Alastair Battson Photography

September was a busy month for our Student Chapters as many held organizational and recruiting meetings in advance of the Product Show, a wildly successful event for students. Funded buses transported about 200 students to the Show, one of our signature events, where two "student specific" educational programs, the Career Fair and the student/YP social, made for a really exciting day.

The Product Show featured two "top tier" educational programs specifically for students this year. First, Laura Poisson from ClearRock Inc., a Boston-based executive coaching and outplacement firm, helped students understand how to network at the Product Show and touched on topics including elevator speeches, making good first impressions and body language. Laura's presentation was well received by those in attendance. Our second presentation featured Theresa McCarthy from Pfizer and Byron Mattingly from Pathfinder Software who provided an excellent introduction to Quality Systems, something that students typically don't study in college. Theresa and Byron are both deeply involved with the American Society for Quality (ASQ) and we were thrilled to have them speak to our students. Copies of these presentations are available on the Product Show website, here: <http://productshow.ispeboston.org/attendees/student-development-program/>.

The Northeastern Student Chapter was highlighted during Chapter President H. Steven Kennedy's opening remarks as winner of the highly coveted "Student Chapter of the Year" award for their significant efforts and accomplishments over the last twelve months. There was a lot of buzz on campus with students and faculty after the Show about the best location to prominently display the ISPE award plaque. Congratulations to everyone at Northeastern!

Our two Student Poster Competition winners, D. Ezra Aurian-Blajeni (undergraduate winner) and Sydney Shaw (graduate winner) had the chance to display their posters and practice their presentations in advance of the upcoming competition at the ISPE Annual Meeting.

The Student Development Committee has been working on a promotional video to show students the benefits of joining ISPE. Interviews were filmed during the Product Show and we expect to have the video completed by Christmas. Thanks to the following Chapter leaders for their participation:

- Paige Kane (Pfizer and Student Development Committee co-chair),
- Diane Hewitt (UMass Lowell Career Counselor),
- Travis Masur (Barry Wehmiller Design Group and UNH alum),
- Nick Sweeney-Cook (UNH Student Chapter President),
- Norline Crossdale-Walker (Genzyme),
- Andre Walker (Biogen and WPI alum),
- Rick Pierro (Superior Controls and UMass Lowell alum),
- Rick Robar (UMass Amherst Dean's office),
- Jillian Willard (Genzyme and Tufts alum),
- Sydney Shaw (Genzyme and Northeastern alum),
- Russell Carr (UNH Professor and Chair of the Department of Chemical Engineering),
- Nathaniel Swanson (UMass Lowell Student Chapter President) and
- Brian Hagopian (Clear Water Consulting and Student Development Committee co-chair).

And lastly, the Chapter's current scholarship application period closed November 1. Awards of up to \$2000 are available so hopefully you have submitted your online application for an excellent chance to receive funding to help with your education. And if you missed the November deadline, go ahead and submit your application now - it will be considered for the next round June 1. Full details and a link to the online application can be found on the Chapter website at <https://scholarships.ispeboston.org/scholarships/>.

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.

United Therapeutics Agrees to Sell Priority Review Voucher to AbbVie for \$350M

United Therapeutics Corporation announced that it has entered into an agreement to sell its Rare Pediatric Disease Priority Review Voucher (PPRV) to a subsidiary of AbbVie Inc. United Therapeutics received the PPRV when Unituxin was approved by the FDA for the treatment of neuroblastoma, a rare pediatric disease. Upon closing of the transaction, United Therapeutics will receive \$350 million in cash in exchange for the PPRV. AbbVie has not disclosed what the PPRV will be used for.

The voucher was awarded by the FDA under a provision that encourages development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. A PPRV is issued to eligible sponsors of a rare pediatric disease product application and entitles the holder to priority review of a single New Drug Application or Biologics License Application, which reduces the target review time. The sponsor receives the PPRV upon approval of the rare pediatric disease product application and it can be sold without limitation.

This is the highest a company has paid for a PPRV. Back in May, Sanofi paid Retrophin Inc. \$245M for its priority review voucher. (Source: United Therapeutics Website, 19 August, 2015; and Retrophin Website, 06 July, 2015)

Genzyme Opts Into Alnylam Hemophilia Program

Alnylam Pharmaceuticals and Genzyme, a Sanofi company, announced that Genzyme has elected to opt into Alnylam's investigational ALN-AT3 hemophilia program for development and potential future commercialization in territories outside of North America and Western Europe.

