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

www.ispeboston.org

NEWSLETTER

September 2014, Volume XXIV, No. 5

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President's Message: Incoming Chapter President Chris Opoloski Shares His Vision for the Chapter

Dear Boston Area Chapter Members,

Welcome to a new year of the ISPE Boston Area Chapter (BAC). Last year was a busy one for the Chapter. With the help of our many volunteers - we sponsored over 20 individual events covering the gamut from educational programs to networking socials to recreational activities. In addition, a variety of student-oriented events took place at the region's colleges and universities sponsored by our Student Chapters. While the Chapter delivered these many events, the board was also involved with successfully integrating the former New England Chapter into the BAC, working on ways to provide value to these Members while also increasing our student development activities throughout New England.

Please allow me to introduce our new Board of Directors for 2014-2015. Their hard work and dedication will help the Chapter and further expand the benefits provided to our membership:

President	Christopher Opolski	SPEC Process Engineering and Construction
Vice President	H. Steve Kennedy	NNE Pharmaplan
Secretary	Janet Tice	GMP Piping
Treasurer	Jack Campion	The Hart Companies
Directors	Sean Burgess	Integrated Builders
	Kevin Chronley	A/Z
	Daniel Rufo	IPM
	Tulsa Scott	Commissioning Agents
	John Spohn, CPIP	Hargrove Life Sciences
	Jim Stout	Natrix Separations
	Jillian Willard	Genzyme
	Darren Wolter	Pfizer
Past President	Daniel Ramsey	Commissioning Agents

I would also like to thank Past President Jay Zaino, GxP Automation, and Director Tom Choyce, Genzyme, for their recent tenures on the board.

As your new board, we have worked through the summer to develop plans for the upcoming year. We reflected upon our previous goals and accomplishments and developed additional objectives to build on the superior work already completed. One of these objectives is to ensure the long-term sustainability of the Chapter by creating and documenting best practices for Chapter and committee operations, including volunteer recruitment and retention. This will allow us to continue our robust program of activities far into the future and provide for the long term health of the Chapter.

The BAC has a long track record of success demonstrated by four consecutive Chapter Excellence Awards, the continued high membership rate, the number of Members with CPIP credentials and a calendar filled with events and activities. As we start our new board year, I would like to highlight the Chapter's key initiatives, significant accomplishments and goals for 2014-15:

GO Initiative - This past year the Chapter formed the Geographic Outreach (GO) Committee. The purpose of the committee was to connect the greater New England ISPE membership to the offerings and value that the Boston Area Chapter was delivering. Members could attend educational programs at remote hubs and enjoy a networking reception followed by a simulcast of the presentation. Their questions were delivered to the presenters electronically during the Q&A portion of the program. The Chapter successfully held its first GO Live meeting in June in the Providence area. This year we plan to continue to broadcast educational programs in Providence as well as expanding to hubs in Worcester and Amherst, MA. Look for the opportunity to sign up for these remote simulcasts in your periodic Chapter emails.

Student Chapters - In the past year the BAC has expanded the number of Student Chapters at local colleges and universities. Today we have 10 active Student Chapters serving over 200 Student Members. In addition to locally run meetings, these Student Members attended our educational programs, Product Show and social events and demonstrated the drive and determination that the industry values in the next

generation of pharmaceutical engineers. Our goals this year are to expand the number of Student Chapters and Student Members and to continue implementing best practices so that each Student Chapter continues to be successful from school year to school year.

Young Professionals - The BAC Young Professionals group continues to be one of the most active groups within the Chapter and in all of the U.S. Multiple events are planned each year including educational programs geared specifically to professionals new to the pharmaceutical industry and networking events that allow these Members to meet up and get to know each other.

Educational Programs - The Educational Programs Committee (EPC) had a busy summer planning events for the Chapter. At the annual strategic planning meeting held in July, more than 20 volunteers began development of programs for the upcoming year. Be on the lookout for these great program topics over the next few months:

- Good Engineering Practices
- Water for Dummies
- Project Stakeholder Management
- Executing Retrofit Projects in Operating GMP Plants
- Biotech 101
- Security & Data Integrity
- Statistical Methods & Optimization for Manufacturing
- Future Trends / Continuous Manufacturing

Educational programs are scheduled on the third Thursday of every month. And remember, while you are at the Product Show on October 1, there will be four educational sessions you can attend for free!

Joel Goldenberg Memorial Scholarship Program - Awards of up to $2,000 are available per semester for applicants. This past year the Chapter increased the maximum lifetime funding that a student can receive from $4,000 to $8,000. To date, the BAC has awarded over $50,000 in scholarships to worthy students. During the most recent round of awards, 22 students from 15 universities applied for scholarships. Check out the Chapter webpage for details - the next scholarship application deadline is November 15.

Annual Product Show at Gillette Stadium - This free event is recognized as one of the nation's outstanding one-day life science shows and attracts more than 2,000 ISPE Members and non-members each year. This year the event will be held on October 1, with 375 vendors exhibiting their products and services, an exciting educational program and unlimited networking opportunities. In addition, life science companies from around New England will be participating in our Career Fair, looking to hire their next engineer or scientist. Remember to register for the Product Show early and download our new smart phone app so you can keep up with all the great events happening during the Show and find the vendors you want to visit.

As you can see, the Chapter has some great things planned for the year ahead. I encourage you to take part in the educational and networking events, participate in our surveys to let us know how we are doing, and volunteer for a committee. This is a great organization and I'm proud to be a part of it! I am honored to have been elected President this year and I will do my best to serve the entire Boston Area Chapter and ensure its continued success.

Sincerely,

Christopher Opolski

President
ISPE Boston Area Chapter

Chapter Bulletin Board

Only a Handful of Product Show Booths Left – It's Now or Never!

This year's Product Show is shaping up to be the biggest and best to date. Read the following articles describing the many new attractions that will ensure attendance tops last year's 2400. Then register at www.ISPEBoston.org/ProductShow or by contacting the Chapter office at 781.647.4773. And while you're at it, be sure to sign up for one (or more!) of the many new sponsorship and advertising opportunities available this year. See you at Gillette on October 1!

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 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, September 18, 2014

Good Engineering Practice, aka, How to Make Friends with Your Validation Group
Waltham Woods Conference Center, Waltham, MA

Has engineering come full circle in the biotech market over the past 30 years? Those old enough to remember projects executed before ISPE was founded, will also remember FDA and quality groups inconsistently judging the quality of design. ISPE has, to its credit, created many guidelines to provide a basis for best practice, but they do not necessarily address the design basis, nor level of risk.

The "new" standard for engineering is risk based design. Whether it is defined in ASTM 2500, IQH Q9, or ISPE Good Engineering Practice Guideline, the new approach is to follow a multi-step process for defining the requirements, evaluating risk, detail design, and validation/qualification.

The intent of this program is to provide 3 different perspectives of cGEP: the owner/drug producer, the outside engineering consultant, and the quality group that needs to justify to the regulatory authorities that the design process is robust. After short presentations, the floor will be opened for feedback and panel comments.

Register Today:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=403

Wednesday, October 1, 2014

23rd Annual Product Show
Gillette Stadium, Foxborough, MA

Although this is our 23rd Annual Product Show, this year's event will be the first since the New England and Boston Area Chapters have become one - making it possibly our biggest and best show yet! Whether you're attending as a vendor or an attendee, this year's Show will provide plenty of opportunities to advance your business or career due to our expanded exhibitor area, educational sessions, career fair, vendor showcases, entertainment zone, and After-Party. Register today to be part of the fun! Attendance and parking are FREE.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=371

Sneak Preview of Upcoming Events

Thursday, November 13, 2014
Facility Optimization and Process Improvement

Thursday, December 11, 2014
Statistical Methods and Optimization for Manufacturing

Thursday, January 15, 2015
Future Trends

23rd Annual Product Show Dazzles with Education, Exhibits, Networking and More!

by H. Steven Kennedy, NNE Pharmaplan, photos by Alastair Battson Photography

The Boston Area Chapter is excited to bring you the 23nd edition of the Annual Product Show to be held at Gillette Stadium on October 1. You asked and we listened. We've made a number of important changes to ensure that this year's Show is our best ever and provides a top-flight experience for attendees and exhibitors alike.

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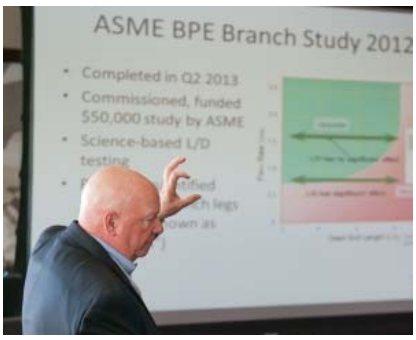
Magnificent views of Gillette Stadium welcome attendees at the Annual Product Show.