This marks the first product from Alnylam's Genetic Medicines pipeline to which Genzyme has opted into since the formation of the companies' global alliance in January 2014, and the third product opt-in overall. (The first two, occurring at the close of the deal in early 2014, were for patisiran and revusiran, investigational RNAi therapeutics for the treatment of transthyretin-mediated amyloidosis.) Genzyme's opt-in decision for ALN-AT3 was based on encouraging clinical data from the Phase 1 trial, including positive interim data that were presented at the International Society on Thrombosis and Haemostasis (ISTH) 2015 Congress in June 2015.

In January 2014, Alnylam and Genzyme formed an alliance to accelerate and expand the development and commercialization of Alnylam's RNAi therapeutics. The alliance covers multiple products and countries. Under the alliance, Alnylam retains product rights in North America and Western Europe, while Genzyme obtained the right to access certain programs in Alnylam's current and future Genetic Medicines pipeline in the rest of the world through the end of 2019, along with certain broader co-development/co-commercialization rights and global rights for certain products. Alnylam maintains development and commercialization control for all programs in its territory.

In the case of ALN-AT3, Genzyme has elected to opt into the program for its Rest of World rights. Genzyme retains its future opt-in right to co-develop and co-promote ALN-AT3 with Alnylam in North America and Western Europe. Specifically, Genzyme has the right to either co-develop and co-promote ALN-AT3 in Alnylam's territory - with Alnylam maintaining development and commercialization control - or to maintain its Rest of World rights for ALN-AT3 and, if exercised by Genzyme, obtain a global license to ALN-AS1, Alnylam's investigational RNAi therapeutic for the treatment of acute hepatic porphyrias. Genzyme will

exercise this selection right upon completion of human proof-of-concept for the ALN-AS1 program, which is expected to occur in 2016. (Source: Alnylam Website, 01 October, 2015)

Lonza and Benitec to Develop Viral Based Therapeutic Manufacturing Process

Lonza and Benitec Biopharma, a clinical stage biotechnology company commercializing a patented gene-silencing technology, DNA-directed RNA interference (ddRNAi), announced that they have entered into a Manufacturing Services Agreement to develop a scalable manufacturing process for Benitec's ddRNAi-based, Adeno-Associated Virus (AAV)-delivered products intended for therapeutic use in humans. Benitec's lead ddRNAi-based therapy is in clinical studies for hepatitis C.

Lonza already has a facility in Houston, Texas with viral based manufacturing processing capabilities, which is anticipated to enable the production of sufficient material to meet the potential demand for treating diseases, such as hepatitis C, that affect millions of people. (Source: Lonza Website, 07 October, 2015)

Global Blood Therapeutics Granted Fast Track designation for Sickle Cell Therapy

Global Blood Therapeutics, a biopharma developing novel therapeutics for the treatment of blood-based disorders announced that the FDA has granted Fast Track designation to GBT440 for the treatment of sickle cell disease (SCD).

GBT440 works by increasing hemoglobin's affinity for oxygen. Since oxygenated sickle hemoglobin does not polymerize, GBT440 blocks polymerization and the resultant sickling of red blood cells (RBCs). With the potential to restore normal hemoglobin function, GBT440 may be capable of modifying the progression of SCD. Currently, GBT440 is being investigated in an ongoing Phase 1/2 clinical trial in both healthy subjects and SCD patients.

The FDA's Fast Track process is designed to expedite the clinical development and submission of a New Drug Application (NDA) for medicines with the potential to treat serious or life-threatening conditions and address an unmet medical need (i.e., a condition whose treatment or diagnosis is not addressed adequately by available therapy). A drug program with Fast Track designation enables the company to have early and frequent communication with the FDA in the development and review of the product candidate, often leading to faster drug approval and access by patients.

This announcement comes two months after the company's IPO of 6,900,000 shares of common stock at a price of \$20.00 per share. Global Blood Therapeutics estimated the net proceeds from the offering to be approximately \$126.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

The company's common stock is listed on the NASDAQ Global Select Market under the ticker symbol "GBT" and is currently trading at over \$48 per share. GBT is also researching and development activities targeted toward hypoxemic pulmonary disorders, including idiopathic pulmonary fibrosis (IPF), and hereditary angioedema (HAE). (Source: Global Blood Therapeutics Website, 11 August, 17 August & 12 October, 2015)

Cambridge-based Editas Medicine Raises \$120M to Expand Genome Editing Platform

Editas Medicine announced that it has raised \$120M in a highly oversubscribed Series B private financing from a number of public and private investors. Editas is researching the use of CRISPR/Cas9 technology to treat a broad range of diseases by enabling precise and corrective molecular modifications to treat disease at the genetic level through the development of their genome editing platform.

Genome editing enables modifications of DNA at specific target sequences. The CRISPR (Clustered, Regularly Interspaced Short Palindromic Repeats)/Cas9 (CRISPR-associated protein 9) system is the newest genome editing approach. CRISPR/Cas9 genome editing uses a protein-RNA complex composed of an enzyme known as Cas9 bound to a guide RNA molecule designed to recognize a particular DNA sequence. The RNA molecule guides the Cas9 complex to the location in the genome that requires repair. Recent advances in CRISPR-Cas9 genome editing have made it possible to modify almost any gene in the human body with the ability to directly turn on, turn off or edit disease-causing genes. (Source: Editas Medicine Website, 10 August 2015)

Sarepta Therapeutics Receives Rare Pediatric Disease Designation from FDA for Eteplirsen for Treatment of Duchenne Muscular Dystrophy

Sarepta Therapeutics announced that the FDA has granted Rare Pediatric Disease Designation for eteplirsen, a potential treatment for patients with Duchenne Muscular Dystrophy (DMD). The Rare Pediatric Disease Designation supplements the Orphan Drug Designation and Fast Track Status previously granted by the FDA for eteplirsen. Sarepta may also qualify for a Rare Pediatric Disease Priority Review Voucher.

The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily aged from birth to 18 years. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application (NDA) or biologics license application (BLA) for a rare pediatric disease may be eligible for a voucher which can be redeemed to obtain priority review for a subsequent marketing application for a different product. The Priority Review Voucher may be sold or transferred an unlimited number of times.

The company also announced that they have been verbally informed that the FDA Advisory Committee is tentatively scheduled to review the New Drug Application (NDA) for eteplirsen on January 22, 2016. Although the company has received verbal notice, there has been no formal communication to the company or Federal Register notice of a confirmed advisory committee meeting date. The action date for

the application is February 26, 2016.

Sarepta Therapeutics is focused on the discovery and development of RNA-targeted therapeutics for the treatment of rare, infectious and other diseases. The Company is primarily focused the development of its DMD drug candidates, including its lead DMD product candidate, eteplirsen, designed to skip exon 51. Sarepta is also developing therapeutics for the treatment of infectious diseases such as drug-resistant bacteria and other rare human diseases.

DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. One of the most common fatal genetic disorders, DMD affects approximately one in every 3,500 boys born worldwide. A devastating and incurable muscle-wasting disease, DMD is associated with specific errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Progressive muscle weakness in the lower limbs spreads to the arms, neck and other areas. Eventually, increasing difficulty in breathing due to respiratory muscle dysfunction requires ventilation support, and cardiac dysfunction can lead to heart failure. The condition is universally fatal, and death usually occurs before the age of 30. (Source: Sarepta Therapeutics Website, 21 August & 14 October, 2015)

GSK to Divest MS Therapy to Novartis for Up to \$1B Plus Royalties

GlaxoSmithKline announced an agreement with Novartis Pharma AG to divest its rights in ofatumumab for auto-immune indications, including multiple sclerosis. Novartis Pharma previously acquired the oncology indications for ofatumumab (Arzerra) as part of the major three-part transaction between GSK and Novartis that completed earlier this year. After completion of the transaction announced today, Novartis Pharma will own rights to ofatumumab in all indications.

The consideration payable by Novartis Pharma to GSK may reach up to \$1,034M and comprises a series of milestone payments as follows:

- \$300 million payable at closing;
- \$200 million payable subject to the start of a Phase 3 study in relapsing remitting multiple sclerosis by Novartis;
- further contingent payments of up to \$534M payable on the achievement of certain other development milestones.