One of the first changes attendees will notice is the location of the entrance. To improve traffic flow, last year's exit has become this year's entrance. Just look for the doors closest to the big football helmet! And remember to register in advance at our website here to avoid lines. Doors open at 10:00am for attendees.

The exhibit floor beckons with 375 vendor booths - and non-stop food, drink & conversation.

This year, the Plenary Session has been moved to the morning time slot and will begin at 10:30am. Incoming Chapter President Chris Opolski will update us in his State of the Chapter address and present several awards recognizing excellence within our Chapter. Following Chris will be keynote speaker Michael Arnold, Business Process Owner for Investigational Products and Senior Director of Strategic Partnerships for Pfizer's Global Clinical Supply Chain. Mike is the current Chair of the ISPE Strategic Forum, current Secretary of the ISPE International Board of Directors and a Member of the Board of Directors Executive Committee. We are looking forward to his insights on the future of our industry and ISPE.

The exhibit area opens at noon, following the Plenary Session. We increased the number of exhibitors to 375 this year and once again we are sold out! Like last year, you will find exhibitors and activities in both east and west clubhouses so be sure to visit both sides of the stadium. With so many exhibitors, we are supplementing the traditional Exhibitor Guide with a mobile app. Be sure to download the free app to your phone from Google Play Store or the Apple App Store. We anticipate that this will be the last year we publish the hard copy of the Guide as we move to a completely electronic format.



Hot-button topics always draw overflow crowds to the educational programs.

In addition to the Plenary Session, we have a full slate of training events being offered throughout the day. Concurrent educational programs start at 12:30pm and 1:45pm. See the article elsewhere in this newsletter for complete details on the four exciting presentations. Product demos will be held in the Vendor Showcase area between 4:00pm and 7:00pm and the winner of the Student Poster Contest will be on hand in the same area to answer questions about her research. Lastly, the annual Career Fair will feature many of the leading area firms. Stop by and see what they have to offer.

Networking with friends and colleagues is one of the many benefits of attending the Product Show.

If you're a student or young professional, there are several events created just for you: a networking social with great food, drink and conversation; a panel of industry professionals discussing career options in the life science industry; and an educational program designed to help you hone your job hunting skills.

Of course, it wouldn't be a Boston Area Chapter Product Show without our fun networking activities. Visit the Entertainment Zone in the West Clubhouse where two of our local "biotech" bands will be providing live music throughout the afternoon. And while you're there, have your picture taken with the Patriots "Cheerleaders for Charity" for a small donation. All proceeds will be matched by ISPE and donated to the New England Patriots Charitable Foundation. Finally, when the exhibitor floor closes at 7:30pm, join us at nearby Bar Louis for the After-Party and meet Patriots defensive end Chandler Jones. This is only a small sampling of what we have planned. See the articles that follow for all the details.

Last year's after party drew over 650 to Bar Louis for food, drink and conversation.

The 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 and soft drinks, and free educational seminars. If you haven't attended in the past, please let us welcome you this year! And to those loyal ISPE Members who have attended year after year, thank you! You're the backbone of this organization. You built the foundation for this event's success over the past twenty years and we thank you for your contribution!

This will be my last year chairing the Product Show Committee, that group of hardworking Chapter volunteers who bring this fantastic Show to life every year, as I will be passing the torch to Committee Vice Chair Sean Burgess. The Show could not succeed without the efforts of this incredible committee and our admin support team at CAMI and I thank them for making my job easy. If you want to be part of this great team, let us know. We are always looking for enthusiastic people to help deliver what is undeniably the best show of its kind. Remember, register today and we'll see you on October 1!

Product Show Career Fair: Maximum Value at Minimum Cost

by Alex MacKinnon, RCM Technologies/Life Sciences Division

The 2014 Product Show and Career Fair offers hiring companies a front seat at one of the largest one-day gatherings of biotechnology and pharmaceutical professionals in the northeast and access to the many talented job seekers attracted by our partner, CareerBuilder.

For area job seekers, the Product Show provides access to most of the top life science companies in New England and the ability to meet HR & hiring managers face-to-face with beautiful Gillette Stadium as a backdrop and the many Product Show activities as added attractions. And it's free!

For hiring companies, the Career Fair provides unparalleled access to engineering, QA, validation, RA, clinical, manufacturing, project management and other life science professionals, a streamlined timeframe and the ability to conduct face-to-face interviews on the spot, with a semi-private area set aside for these conversations. And this year, we've hired CareerBuilder, the "global leader in human capital solutions," with their sourcing expertise and best-in-class recruitment technology to help build attendance and ensure that attendees include top talent. In addition to using the added value of their sourcing capabilities, CareerBuilder will run targeted ads and personally contact selected professionals to attract the type of

senior talent that can be hard to find.

In short, the Career Fair provides a unique opportunity for both hiring companies and job seekers to discuss open positions and career advancement. Prior year participants have included Shire, Alkermes, Wyeth, Bristol-Myers Squibb, AstraZeneca, Biogen Idec, Abbott, Lonza, Pfizer, Genzyme, Vertex, Acceleron, Alexion …and more.

So if you're in the job market, be sure to visit the 2014 Product Show & Career Fair – it's a great venue, great value and great opportunity for hiring companies and New England job seekers alike. Don't miss it!

Keynote Address to Highlight the Future of the Industry and ISPE

The ISPE Boston Area Chapter is privileged to announce that Michael Arnold, R.Ph. will be the keynote speaker at this year's Product Show at Gillette Stadium on October 1. His address, discussing the current state of the pharma and biotech industry and what the future holds for the industry and ISPE, will be the highlight of the Plenary Session beginning at 10:30am in the East Clubhouse.

Michael is a licensed, registered pharmacist and is currently the Business Process Owner for Investigational Products and Senior Director of Strategic Partnerships for Pfizer's Global Clinical Supply Chain. He has worked in the pharmaceutical industry for the past 32 years. His responsibilities have included managing Pfizer's global clinical supply operations, directing supply chain management activities, clinical supply forecasting, warehousing, packaging, labeling and distribution, comparative agent manufacturing, writing manufacturing sections supporting Investigational New Drug Applications, establishing an Import/Export process, designing, validating and implementing new computer systems, and establishing Pfizer's outsourcing program for packaging, labeling, warehousing, distribution of clinical supplies and placebo and comparator agent manufacturing processes.

Michael is a past member of the IBM Cloud Coalition promoting innovative ways for clinical trial data sharing and continues to be actively involved in a number of other professional organizations. He is a member and Past-Chair of the ISPE Investigational Products Community of Practice, ISPE Regulatory Subcommittee member, a member and Past-Chair of the ISPE Community of Practice Council, current Chair of the ISPE Strategic Forum, current Secretary of the ISPE International Board of Directors, a member of the ISPE Board Executive Committee and an active member of the International Leadership Forum (ILF).

In collaboration with the European Medicines Agency (EMA), the International Society of Pharmaceutical Engineers (ISPE), and Health Canada, he directed the publication of an Industry Good Practice Guide on the use of Interactive Response Technology (IRT) to manage clinical supply use-by dates and Program level pooling of clinical trial supplies. He has published other Webcasts and White Papers on Clinical Trial Supply processes. He has made numerous international presentations on clinical supply processes and supply chain security.

Michael is actively working with world-wide regulators and local agencies to promote efficiency, compliance and enhanced safety of clinical trial supplies. He was also the 2012-2013 Program Leader for Pfizer's Investigational Products Fellowship Program with University of Massachusetts College of Pharmacy and Health Sciences (MCPHS) and elected 2012 Connecticut Society of Health Systems Pharmacists, "Pharmacist of the Year".

Learn What's New in the Industry at the Product Show Educational Program

by Tom Struble, Commissioning Agents, with photos by Alastair Battson Photography

The Boston Area Chapter is exceptionally proud of the 2014 Product Show's educational program. We have listened to your feedback and feel confident we are offering the best lineup to date. The four sessions balance current, relevant industry topics with the latest local and global developments and a constant eye to the future, while maintaining an appeal to a wide range of industry professionals. Whether you've been working in pharmaceuticals for 40 days or 40 years, there is a session here for you!

This year's afternoon educational program balances current industry topics with the latest local and global developments and future trends.

Be sure to register early at www.ispeboston.org/productshow to ensure a seat at the session(s) of your choice. Two sessions run simultaneously during each of the two time slots. The first sessions begin immediately following the keynote address.

12:30pm – 1:30pm

Biotechnology: The Challenge for Tomorrow

Kamal Rashid, Ph.D., Director, Biomanufacturing Education & Training Center at WPI

This seminar is an introduction to the principles and techniques of biomanufacturing and how human therapeutic products are made from living cells and their components such as bacteria and enzymes.