Novartis Pharma will also pay royalties of up to 12 per cent to GSK on any future net sales of ofatumumab in auto-immune indications. (Source: GSK Website, 21 August, 2015)

Sanofi and Google Life Sciences to Collaborate on Diabetes

Sanofi and the life sciences team at Google announced that they are collaborating to improve care and outcomes for people with type 1 and type 2 diabetes. The collaboration will pair Sanofi's experience in diabetes treatments and devices with Google's expertise in analytics, miniaturized electronics and low power chip design. Sanofi and the life sciences team at Google will work on better ways to collect, analyze and understand multiple sources of information impacting diabetes. The hope is that it will be easier for patients to successfully manage their diabetes, which would reduce the risk of complications, improve outcomes and ultimately lower costs. (Source: Sanofi Website, 31 August, 2015)

AGTC Achieves Milestone in Biogen Collaboration, Earns \$5M Payment, to Open Cambridge Office

Applied Genetic Technologies Corporation (ATGC), a biotech conducting human clinical trials of adeno-associated virus (AAV)-based gene therapies for the treatment of rare eye diseases, announced it met a patient enrollment milestone in the X-Linked Retinoschisis (XLRS) clinical study, which will earn AGTC a \$5M payment from Biogen.

AGTC filed an Investigational New Drug (IND) application with the FDA in March to conduct a Phase 1/2 clinical trial of the company's candidate for the treatment of XLRS. This marks the first milestone since AGTC and Biogen announced in July a broad collaboration agreement focused on the development of gene-based therapies for two orphan diseases of the retina and three options for early stage discovery programs in two ophthalmic and one non-ophthalmic condition. Biogen has completed the \$124M equity purchase and up-front payment.

The company also announced the opening of a new office facility in Cambridge. The office, which will be located at One Kendall Square, is a second U.S. location to the company's headquarters in Gainesville, Florida. The new location in Cambridge, consisting of office and laboratory space, will focus on business development, pharmacology and basic R&D. (Source: Applied Genetic Technologies Corporation Website, 27 August and 02 September, 2015)

Shire Drug Receives FDA Fast Track Designation for Treatment of Antibody Mediated Rejection (AMR) in Kidney Transplant Patients

Shire plc announced that the FDA has granted Fast Track designation for the investigation of CINRYZE® for intravenous administration in subjects with Antibody Mediated Rejection (AMR) in renal transplant recipients. CINRYZE is being studied as an adjunct treatment to Donor Specific Antibodies (DSA) reduction therapy in kidney transplant patients with acute AMR. CINRYZE is already approved for routine prophylaxis against angioedema attacks in adolescent and adult patients with Hereditary Angioedema (HAE).

Shire is planning a Phase 3 trial to evaluate the efficacy of CINRYZE as an adjunct to DSA reduction therapy for the treatment of acute AMR in kidney transplant recipients. The trial will be conducted in the United States, Europe and Canada and the study will open for enrollment by the end of October 2015.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs that address serious or life-threatening conditions and that demonstrate the potential to address unmet

medical needs. Fast Track designation may provide increased opportunities to interact and meet with FDA, and potentially increases the likelihood of being eligible for priority review if relevant criteria are met. (Source: Shire Website, 13 October, 2015)

BMS Enters Agreement to Acquire Promedior and Drug in Development for Fibrotic Diseases

Bristol-Myers Squibb Company and Promedior, Inc. announced the companies have entered into an agreement that grants Bristol-Myers Squibb an exclusive right to acquire Promedior and gain worldwide rights to its lead asset PRM-151, a recombinant form of human pentraxin-2 protein in Phase 2 development for the treatment of idiopathic pulmonary fibrosis (IPF) and myelofibrosis (MF). PRM-151 has been granted Fast Track designation in the U.S. and Orphan designation in the U.S. and Europe for the treatment of MF and Orphan Designation in the U.S. and Europe for the treatment of IPF.

Promedior is a clinical stage immunotherapy company pioneering the development of targeted therapeutics to treat fibrotic diseases. Total aggregate payments to Promedior under the agreement have the potential to reach \$1.25B, which includes an upfront cash payment for the right to acquire Promedior, an exercise fee payable if Bristol-Myers Squibb elects to exercise its right to acquire the company, and subsequent clinical and regulatory milestone payments.

PRM-151 has been shown in multiple preclinical models to regulate monocytes and macrophages at areas of tissue damage to prevent and reverse fibrosis, including IPF, acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration. Promedior has advanced PRM-151 into clinical trials focused on two orphan fibrotic diseases (MF and IPF).

Bristol-Myers Squibb is developing an early stage fibrosis portfolio that includes BMS-986020, a lysophosphatidic acid 1 (LPA1) receptor antagonist in Phase 2 development for the treatment of idiopathic pulmonary fibrosis. Other areas of focus include nonalcoholic steatohepatitis (NASH), systemic sclerosis, and chronic kidney disease. Additionally, the company has executed a series of agreements aimed at further advancing its fibrosis development program, including an option to acquire Galecto Biotech AB, a company with an inhaled inhibitor of galectin-3 in Phase 1 development for the treatment of idiopathic pulmonary fibrosis, a research collaboration and license agreement with the California Institute for Biomedical Research (Calibr), and a translational research collaboration with The Medical University of South Carolina.

Under the terms of the agreement, Bristol-Myers Squibb will make payments aggregating up to \$1.25B that includes an upfront cash payment of \$150M as consideration for both the right to acquire Promedior and as payment for services in support of the MF and IPF Phase 2 clinical trials. The companies have agreed on a development plan that will be executed by Promedior. It is anticipated that the Phase 2 trials in MF and IPF will be initiated in the coming weeks. Bristol-Myers Squibb can exercise its right to acquire Promedior upon completion of either of these trials. (Source: Bristol-Myers Squibb Website, 31 August, 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 Extends Use of Novartis Drug Promacta

The FDA has approved the Novartis drug Promacta to treat low blood platelet count in pediatric patients - ages one year and older - with a rare blood disorder called chronic immune thrombocytopenic purpura (ITP). Promacta can be used in these children when they have not achieved an appropriate response using other ITP medicines or surgery to remove the spleen.

ITP is a disorder that results in an abnormally low number of platelets, the cells that help blood clot. Without enough platelets, bleeding can occur under the skin, in mucous membranes (such as in the mouth) or in other parts of the body. Promacta helps increase blood platelet production and is available as a tablet taken once-daily or as a powder that is mixed with liquid for children ages one to five to take orally. It was first approved in 2008 to treat adult patients with the same condition as the new pediatric indication. (Source: FDA Website, 24 August, 2015)

Amgen's Repatha Approved to Treat High Cholesterol

The FDA has approved Repatha injection for some patients who are unable to get their low-density lipoprotein (LDL) cholesterol under control with current treatment options. Repatha is marketed by Amgen of Thousand Oaks, Calif. It is the second drug approved in a new class of drugs known as PCSK9 inhibitors. Repatha approved for use in addition to diet and maximally-tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or clinical atherosclerotic cardiovascular disease, such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

Familial hypercholesterolemia (encompassing both HeFH and HoFH) is an inherited condition that causes high levels of LDL cholesterol. A high level of LDL cholesterol in the blood is linked to cardiovascular or heart disease. Heart disease is the number one cause of death for Americans, both men and women. According to the CDC, about 610,000 people die of heart disease in the United States every year - that equals one in every four deaths.

Repatha is an antibody that targets a specific protein called PCSK9 that reduces the number of receptors on the liver that remove LDL cholesterol from the blood. By blocking PCSK9's ability to work, more receptors are available to get rid of LDL cholesterol from the blood and, as a result, lower LDL cholesterol levels. (Source: FDA Website, 27 August, 2015)

FDA Approves New Drug from Waltham-based Tesaro

The FDA has approved Varubi to prevent delayed phase chemotherapy-induced nausea and vomiting. Varubi is approved in adults in combination with other drugs that prevent nausea and vomiting associated with initial and repeat courses of vomit-inducing cancer chemotherapy. Varubi is marketed Waltham-based Tesaro Inc.