Biotechnology is one of the fastest growing industries worldwide, an interdisciplinary field that incorporates the expertise of life sciences and various engineering disciplines to produce unique biological products. Successful operations require achieving high productivity at low operating cost while meeting the requisite quality specifications set by the FDA.

This presentation will examine what biologics are and how they are processed from a seed stock to a final product, including an overview of the various manufacturing unit operations and critical parameters for each, as well as guidance and requirements for operating in a regulatory environment.

"Harder Than It Looks" – Projects Executed Concurrently with Manufacturing Operations

Rick Kotosky, P.E., CPIP, Solution Manager, Altran
John Spohn, CPIP, Senior Project Manager, Hargrove Life Sciences, New England Operations

From simple tasks like adding a WFI drop to major process change or expansion, performing project work in an operating GMP facility presents significant challenges. Under the best conditions, proper execution of engineering projects for GMP use is complex, but retrofit projects in an operating plant involve additional layers of complexity such as the need for extreme preparation and planning, maintaining a production schedule and choreographing every activity to limit risk to product-in-process.

This session will first examine some of the not-so-obvious ways that facility design can impact project design and planning, and then focus on operational considerations that constrain project execution and planning techniques to offset those constraints.

1:45pm – 2:45pm

Water Based Critical Utilities – RO, WFI, Steam: The Bottom of the Iceberg that Makes a Plant Actually Run!

Brian Hagopian, CPIP, Clear Water Consulting

Regardless of whether water is used to produce RO grade, USP Purified, Water for Injection (WFI) or as a source for plant or clean steam, water is the most widely used material in the manufacture and purification of many biotech or pharmaceutical products. Used as an ingredient, a solvent, a diluent, a cleaner, a sterilant, and for other purposes, it is important to understand why water needs to be purified and how municipal water supplies are treated to yield the grades of water and steam required for various uses. By attending this presentation, you will develop an understanding of why different grades of purity exist and why a drug's place in its product life cycle may dictate different purity requirements.

Successful Project and Organizational Change through Effective Stakeholder Management

Neeraj Shah, MBA, PMP, SCPM, Associate Director of Global Supply Chain IT, Shire Pharmaceuticals

The success of a project or change initiative is not only limited to a strong business case or delivering a quality product or service. It is critically important to manage stakeholders' expectations so that they stay supportive throughout the lifecycle of the project and look forward to adopting the outcome of the project. During this session, you will learn about a highly effective yet simple stakeholder management framework and valuable tools that will help you proactively identify your stakeholder ecosystem, analyze your stakeholders and develop a strategy, tailored to your project, to optimally engage your stakeholders throughout the project lifecycle. Applying these strategies will improve your stakeholders' participation, enhance their support for the project and increase the probability of your project's success.

For speaker bios and more in-depth session descriptions please visit the Product Show Educational Program page of the ISPE Boston Area Chapter website at http://www.ispeboston.org/ProductShow/programs/index.html

Young Professionals Find Much to Like at the Product Show

by Peter Trearchis, Pfizer, with photos by Alastair Battson Photograph

When I arrived at Gillette Stadium for the ISPE Boston Area Chapter Product Show last year I didn't know what to expect. I assumed there would be a few vendors and some educational events but I didn't know how much a Young Professional fresh out of college could benefit from the event. Wow, was I surprised when I walked in! The multitude of vendor booths, educational events and entertainment was amazing (not to mention the free food and drink and the panoramic views of the stadium). And the dozens and dozens of vendors were more than happy to explain their products. For a YP this was a fantastic opportunity to explore hundreds of the products and services used by the pharmaceutical industry – all in one day.

Young professionals can explore hundreds of products and services used by the pharmaceutical industry - all in one day - at the Annual Product Show.

This year I'm looking forward to learning even more than I did last year. The Plenary Session opens the

Show at 10:30am, followed by the educational program at 12:00pm with four sessions to choose from: an overview of the principles and techniques behind biomanufacturing; managing projects concurrently with operations; critical utilities – RO, WFI, steam; and stakeholder management for successful project execution. In addition, the Show floor on both sides of the stadium has been expanded to make room for over 375 exhibitors. Be sure to check them all out, learn about some amazing products and see how they could be applied in your lab, manufacturing floor or industry.

For students (and some YPs) the Career Fair is a great resource with interviews occurring throughout the day. This year's YP social is geared towards both students and YPs and will be a networking session with great food, drink and conversation plus some friendly competition (plus valuable prizes!) to keep things lively. This is a special event promoted solely for the benefit of young professionals and students so be sure to check it out! And don't forget the After-Party with Chandler Jones from the New England Patriots - who doesn't want a free autograph?!

With all of these great activities in store, I can't wait for October 1 to roll around. I highly encourage all YPs to attend this outstanding event. Attendance, parking, food and drink and all of the activities are free whether or not you're an ISPE Member. So invite your non-member friends and colleagues and give them a chance to learn more about ISPE and the biopharm industry. (And be sure to tell them that the Product Show is only one of the many professional development opportunities ISPE offers its Members.) See you on October 1!

Product Show Welcomes Students with Special Activities & Free Bus Transportation

by Brian Hagopian, CPIP, Clear Water Consulting

The Annual Product Show at Gillette Stadium is one of the industry's premier events – and it's right here in our own back yard! To encourage students to attend this year's Show on October 1, ISPE will provide free bus transportation from several area campuses. And you don't have to be an ISPE Student Member to ride the bus and attend the Show for free, so sign up now at www.ISPEBoston.org/Events and secure your spot on one of the buses.

This year's Show will have a great mix of educational and social programs geared specifically to students. We've taken over both luxury clubhouse areas and there will be tons of free food and drink available all day long. Sign up now for the unique chance to meet and network with over 2,400 professionals working in the local life sciences industry, view the products and services offered by over 375 of the industry's top-tier suppliers and attend a variety of activities created especially for you.

Access to industry leaders is a Product Show plus for the Chapter's Student Members.

Zhiyuan Shen says it all. Now a WPI alum working at Phosphorex, Zhiyuan attended last year's Product Show as a Student Member:

The Show incorporates many activities that Student Members like me found very helpful. These include the educational seminars, keynote presentation and Career Fair. In addition to these, the exhibit area is a place where students who aspire to a career in the pharmaceutical industry can learn about the latest technology. Talking with the exhibitors was also a great way to get information about what it's like to work in the pharmaceutical industry. And we all enjoyed the fantastic views of the stadium, the live music and great food!

In addition to the full range of activities described above, don't miss the following activities designed especially for students:

Student Poster Contest Winning Exhibition
2:00-3:00PM, Vendor Showcase
Meet the Chapter's 2014 Poster Contest winner from Northeastern University, Nidhi Maniar, who will be competing in the ISPE International Poster Competition at this year's ISPE Annual Meeting in Las Vegas. Nidhi will be exhibiting her winning poster during the Product Show. Come see her work and ask her questions to help her prepare for the international competition later in the month.

Student and Young Professional Social
3:00-4:00pm, West Clubhouse, Club Level, Northwest Lounge
Attend an informal social with life sciences industry young professionals. Meet recent graduates and learn about career path choices made by those who have traveled in the footsteps you are about to take. This will be a great opportunity to meet young professionals from different areas of the industry and get involved with ISPE - with a little friendly competition thrown in to keep things interesting!

"How to Network at the Product Show" Educational Program by Dave Novak
4:15-5:15PM, Red Level, Room R10
Learn how to make the right first impresion, build a good elevator speech, and the essentials of networking.

"Careers in Life Sciences" Panel Discussion
5:30-6:30PM, Red Level, Room R10
Attend this educational session to learn about career paths available in the life science industry. The panel, comprised of industry professionals at various stages of their careers, has been assembled to help you better understand your options.

See you at Gillette on October1!

Sun Shines on Summer Golf Outing at Kernwood Country Club

by Paul Sullivan, R.W. Sullivan Engineering with photos by Patty Ascanio, Mangan Biopharm, and H. Steven Kennedy, NNE Pharmaplan

The Boston Area Chapter hosted the annual Summer Golf Tournament on August 18 at the beautiful Kernwood Country Club in Salem, Massachusetts. The sun was shining on this perfect summer day as ISPE Members and guests from all over New England put their busy schedules aside to join in a fun-filled day of golf and networking. In addition to the gorgeous weather, the course was spectacular and the staff went over and above to make the day a success.

The day started with an impressive buffet lunch ensuring that no one went out on the course hungry. Once play began, laughs and cheers could be heard from every direction – a good sign that the day was another big success for the Chapter. After an elegant dinner, awards were presented to the lucky winners. In addition to a thoroughly enjoyable event, the many great raffle items and putting contest succeeded in raising $2,535 for the Chapter's Joel Goldenberg Memorial Scholarship Fund.