Nausea and vomiting are common side effects experienced by cancer patients undergoing chemotherapy. Symptoms can persist for days after the chemotherapy drugs are administered. Nausea and vomiting that occurs from 24 hours to up to 120 hours after the start of chemotherapy is referred to as delayed phase nausea and vomiting, and it can result in serious health complications. Prolonged nausea and vomiting can lead to weight loss, dehydration and malnutrition in cancer patients leading to hospitalization.

Varubi is a substance P/neurokinin-1 (NK-1) receptor antagonist. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by certain cancer chemotherapies, particularly in the delayed phase. Varubi is provided to patients in tablet form. (Source: FDA Website, 02 September, 2015)

FDA Approves New Drug to Treat Schizophrenia and Bipolar Disorder

The FDA has approved Vraylar capsules to treat schizophrenia and bipolar disorder in adults. Vraylar is manufactured by Forest Laboratories of Jersey City, New Jersey and distributed by Actavis Pharma of Parsippany, New Jersey.

Schizophrenia is a chronic, severe and disabling brain disorder affecting about one percent of Americans. Typically, symptoms are first seen in adults younger than 30 years of age and include hearing voices or seeing things that are not there, believing other people are reading their minds or controlling their thoughts, and being suspicious or withdrawn.

Bipolar disorder, also known as manic-depressive illness, is another brain disorder that causes unusual shifts in mood, energy, activity levels and the ability to carry out day-to-day tasks. The symptoms of bipolar disorder include alternating periods of depression and high, irritable mood, increased activity and restlessness, racing thoughts, talking fast, impulsive behavior and a decreased need for sleep.

Vraylar and all other FDA-approved drugs used to treat schizophrenia and bipolar disorder have a Boxed Warning alerting health care professionals about an increased risk of death associated with the use of these drugs in older people with dementia-related psychosis. Neither Vraylar nor any other drug in this class is approved to treat such patients. (Source: FDA Website, 17 September, 2015)

FDA Approves Alkermes Injectable Drug to Treat Schizophrenia

The FDA has approved Aristada extended release injection to treat adults with schizophrenia. Aristada is administered by a health care professional every four to six weeks. Aristada is manufactured by Alkermes, of Waltham, Massachusetts

Schizophrenia is a chronic, severe and disabling brain disorder affecting about one percent of Americans. Typically, symptoms are first seen in adults younger than 30 years of age and include hearing voices, believing other people are reading their minds or controlling their thoughts, and being suspicious or withdrawn.

Aristada and other atypical antipsychotic drugs used to treat schizophrenia have a Boxed Warning alerting health care professionals about an increased risk of death associated with the off-label use of these drugs to treat behavioral problems in older people with dementia-related psychosis. No drug in this class is approved to treat patients with dementia-related psychosis. Aristada must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. (Source: FDA Website, 05 October, 2015)

FDA Approves Two New Drug Treatments for Diabetes

The FDA approved Tresiba and Ryzodeg 70/30 to improve blood sugar (glucose) control in adults with diabetes mellitus. Tresiba is a long-acting insulin analog indicated to improve glycemic control in adults with type 1 and 2 diabetes mellitus. Dosing of Tresiba should be individualized based on the patient's needs. Tresiba is administered subcutaneously once daily at any time of day.

Ryzodeg 70/30 is a mixture of insulin degludec, a long-acting insulin analog, and insulin aspart, a rapid-acting human insulin analog. It is indicated to improve glycemic control in adults with diabetes mellitus. Tresiba and Ryzodeg are manufactured by Novo Nordisk in Plainsboro, New Jersey. (Source: FDA Website, 25 September, 2015)

FDA Approves Keytruda for Advanced Non-Small Cell Lung Cancer

The FDA has granted accelerated approval for Keytruda to treat patients with advanced (metastatic) non-small cell lung cancer (NSCLC) whose disease has progressed after other treatments and with tumors that express a protein called PD-L1. Keytruda is approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test, the first test designed to detect PD-L1 expression in non-small cell lung tumors.

Keytruda 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, Keytruda may help the body's immune system fight the cancer cells. In 2014, Keytruda was approved to treat patients with advanced melanoma following treatment with ipilimumab, a type of immunotherapy. Another drug, Opdivo, manufactured by Bristol-Meyers Squibb, also targets the PD-1/PD-L1 pathway and was approved to treat squamous non-small cell lung cancer (a certain kind of NSCLC) in 2015.