Congratulations go to our winning foursomes, our six individual winners and putting contest winner, Mike

Mattau, the only person to sink the 10-foot putt:

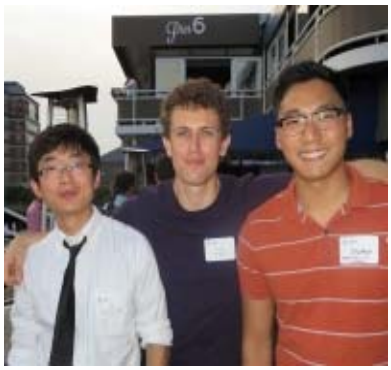
First Place	Second Place	Third Place
The Wilkinson Company	**DECCO**	**FW Webb – High Purity Process**
Dan Paquette	Ed Kozloski	Chris Sears
Herbie Aikens	JD Fier	Ted Haley
Geoff Wilkinson Jr.	Andrew McKinney	Kevin Shield
Mike Mattau	Bill McCarthy	Brian Meldrum

The Chapter would like to thank everyone who attended the Summer Golf Tournament and extend a special thank you to the sponsors who played such a vital role in making this great day possible: A/Z Corporation, Burkert Fluid Control Systems, BR+A Engineering, Commissioning Agents, Cox Engineering, Crosspoint Engineering, DPS Engineering, F.W. Webb, GxP Automation, Interstate Electrical Services, J.C. Cannistraro, Mangan Biopharm, Middlesex Gases & Technologies, R.W. Sullivan Engineering, Rolf Jensen & Associates, RoviSys, Schneider Electric, Superior Controls, The Wilkinson Company, and TRG Builders. We couldn't have done it without you!

Members Enjoy Charlestown Waterfront at Summer Social

by Jim Grunwald, Commissioning Agents.

Attendees at the Chapter's Summer Social enjoyed a warm summer evening and a spectacular view of Boston at Pier 6 in the Charlestown Navy Yard on July 23. The turnout was excellent with many longtime Chapter Members mingling with a large contingent of new Members and Young Professionals. Outgoing Chapter President, Dan Ramsey, used the occasion to deliver his final comments as Chapter President and introduce Incoming President Chris Opolski, who will take over from Dan in August.



Summer weather, a view of the Boston skyline, and the company of friends and colleagues - who could ask for more?!

Heading Home was the evening's designated charity and beneficiary of donations by Chapter Members. Heading Home provides emergency, transitional and permanent housing and support services to low-income homeless and formerly homeless families and individuals in Greater Boston. The evening raised over $650 via a 50/50 raffle, with longtime Chapter Member and volunteer, Aarash Navabi, the lucky winner. Thanks to Aarash for generously donated his winnings back to Heading Home, a gesture appreciated by all attendees.

And a big thank you to the Chapter's Social Committee for organizing another great event and enlisting the Chapter's support for a very deserving charity. We recognize Social Committee members Dan Kenny, Fasha Onorato, Paul Sullivan and Jim Grunwald for their efforts on behalf of the Chapter.

Young Professionals Sponsor Harbor Cruise for All Ages

by Jared Marshall, Genzyme with photos by Joyce Chiu, Honeywell Safety Products

On Thursday, September 4, the Boston Area Chapter Young Professionals sponsored an evening boat cruise touring Boston Harbor to kick off the season. Over 60 attendees, both young and seasoned professionals, boarded at Rowes Wharf and set sail for what was the most successful YP harbor cruise to date. The congenial crowd enjoyed the perfect weather, great views of Boston and the surrounding islands and non-stop networking and socializing. Attendees included new Members of the Chapter who had a perfect opportunity to meet other people from various areas of the industry. Overall, a fun time for all who attended!


LIFE RING

Student Chapters Hit the Ground Running in September!

text and photos by Brian Hagopian, CPIP, Clear Water Consulting, Inc.

September is a busy month for all of our Student Chapters. Semester starting, new classes and ISPE participation in a record number of campus events! Look for ISPE activities on your campus in September and throughout the fall semester - the benefits of joining are HUGE!

Product Show Welcomes Students to Gillette Stadium on October 1
The Chapter's flagship event is coming up on October 1. See related article for the many student activities planned at the Product Show. Sign up here.

Biogen Idec Hosts MCPHS University Students from Korea
Over the summer, Student Members from MCPHS University took a plant tour of Biogen Idec's manufacturing facility in Cambridge. Many thanks to the folks at Biogen Idec for arranging this tour!

Job, Internship and Co-op Postings Poised for Another Great Year
One of the major reasons that students join ISPE is to find jobs. This year, the Chapter began to post entry-level positions, internships, and co-op positions in the Student Development section of the website to help ISPE Student Members find positions in the industry. This past year, our goal was to post at least 50 positions on our website and we're proud to report that we've exceeded that goal. And, this FREE service is working! Our Student Members have landed positions at Biogen Idec, MASY Systems, Genzyme, Vertex, Takeda/Millennium, Phosphorex, Dicerna, and Process Design Solutions. Stay tuned and watch this program mushroom as more companies and students learn about this valued service.

Scholarship Program Reaches New High
The Chapter's scholarship program has been building momentum for the past three years, awarding over $42,000 in scholarship monies to date. In fact, the program has been so successful that the Chapter's Board of Directors is evaluating ways to increase funding in the future. With student memberships at an all-time high, we've received a record number of applicants for the upcoming fall semester. This is one of the many ways that the Chapter is "giving back" and helping to usher the next generation into the life sciences industry. Full details, including an application, can be found on the Chapter's website at www.ISPEBoston.org/Scholarship. And remember, the next application deadline is November 15.

The ISPE Message is Spreading!
Word is really starting to spread across local campuses. Student membership is reaching new highs but the best news is that we've formed three new Student Chapters this past year at Boston University, MCHPS University, and UMass Dartmouth and we have additional prospective Student Chapters in the pipeline.

Students Attend ISPE Educational Events for Free Remember, once you join ISPE as a Student Member (www.ispe.org/join-or-renew), you will be able to attend all Chapter educational and related events for free! Membership in the Boston Area Chapter truly does have its privileges!

Want to Get Involved?
The Chapter has many dedicated volunteers coordinating these efforts but this level of activity takes lots of hard work. If you're interested in helping out, just shoot us an email. Whether you have an hour a year or an hour a month, we could sure use the help. Trust me, this is a decision I guarantee you won't regret! As our efforts continue to gear up, the Chapter will be producing targeted informational videos to help spread the word.

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.

FDA Approves Biogen Idec Treatment for Hemophilia A
The FDA has approved Biogen Idec's Eloctate, Antihemophilic Factor (Recombinant), Fc fusion protein, for use in adults and children who have Hemophilia A. Eloctate is the first Hemophilia A treatment designed to require less frequent injections when used to prevent or reduce the frequency of bleeding. Eloctate is approved to help control and prevent bleeding episodes, manage bleeding during surgical procedures and prevent or reduce the frequency of bleeding episodes.

Eloctate consists of the Coagulation Factor VIII molecule (historically known as Antihemophilic Factor) linked to a protein fragment, Fc, which is found in antibodies. This makes the product last longer in the patient's blood. Eloctate received orphan-drug designation for this use by the FDA because it is intended for treatment of a rare disease or condition. (Source: FDA Website, 06 June, 2014)

Cubist Wins FDA Approval for Sivextro to Treat Skin Infections
The FDA has approved Sivextro (tedizolid phosphate), a new antibacterial drug, to treat adults with skin infections marketed by Cubist Pharmaceuticals, of Lexington, Massachusetts. Sivextro is approved to treat patients with acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria, including Staphylococcus aureus, methicillin-resistant strains (MRSA) and methicillin-susceptible strains, various Streptococcus species and Enterococcus faecalis. Sivextro is available for intravenous and oral use.

Sivextro is the second new antibacterial drug recently approved by the FDA to treat ABSSSI. On May 23, the agency also approved Dalvance (dalbavancin) to treat patients with ABSSSI caused by Staphylococcus aureus and various Streptococcus species.

The application for Sivextro, intended to treat serious or life-threatening infections, was designated as a qualified infectious disease product (QIDP) and received an expedited review. Sivextro's QIDP designation also qualifies it 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, 20 June, 2014)

Shire and AbbVie to Combine
The boards of AbbVie and Shire announced that they have reached agreement on the terms of a recommended combination of Shire with AbbVie. In order to undertake the transaction, AbbVie has formed a new company, New AbbVie, which is incorporated in Jersey, Shire's current place of incorporation. The company will be resident in the UK for tax purposes.

The AbbVie board expects the transaction to reduce New AbbVie's effective tax rate to approximately 13 per cent by 2016 and provide New AbbVie with access to its global cash flows. Following completion of the transaction, New AbbVie will become the holding company of the Shire Group and the AbbVie Group. The New AbbVie Shares will be listed on the New York Stock Exchange. The transaction is expected to be completed in the fourth quarter of 2014. (Source: Shire Website, 18 July, 2014)

Connecticut-based MannKind Wins FDA Approval for Afrezza to Treat Diabetes
The FDA has approved Afrezza (insulin human) Inhalation Powder, a rapid-acting inhaled insulin to improve glycemic control in adults with diabetes mellitus manufactured by MannKind Corporation of Danbury, Connecticut. Afrezza is a rapid-acting inhaled insulin that is administered at the beginning of each meal.

An estimated 25.8 million (18.8 million diagnosed and 7.0 million undiagnosed) people in the United States, or approximately 8.3 percent of the population, have diabetes. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage.

Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes, and it is not recommended for the treatment of diabetic ketoacidosis, or in patients who smoke.

Afrezza has a Boxed Warning advising that acute bronchospasm has been observed in patients with asthma and chronic obstructive pulmonary disease (COPD). Afrezza should not be used in patients with chronic lung disease, such as asthma or COPD because of this risk. The most common adverse reactions associated with Afrezza in clinical trials were hypoglycemia, cough, and throat pain or irritation.

The FDA approved Afrezza with a Risk Evaluation and Mitigation Strategy, which consists of a communication plan to inform health care professionals about the serious risk of acute bronchospasm associated with Afrezza. (Source: FDA Website, 27 June, 2014)

Bristol-Myers Squibb to Collaborate with Allied Minds
Boston-based Allied Minds and Bristol-Myers Squibb have announced the formation of Allied-Bristol Life Sciences LLC, a new jointly owned enterprise created to identify and foster research and pre-clinical development of biopharmaceutical innovations from leading university research institutions across the U.S. Allied-Bristol Life Sciences LLC will focus on converting discoveries from university research institutions into therapeutic candidates for clinical development, and ultimately approved therapies. For programs identified by the new enterprise, university researchers will be able to access Bristol-Myers Squibb's drug discovery research expertise, and Allied Minds' financial and management experience.

Allied Minds, which has been in operation since 2006, forms, funds, manages and builds products and businesses based on innovative technologies developed at leading U.S. universities and federal research institutions. Allied Minds serves as a diversified holding company that supports its businesses and product development with capital, central management and shared services. The company takes a majority ownership stake in each business it establishes, and provides funding and central management. Allied Minds currently works with more than 33 leading universities, several of which exceed $1 billion each in annual research spending, as well as 32 federal research centers and laboratories managed by the U.S. Departments of Defense and Energy on a similar commercialization structure. It currently has 18 operating companies in the U.S.

Allied Minds and Bristol-Myers Squibb together will form and fund new companies to conduct feasibility and full-phase discovery programs. Once a program succeeds in identifying a pre-clinical candidate, Bristol-Myers Squibb will have the option to acquire the company from Allied-Bristol Life Sciences LLC under pre-agreed terms. (Source: Bristol-Myers Squibb Website, 04 August, 2014)

Boehringer Ingelheim Wins FDA Approval for Treatment for COPD
The FDA has approved Striverdi Respimat (olodaterol) inhalation spray to treat patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema that are experiencing airflow obstruction. Striverdi Respimat is a long-acting beta-adrenergic agonist (LABA) that helps the muscles around the airways in the lungs stay relaxed to prevent symptoms. Striverdi Respimat is distributed by Boehringer Ingelheim Pharmaceuticals of Ridgefield, Connecticut.

COPD is a serious lung disease that makes breathing difficult and worsens over time. Symptoms can include wheezing, cough, chest tightness, and shortness of breath. Cigarette smoking is the leading cause of COPD. According to the National Heart, Lung, and Blood Institute, COPD is the third leading cause of death in the United States.

The FDA approved Striverdi Respimat with a patient medication guide that includes instructions for use and information about the potential risks of taking the drug. (Source: FDA Website, 31 July, 2014)

FDA Approves Boehringer Ingelheim Drug to Treat Type 2 Diabetes
The FDA has approved Jardiance (empagliflozin) tablets as an addition to diet and exercise to improve glycemic control in adults with type 2 diabetes. Type 2 diabetes affects approximately 26 million people and accounts for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney damage.

Jardiance is a sodium glucose co-transporter 2 (SGLT2) inhibitor. It works by blocking the reabsorption of glucose (blood sugar) by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels. The drug's safety and effectiveness were evaluated in seven clinical trials with 4,480 patients with type 2 diabetes receiving Jardiance. The pivotal trials showed that Jardiance improved hemoglobin A1c levels (a measure of blood sugar control) compared to placebo.

Jardiance has been studied as a stand-alone therapy and in combination with other type 2 diabetes therapies including metformin, sulfonylureas, pioglitazone, and insulin. Jardiance is distributed by Boehringer Ingelheim Pharmaceuticals of Ridgefield, Connecticut. (Source: FDA Website, 01 August, 2014)

Natick Firm Karyopharm Receives Orphan Drug Designation for Selinexor
Karyopharm Therapeutics has announced that its drug candidate, Selinexor oral, has received orphan drug designation from the FDA for the treatment of acute myeloid leukemia (AML). Karyopharm Therapeutics is a clinical-stage pharmaceutical company focused on the discovery and development of novel first-in-class drugs directed against nuclear transport targets for the treatment of cancer and other major diseases. The orphan drug designation is designed to encourage the development of drugs which may provide significant benefit to patients suffering from rare diseases.

Acute myeloid leukemia (AML) is the most common form of acute leukemia in adults, accounting for over 80 percent of all acute leukemias in individuals over 18 years of age. According to the American Cancer Society, an estimated 18,860 people will be diagnosed with AML in the United States in 2014 and 10,460 patients will die of the disease.

The firm has also announced Selinexor has received orphan drug designation for the treatment of diffuse large b-cell lymphoma. Diffuse large B-cell lymphoma (DLBCL) is a form of non-Hodgkin lymphoma (NHL) and is the most common of the aggressive NHLs, accounting for up to 30 percent of newly-diagnosed cases of NHL in the United States. According to the American Cancer Society, about 70,800 patients will be diagnosed with NHL in the U.S. in 2014 and an estimated 18,990 patients will succumb to the disease. (Source: Karyopharm Therapeutics Website, 20 May 2014)

Ipsen US R&D Relocating to Cambridge
French company Ipsen has relocated its U.S. R&D operations from Milford to Cambridge, MA. The site will be key for innovation in targeted therapies across Ipsen's specialty areas as well as a center of excellence for peptides. The move also brings Ipsen closer to several key partners based in the Cambridge area, including prominent hospital centers, medical schools, biotech companies and universities.

The company signed an eleven-year lease on 62,600 rentable square-feet of laboratory and office space within the 280,000 square-foot building located at 650 East Kendall Street. The deal was brokered by Cresa Corporate Real Estate and the property is owned by BioMed Realty Trust. (Source: Ipsen US Website, 26 September, 2013)

Biogen Idec's Plegridy Approved for Treatment of Multiple Sclerosis
Biogen Idec has announced that the FDA has approved Plegridy, a new treatment for people with relapsing forms of multiple sclerosis (RMS). Plegridy is the only pegylated beta interferon approved for use in RMS. It is dosed once every two weeks and can be administered subcutaneously with the Plegridy Pen, a new, ready-to-use autoinjector, or a prefilled syringe.

In the first year of the clinical trial, Plegridy dosed once every two weeks significantly reduced annualized relapse rate at one year by 36 percent compared to placebo. Plegridy reduced the risk of 12-week confirmed disability progression, as measured by the Expanded Disability Status Scale, by 38 percent compared to placebo. Plegridy has also been recently approved by the European Commission. (Source: Biogen Idec Website, 15 August, 2014)

FDA Expands Approval of Genzyme's Lumizyme for Pompe Disease
The FDA has announced the approval of Genzyme's Lumizyme (alglucosidase alfa) for treatment of patients with infantile-onset Pompe disease, including patients who are less than 8 years of age. This approval provides access to Lumizyme for all Pompe disease patients, regardless of their age. In addition, the Risk Evaluation and Mitigation Strategy (REMS) known as the Lumizyme ACE (Alglucosidase Alfa Control and Education) Program is being eliminated.

Pompe disease is a rare genetic disorder and occurs in an estimated 1 in every 40,000 to 300,000 births. Its primary symptom is heart and skeletal muscle weakness, progressing to respiratory weakness and death from respiratory failure.