The FDA granted Keytruda breakthrough therapy designation for this indication because Merck demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies. The drug also received priority review status, which is granted to 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.

Keytruda is marketed by Merck & Co., based in Whitehouse Station, New Jersey. The PD-L1 IHC 22C3 pharmDx diagnostic test is marketed by Dako North America based in Carpinteria, California. (Source:

FDA Expands Approved Use of Bristol-Myers Drug Opdivo for Lung Cancer

The FDA has approved Opdivo to treat patients with advanced (metastatic) non-small cell lung cancer whose disease progressed during or after platinum-based chemotherapy. 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.

While patients who received Opdivo lived longer than those who received docetaxel across the study, an evaluation of samples from a subgroup of patients' tumors suggests that the level of PD-L1 expression in NSCLC tumors may help identify patients who are more likely to live longer due to treatment with Opdivo. Therefore, today the FDA also approved the PD-L1 IHC 28-8 pharmDx test to detect PD-L1 protein expression levels and help physicians determine which patients may benefit most from treatment with Opdivo.

The FDA granted Opdivo breakthrough therapy designation for this indication based on preliminary clinical evidence that suggested Opdivo may offer a substantial improvement over available therapies.

Another drug called Keytruda (pembrolizumab), manufactured by Merck, also targets the PD-1/PD-L1 pathway and was granted accelerated approval last week for treating NSCLC specifically for patients whose tumors expressed PD-L1.

Opdivo is marketed by Bristol-Myers Squibb based in Princeton, New Jersey. The PD-L1 IHC 28-8 pharmDx test is marketed by Dako North America based in Carpinteria, California. (Source: FDA Website, 09 October, 2015)

BMS Receives FDA Approval for Combo Drug Therapy for Certain Melanomas

Bristol-Myers Squibb has announced that the FDA approved Opdivo in combination with Yervoy for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma. The announcement marks the first and only FDA approval of a regimen of two immuno-oncology agents in cancer. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

"Targeting the immune system in the treatment of cancer has been of interest to the oncology community for decades, and our first Immuno-Oncology agent, Yervoy, was approved in 2011 for metastatic melanoma. Opdivo reinforced the power of the immune system in the fight against cancer, and is quickly becoming a foundational component in how the oncology community treats this devastating disease," said Giovanni Caforio, chief executive officer, Bristol-Myers Squibb. "Today's approval of the Opdivo + Yervoy Regimen marks another first for our research in Immuno-Oncology and represents our unwavering commitment to continually redefine cancer care, and offer patients new treatment options with the goal of improved outcomes." (Source: Bristol-Myers Squibb Website, 01 October, 2015)

FDA Allows Marketing of First Nucleic Acid-Based Test to Detect Multiple Pathogens in a Single CSF Sample

The FDA allowed marketing of the first cerebrospinal fluid (CSF) nucleic acid-based test for simultaneous detection of multiple pathogens that can cause central nervous system infections.

The FilmArray Meningitis/Encephalitis (ME) Panel uses CSF specimens from patients who have signs and/or symptoms of meningitis or encephalitis. It is intended as an aid in the diagnosis of those diseases when used in conjunction with other clinical and laboratory findings. Meningitis and encephalitis are inflammatory diseases of the membranes that surround the brain and spinal cord and can be caused by bacterial, viral or yeast infections. Such infections can cause brain damage and can be fatal if not treated rapidly.

The FDA reviewed data for the FilmArray ME Panel through the de novo classification process, a regulatory pathway for some low- to moderate-risk devices that are novel and not substantially equivalent to any legally marketed device. The FilmArray ME Panel is manufactured by BioFire Diagnostics in Salt Lake City, Utah. (Source: FDA Website, 08 October, 2015)