The disease causes gene mutations to prevent the body from making enough of the functional form of an enzyme called acid alpha-glucosidase (GAA). This enzyme is necessary for proper muscle functioning. GAA is used by the heart and muscle cells to convert a form of sugar called glycogen into energy. Without the

enzyme action, glycogen builds up in the cells and, ultimately, weakens the heart and muscles. Lumizyme is believed to work by replacing the deficient GAA, thereby reducing the accumulated glycogen in heart and skeletal muscle cells. (Source: FDA Website, 01 August, 2014)

Genzyme's Cerdelga Wins FDA Approval to Treat Type 1 Form of Gaucher Disease
The FDA has approved Genzymes's Cerdelga (eliglustat) for the long-term treatment of adult patients with the Type 1 form of Gaucher disease, a rare genetic disorder. Gaucher disease occurs in people who do not produce enough of an enzyme called glucocerebrosidase. The enzyme deficiency causes fatty materials to collect in the spleen, liver and bone marrow. The major signs of Gaucher disease include liver and spleen enlargement, low red blood cell counts (anemia), low blood platelet counts and bone problems.

Cerdelga is a hard gelatin capsule containing eliglustat that is taken orally. In patients with Gaucher disease Type 1, the drug slows down the production of the fatty materials by inhibiting the metabolic process that forms them. Type 1 Gaucher disease is estimated to affect about 6,000 people in the United States. (Source: FDA Website, 19 August, 2014)

Amgen to Expand Presence in Cambridge
Despite overall plans to cut 2,400-2,900 positions companywide and close facilities in Washington and Colorado, Amgen plans to expand its presence in Cambridge, MA. The company will keep its headquarters in Thousand Oaks, CA, but with reduced staff consolidated into fewer buildings. (Source: Amgen Website, 19 July, 2014)

Beth Israel Deaconess Cancer Center Launches Institute for RNA Medicine
The Cancer Center at Beth Israel Deaconess Medical Center (BIDMC) has launched a new research institute to harness the potential of RNA to revolutionize the way cancer and ultimately other diseases are treated and diagnosed. The Institute for RNA Medicine (iRM), established under the leadership of cancer geneticist and BIDMC Cancer Center Director Pier Paolo Pandolfi, MD, PhD, will bring together leading investigators in the field to pursue new lines of inquiry into non-coding RNA. The iRM will capitalize on BIDMC's patient population, as well as its unique mouse modeling facility and streamlined co-clinical trial platform, to bring non-coding RNA laboratory discoveries into the clinical setting. (Source: Beth Israel Deaconess Medical Center Website, 30 June, 2014)

Baxter Acquires Newton Company AesRx, LLC
Baxter International has announced the acquisition of AesRx, a private U.S. biopharmaceutical company focused on orphan drug targets, including the development and commercialization of Aes-103, an investigational prophylactic treatment for sickle cell disease (SCD). Aes-103 is a first-in-class, oral, small molecule compound. It has received orphan drug designation from the FDA and is eligible for orphan designation in Europe.

The Aes-103 program is currently in a Phase 2 clinical trial as part of an ongoing collaboration with the NIH's National Center for Advancing Translational Sciences (NCATS) through its Therapeutics for Rare and Neglected Diseases (TRND) program. The compound, originally patented by Virginia Commonwealth University, was developed by a team from the VCU Institute for Structural Biology and Drug Discovery, an interdisciplinary research center spanning the university's Schools of Medicine and Pharmacy.

Baxter made an initial payment to acquire the company and may make additional future payments based on specified development, regulatory and commercial milestones. The specific terms of the agreement were not disclosed. (Source: Baxter International and AesRx Websites, 09 July, 2014)

Baxter Sells Commercial Vaccines Business to Pfizer
Baxter International Inc. announced that it has entered into a definitive agreement to sell its two commercially marketed vaccines and related production facilities to Pfizer Inc. for a total cash consideration of $635 million, subject to certain adjustments.

The sale includes the company's commercial vaccines business, which is comprised of NeisVac-C, a vaccine which helps protect against meningitis caused by group C meningococcal meningitis (MenC), and FSME-IMMUN, which helps protect against tick-borne encephalitis (TBE), an infection of the brain transmitted by the bite of ticks infected with the TBE-virus. Both vaccines are currently available outside the United States, primarily in a number of European markets. Baxter continues to explore strategic options, including the potential for partnering or divesting its R&D development programs focused on influenza and Lyme disease.

Subject to regulatory approvals and other customary closing conditions, the companies expect to close the transaction by the end of 2014. Baxter expects 2014 vaccines revenues to total approximately $300 million and adjusted earnings of approximately $0.25 per diluted share, including approximately $50 million of one-time milestone payments related to the ongoing government collaborations for development of influenza vaccines. Baxter expects the transaction to be modestly dilutive to fourth quarter 2014 adjusted earnings and dilutive to 2015 adjusted earnings by approximately $0.15 per diluted share. (Source: Baxter International Website, 30 July, 2014) baxter.com

GE Healthcare Life Sciences to Create New US Headquarters in Massachusetts
GE Healthcare Life Sciences has announced that it will open a new 160,000 square-foot facility in Marlborough, as the new headquarters for its US operations. A $21M investment in the long-term future of this key GE Healthcare growth business, it will establish a new site for more than 500 GE Healthcare Life Sciences employees, including the creation of more than 220 new jobs. Recruitment has begun with the site scheduled to open in the spring of 2015.

This investment will transform a currently unoccupied space into labs, customer application facilities, and office space to complement GE Healthcare Life Sciences' existing manufacturing capability in Westborough. The facility will consolidate GE Healthcare Life Sciences' east coast presence. When fully operational, the new facility will bring more than 220 new job opportunities to the area, including highly-skilled positions such as lab technicians, biologists, medical doctors, process engineers, and customer service representatives.

GE Healthcare Life Sciences' $4B business has more than 11,500 employees in over 100 countries. The new US headquarters will house employees from across the Life Sciences business, including its research, bioprocessing, medical imaging, in vitro diagnostics and services segments. (Source: GE Website, 20 August, 2014)

Moderna Therapeutics Named to CNBC Disruptor 50 List
Moderna Therapeutics, the pioneer in developing messenger RNA (mRNA) therapeutics, has been named

to the 2014 CNBC Disruptor 50 list. CNBC recognized Moderna as one of the top 50 companies whose innovations are having a dramatic impact across their industries and are poised for hyper-growth.

Moderna is considered a Disruptor 50 for its revolutionary messenger RNA (mRNA) Therapeutics technology platform, which has the potential to speed the development and manufacture of treatments for many diseases that are currently untreatable with existing technologies. mRNA Therapeutics have unique advantages over other drug modalities, as they can be made and dosed with unprecedented ease and speed, reducing time and costs involved in the traditional drug development and manufacturing process. (Source: Moderna Therapeutics Website, 17 June, 2014)

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 Issues Guidance to Support Development of Nanotechnology Products
Three final guidance and one draft guidance were issued by the FDA providing greater regulatory clarity for industry on the use of nanotechnology in FDA-regulated products. One final guidance addresses the agency's overall approach for all products that it regulates, while the two additional final guidances and the new draft guidance provide specific guidance for the areas of foods, cosmetics and food for animals, respectively.

Nanotechnology is an emerging technology that allows scientists to create, explore and manipulate materials on a scale measured in nanometers—particles so small that they cannot be seen with a regular microscope. The technology has a broad range of potential applications, such as improving the packaging of food and altering the look and feel of cosmetics.

The FDA does not make a categorical judgment that nanotechnology is inherently safe or harmful, and will continue to consider the specific characteristics of individual products. (Source: FDA Website, 24 June, 2014)

FDA Approves Beleodaq to Treat Rare Form of Non-Hodgkin Lymphoma
The FDA has approved Beleodaq (belinostat) for the treatment of patients with peripheral T-cell lymphoma (PTCL), a rare and fast-growing type of non-Hodgkin lymphoma (NHL). The action was taken under the agency's accelerated approval program.

PTCL comprises a diverse group of rare diseases in which lymph nodes become cancerous. In 2014, the National Cancer Institute estimates that 70,800 Americans will be diagnosed with NHL and 18,990 will die. PTCL represents about 10 to 15 percent of NHLs in North America.

Beleodaq works by stopping enzymes that contribute to T-cells, a type of immune cell, becoming cancerous. It is intended for patients whose disease returned after treatment or did not respond to previous treatment. Beleodaq is marketed by Spectrum Pharmaceuticals based in Henderson, Nevada. (Source: FDA Website, 03 July, 2014)

FDA Approves Zydelig for Three Types of Blood Cancers
Zydelig is being granted traditional approval to treat patients whose chronic lymphocytic leukemia (CLL) has returned. Used in combination with Rituxan (rituximab), Zydelig is to be used in patients for whom Rituxan alone would be considered appropriate therapy due to other existing medical conditions. Zydelig is the fifth new drug with breakthrough therapy designation to be approved by the FDA and the third drug with this designation approved to treat CLL.

The FDA is also granting Zydelig accelerated approval to treat patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL), another type of non-Hodgkin lymphoma.

Zydelig carries a Boxed Warning alerting patients and health care professionals of fatal and serious toxicities including liver toxicity, diarrhea and colon inflammation, lung inflammation and intestinal perforation that can occur in Zydelig-treated patients. Zydelig is also being approved with a Risk Evaluation and Mitigation Strategy (REMS) comprised of a communication plan to ensure healthcare providers who are likely to prescribe Zydelig are fully informed about these risks.

Zydelig is marketed by Foster City, California-based Gilead Sciences. Rituxan is marketed by Genentech, a member of the Roche Group, based in South San Francisco, California. (Source: FDA Website, 23 July, 2014)

FDA Expands Approved Use of Imbruvica for Chronic Lymphocytic Leukemia
The FDA has expanded the approved use of Imbruvica (ibrutinib) to treat patients with chronic lymphocytic leukemia (CLL) who carry a deletion in chromosome 17 (17p deletion), which is associated with poor responses to standard treatment for CLL. Imbruvica received a breakthrough therapy designation for this use.

The FDA is also approving new labeling to reflect that Imbruvica's clinical benefit in treating CLL has been verified. A type of non-Hodgkin lymphoma, CLL is a rare blood and bone marrow disease that usually gets worse slowly over time, causing a gradual increase in white blood cells called B lymphocytes, or B cells.

Imbruvica's new use was approved more than two months ahead of the product's prescription drug user fee goal date of October 7, 2014, the date the FDA was scheduled to complete review of the drug application. The FDA reviewed Imbruvica'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.

Imbruvica is co-marketed by Pharmacyclics, based in Sunnyvale, California and Janssen Biotech, based in Horsham, Pennsylvania. (Source: FDA Website, 28 July, 2014)

FDA Takes Steps to Help Ensure Reliability of Certain Diagnostic Tests

The FDA took important steps to ensure that certain tests used by health care professionals to help diagnose and treat patients provide accurate, consistent and reliable results. First, the FDA is issuing a final guidance on the development, review and approval or clearance of companion diagnostics, which are tests used to identify patients who will benefit from or be harmed by treatment with a certain drug. Companion diagnostic tests are intended to aid physicians in selecting appropriate therapies for individual patients. These tests are commonly used to detect certain types of gene-based cancers.

Second, consistent with the requirements of the Food and Drug Administration Safety and Innovation Act of 2012, the agency is notifying Congress of its intention to publish a proposed risk-based oversight framework for laboratory developed tests (LDTs), which are designed, manufactured and used within a single laboratory. They include some genetic tests and tests that are used by health care professionals to guide medical treatment for their patients.

The FDA already oversees direct-to-consumer tests regardless of whether they are LDTs or traditional diagnostics. The agency intends to propose continuing to exercise enforcement discretion for low-risk LDTs, LDTs for rare diseases and, under certain circumstances, LDTs for which there is no FDA-approved or cleared test. (Source: FDA Website, 31 July, 2014)

FDA Approves Orbactiv to Treat Skin Infections
The FDA approved Orbactiv (oritavancin), a new antibacterial drug to treat adults with skin infections. Orbactiv is approved to treat patients with acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria, including Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), various Streptococcus species and Enterococcus faecalis. Orbactiv is administered intravenously.

Orbactiv is the third new antibacterial drug approved by the FDA this year to treat ABSSSI. The agency approved Dalvance (dalbavancin) in May 2014 and Sivextro (tedizolid) in June 2014. Orbactiv is marketed by The Medicines Company of Parsippany, New Jersey. (Source: FDA Website, 06 August, 2014)

FDA Approves New Type of Sleep Drug
The FDA has approved Belsomra (suvorexant) tablets for use as needed to treat difficulty in falling and staying asleep (insomnia). Belsomra is made by Merck, Sharpe & Dohme of Whitehouse Station, New Jersey.

Belsomra is an orexin receptor antagonist and is the first approved drug of this type. Orexins are chemicals that are involved in regulating the sleep-wake cycle and play a role in keeping people awake. Belsomra alters the signaling (action) of orexin in the brain.

Belsomra will be dispensed with an FDA-approved patient Medication Guide that provides instructions for its use and important safety information. Belsomra is a controlled substance (Schedule-IV) because it can be abused or lead to dependence. (Source: FDA Website, 13 August, 2014)

FDA Approves Genentech's Avastin for Aggressive and Late-Stage Cervical Cancer
The FDA has approved a new use for Avastin (bevacizumab) to treat patients with persistent, recurrent or late-stage (metastatic) cervical cancer.

Cervical cancer grows in the tissues of the lower part of the uterus known as the cervix. It commonly occurs when human papillomaviruses (HPV), a virus that spreads through sexual contact, cause cells to become cancerous. Although there are two licensed vaccines available to prevent many types of HPV that can cause cervical cancer, the National Cancer Institute estimates that 12,360 American women will be diagnosed with cervical cancer and 4,020 will die from the disease in 2014.

Avastin works by interfering with the blood vessels that fuel the development of cancerous cells. The new indication for cervical cancer is approved for use in combination with chemotherapy drugs paclitaxel and cisplatin or in combination with paclitaxel and topotecan.

The FDA reviewed Avastin for treatment of patients with cervical cancer under its priority review program because 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.

Avastin is marketed by South San Francisco, California-based Genentech, a member of the Roche Group. (Source: FDA Website, 14 August, 2014)

New Members

Mr. James Araujo, Jr., *Project Manager*, Lonza Biologics Inc

Mr. Joe Barry, *Business Development Director*, Hyde Engineering + Consulting

Mr. Eric D. Briggs, *Account Executive*

Ms. Catherine Choung, MCPHS Boston

Francis L. Corden, Jr., *Director of Advanced Services*, New England Controls, Inc.

Brian Earley, *Validation Specialist*, Commissioning Agents, Inc

Ms. Amanda Grimes, *Validation Engineer*, Commissioning Agents, Inc

Mr. Matthew R. Hodgdon, *National Account Manager*, CCL LABEL

Jeff Holmes, *Process Engineer*, Genzyme Corp

Mr. Timothy King, *Director of Business Development*, Alternative Business Resources

Mikhail Lara

Thomas H. Lauzon, *Vice President*, Synageva Biopharma

Ms. Sarah B. McKellick, *Development Associate I*, Alexion Pharmaceuticals

Mr. Steve Moser, *President*, Cambridge Cleanroom Corp.

Mr. John Nguyen, *Validation Engineer III*, ImmunoGen, Inc.

Mr. Peter E. Przybycien, *Capital Portfolio Manager*, Genzyme

Mr. Trevor Rancourt, *Sales Engineer*, Azima DLI

Mr. Martin Razo, *Manager*, Sanofi Pasteur

Mr. Charles Respess

Mr. Benjamin A. Rizkin, *Student*, University of Massachusetts at Amherst

Mr. Mark J. Ryan, *HVAC Designer*, DPS Engineering

Ms. Sarah Vesey, *Junior Engineer*, DPS Engineering

Mr. Matthew J. Wainwright, *Validation Engineer III*, ImmunoGen, Inc

Ryan D. Wills, *Process Architectural Engineer*, DPS Engineering

Mr. Ziyi Xu, *Student,* Northeastern University

Mr. Ronald Belling, *Sales Executive*, Terracon Corporation

Mr. Mark Braatz, *Life Sciences Account Manager*, F.W. Webb Process Controls Division

Mr. John P. Busanovich, Boston College

Daniel Cancelliere, *New England Territory Manager*, Micro-Clean, Inc.

Ms. Linda Hao Yun Chen, *Student,* Massachusetts College of Pharmacy and Health Sciences

Ms. May L. Chin, *Process Engineer III*, Genzyme

Mark Collamer, *Senior Process Engineer*, NNE Pharmaplan

Mr. Michael D. Corbett, *Senior Process Engineer*, NNE Pharmaplan

Mr. Aaron R. Duffy, *Process Engineer*, APECS Engineering

Justin Frey, *Major Account Executive*, B&V Testing, a Stericycle Business

Dr. Stuart Gallant, *Senior Consultant*, Compass Biotechnology

Mr. John C. Giner, P.E., *Facilities and Engineering Project Manager*, MedImmue/AstraZeneca Supply Biologics

Mr. Tyler Hassenpflug, *Consultant*, Integrated Commissioning and Quality Corporation

Mr. Zvonko Ilic, *Validation Engineer*, Genzyme

Mr. Sujit G. Jain, *Process Engineer*, Lonza Biologics Inc

Ms. Kristen N. Kelly, *Student*, Northeastern University

Mr. Douglas J. Lantigua, *Managing Partner*, MUSA Technology Partners LLC

Mr. Donal Lyons, *Virtual Construction Coordinator*, Structure Tone

Mr. Hemant D. Mehta, *Manager of Operations*, M+W U.S., Inc.