New Members

Curty Delfino Alvarenga Pinheiro, Jr., University of New Hampshire

Jason Auer, B.S., BIND Therapeutics

Daniel Balentine, Lantheus Medical Imaging

Stacy Beal, Alexion Pharmaceuticals

Vicentia Boateng, Middlesex Community College

John Bonilla, Middlesex Community College

Stephen E. Brodeur

Dellihor Bunchhoeun, Middlesex Community College

Paul Buraczynski, BMS

Frank R. Busch, PhD, Pfizer Pharma-Therapeutics R&D

Marte Cabello, Alexion Pharmaceuticals

William O Ordonez Camposano, Middlesex Community College

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Eric Cobane, Shire

Jesseria Colon, Middlesex Community College

Leandro Cruz, University of Massachusetts-lowell

Rochelly Cruz, Middlesex Community College

Lateffa S. Curry

John De La Parra, Northeastern University

Michael DeGirolamo, Azzur Group

Carlos Marvin Delgado, PE, MS, Shire

Mark Denning

Alexandrea Dustin, BS

Michael Farrell, Alnylam Pharmaceuticals

Eduard Fidler, University of Massachusetts-Lowell

Katherine Galindo

Sarah Garant, BS MS, Seres Therapeutics

Thomas Gende, University of New Hampshire

Tyler D. Gilpatrick, Azzur

Christian Giotas, University of New Hampshire

Steven Glover, CRB

Emily A. Gomes, Amgen

Cameron Hay, University of Massachusetts

Thomas F. Hehir, Middlesex Community College

Nicole Henry, University of Connecticut

Santiago Hernandez, Jr., Decco Inc

Mina Jung, DPS Engineering

Kimberly Kitch, AS

Evangelos Kustubardis, Azzur Group

Leo William Kutlowski, University of Massachusetts-Lowell

Angela Langford, DPS Engineering

Austin Lent, Boston University

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James Leverone, ImmunoGen

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Miss Irene Martinez, BS, Genzyme

Laura May

Emily Jean McGlame, WPI

Robert Melchionda, BS, MS

Joseph Menafra, University of New Hampshire

Ryan Patrick Molloy, Pfizer

Pegah N. Abadian

Elliot Nash, DPS Engineering

Salina Nop, Middlesex Community College

John Nottage, Rhodes Technologies

Himanshu Oberoi, Ph.D.

Gary Oliveira, Rhodes Technologies

Alba Ouellette, Middlesex Community College

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Sean Rahill, Rhodes Technologies
Kyle Roberts, CAI
Jarro Rodominick, Genzyme
Nicholas Ryan Sapack
Antonio Marco Scarvaglieri, University of Connecticut
Marissa Schaffer
Sonja A. Sharpe, PhD, GlaxoSmithKline
Ted Silva, MBA, BA, Integra Companies
Sophana Sopha, Middlesex Community College
Tim Sowell, Astro Pak Corporation
Ming Sun
Cory Thomas, University of Massachusetts
Brian Timmins, B.S., Sanofi Pasteur Biologics
Dariana Torres Rios, Middlesex Community College
Mong Tran Tran, Middlesex Community College
Saranny Va, Middlesex Community College
Rohit Voruganti, University of New Hampshire
Lila Whalen, Middlesex Community College
Whitney Withington, ImmunoGen Inc
Jessica Woods, University of Massachusetts-Lowell
Li-En Yaom, Middlesex Community College

Member Anniversaries

Join us in celebrating the 5, 10, 15 and 20+ year anniversaries of Boston Area Chapter Members. Congratulations to all of our long term Chapter members - your loyalty helps make us successful, year after year!

Over Twenty Years

- Frederick C. DeCicco, Sharpe Mixers (25 years)
- James R. Dube, Alexion Pharmaceuticals (22 years)
- Mostafa N. Elmorsi, Boehringer Ingelheim Pharma (29 years)
- Thomas G. Larkin, Amgen Inc (22 years)
- Pasquale M. Sacco, Shire HGT (25 years)

Fifteen Years

- William C. Dawes, Jr., Lantheus Medical Imaging
- Paige E. Kane, CPIP, Pfizer Global Supply
- Arthur L. Pelletier
- Leighton S. Terwilliger, Integra Companies Inc
- Lloyd Vallance, Barry Wehmiller Design Group

Ten Years

- David A. Campanella, 3R Engineering
- James Curry, OpStat Group Inc.
- Paul S. Tierney, Jr.

Five Years

- Robert E. Christman, CMRP, CPMM, Genzyme Corp
- Jason Dunklee, Genzyme Corporation
- Brian Mulcahy, Bothwell Engineering
- William B. Okita, EMD Serono, Inc.