Mr. Christopher J. Ouimet, couimet, *Senior Vice President*, Global Sales, AM Technical Solutions

Guddi Patel, *Manager, Risk Mgmt and Regulatory Compliance*, Oracle/HSGBU

Mrs. Margaret Pflugh, *Reliability Engineer*, Lonza Biologics Inc.

Mr. Steven Pieroni, *Manufacturing Sciences Engineer*, ImmunoGen Inc

Héctor M. Rosado, *Principal Project Management*, Sanofi

Vatsala Sadasivan, *Sr Continuous Improvement Analyst*, Genzyme

Mr. Joseph Shaw

Tom Stone, Denison Pharmaceuticals

David Vario, *Director, QA,* ImmunoGen, Inc.

Mr. Robert D. Whipple, *Director Quality Assurance - QORCoE*, Pfizer Inc

Member Anniversaries

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp

Mr. John P. Alleruzzo,

Mr. Fred H. Arbogast, Critical Process Filtration Inc.

Mr. Joseph M. Baumann, Genzyme Corp

Mr. Simon Bedigian, Olympic Systems Corp

Dr. James V. Blackwell, PhD, MBA, The Windshire Group, LLC

Mr. Richard F. Caires, Jr., Shire HGT

Mr. John G. Campion, P.E., The Hart Companies

Mr. Richard P. Capobianco,

Mr. Ronald C. Case, Aztec Technologies, Inc.

Mr. Michael S. Cheney, Biogen Idec

Mr. Brian L. Clark, GMP Operations Consulting

Mr. Robert T. Clark, Perrigo Inc

Mr. Donald Cole, Hart Passivation Services, Inc.

Dr. Charles L. Cooney, Massachusetts Institute of Technology

Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation

Mr. Andrew A. Coull, JM Coull Inc

Michael B. Cronin, Alexion Pharmaceuticals

Mr. George A. Dainis, P.E., Industrial Facilities Design Inc

Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. Edward F. Dean, III, Eagle Electrical Supply Co

Mr. David Dears, Victaulic

Mr. Frederick C. DeCicco, Sharpe Mixers

Mr. William O. Downie, AstraZeneca

Mr. Brian P. Druce, Genzyme

Mr. James R. Dube, Alexion Pharmaceuticals

Mr. Daniel J. Dumont, Dynamic Systems Inc

Mr. Mostafa N. Elmorsi, Boehringer Ingelheim Pharma

Mr. Abel A. Erdman, Bristol-Myers Squibb Co

Mr. John H. Evers, Lantheus Medical Imaging

Mr. Ric Feldt, Jeff Smith & Associates

Mr. Timothy J. Fields, Protein Sciences Corporation

Mr. Michael J. Fisher, Genzyme, Sanofi

Mr. Christopher J. Fournier, Mar Cor Purification

Mr. Joshua Froimson, AbbVie Bioresearch Center

Mr. Michael S. Giorgetti, Sr., Alkermes Inc

Mr. Brian M. Hagopian, CPIP, Clear Water Consulting, Inc.

Mr. Andrew R. Hahn

Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz

Mr. Edwin L. Harmon, III, Genzyme Corp

Mr. David G. Harney, Microfluidics

Mr. Richard R. Harper, Flow Tech Inc

Ms. Shelly Henderson, HCA

Mr. Paul F. Herbert, Alkermes Inc

Mr. Stephen R. Higham, PE, Genzyme Corp

Mr. Johnson Hoey, Forest Laboratories, Inc.

Mr. Mitchell I. Hollander, Lantheus Medical Imaging

Mr. David L. Hyde, CPIP, Lantheus Medical Imaging, Inc.

Mr. Michael J. James, Northeast Water Services

Mr. Robert W. Juffras, MS, Olympus Biotech

Ms. Pauline Jurasinski, Genzyme a Sanofi Company

Mr. Jerome E. Justin, Shire Pharmaceuticals

Mr. Frank J. Kuszpa, Jr., Jones Lang LaSalle

Mr. Stephen P. Kuzil

Mr. Thomas G. Larkin, Amgen Inc

Mr. Thomas H. Lauzon, ImmunoGen Inc

Mr. Howard L. Levine, PhD, BioProcess Tech Consultants, Inc.

Mr. Richard V. Levy, PhD, PDA

Peter F. Levy, PL Consulting, LLC

Mr. Robert M. Luke, Georg Fischer Inc

Mr. William C. Lynch

Mr. Allan J. MacDonald, CPIP, BosBio

Mr. Frank J. Manning, VNE Corp

Mr. Daniel J. Mariani, M+W Group

Mr. Denis M. Mathiowetz, DM BioPharm Associates Inc.

Mr. Gary E. McKiernan, PM Group

Mr. Todd McLaren

Ms. Lynda S. Miller, Eisai, Inc.

Stephen P. Miraglia, Sapphire Project Services LLC

Mr. Hank Moes

Mr. David Monette, Olympus Biotech

Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc

Mr. Thomas W. Moss, Integra Companies

Mr. Armen J. Nahabedian, Pfizer

Mr. Russell B. Parry

Mr. Christopher R. Perley, Dyax

Mr. Peter A. Petrillo, Millennium Facilities Resources Inc

Mr. Stephen R. Potter, Baxter

Mr. Tim J. Potvin, PE, Quality Air Control

Mr. Richard D. Priester, Strategic Facility Planning LLC

Dr. John J. Prior, Genzyme Corp

Mr. Douglas A. Queen, TRG Builders LLC

Mr. Thomas A. Ramundo, New England Controls Inc

Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc

Ms. Cheri M. Redman, Amgen

Mr. David A. Rielly, CEM, LEED GA, Novartis Pharmaceuticals

Mr. Scott Ripatrazone, Insco Group

Mr. Stephen P. Rossmeisl

Mr. Stanley E. Rotkiewicz, Jr., Genzyme Corporation

Mr. Tom J. Routliffe, Medimmune

Mr. Paul E. Rowe, Millipore Corporation

Mr. John J. Rozembersky, Rozembersky Group

Mr. Gregory M. Ruklic, Independent

Mr. Pasquale M. Sacco, Shire HGT

Mr. William S. Seaver, TEK Stainless Piping Products

Mr. Robert J. Sheehan

Mr. Peter K. Silverberg, Abec, Inc.

Mr. Alexander E. Smith, Jr., M+W U.S., Inc.

Mr. Michael G. Sprague, Ethide Laboratories

Mr. Michael J. Sweeney, Hart Design Group

Mr. David A. Tomsik, CRB Consulting Engineers

Dr. Donald L. Towns, Donald L Towns Professional Engineer

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. Jeffrey L. Werner

Mr. James L. Whalen, Watson-Marlow Flexicon

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Jay F. Zaino, GxP Automation LLC

Mr. Gary V. Zoccolante, Evoqua Water Technologies LLC (formerly Siemens Water Technologies Corp)

15 Year Anniversary

Mr. Gordon W. Brailsford, Jr., Sanofi

Mr. William J. Jacobsen, Dovetail Integrated Systems

Mr. Daniel J. Rufo, Jr., IPM

Ms. Kristin Scharf, New England Controls

10 Year Anniversary

Ms. Allison A. Cacciatore, Genzyme

Mr. Timothy A. Elliott, Arden Engineering & Construction LLC

Jay Glasel, Univ of CT Health Ctr

Mr. William Held, Lend Lease

Mr. Sean Hoban, DPS Engineering

Mr. Juergen A. Martens, PhD, MannKind Corporation

Mr. Ernest Penachio, Civitas Therapeutics

Mr. William Piombino, Lonza Biologics Inc

Mr. Fred Scribner, Columbia Construction Co

Mr. Glenn M. Slawson, Commissioning Agents

Mr. Michael C. St Louis, NEHP

Ms. Olive Sturtevant, Dana Farber Cancer Institute

Mr. Jay Sullivan, AbbVie Bioresearch Center

Mr. Brandon S. Varnau, Genzyme - Allston Landing Facility

Mr. Joseph M. Whitney, North Shore Mechanical Contractors

5 Year Anniversary

Mr. Ryan J. Adams, Shire HGT

Ms. Denise Aronson, Safety Partners Inc

Ms. Kelli Y. Barrett, Genzyme Corp

Mr. Jeffrey Bruno, Genzyme Corp

Ms. Michelle A. Daunais, Nitto Denko Avecia

Dr. Chase E. Duclos-Orsello, EMD Millipore

Mr. Paul Esteves, SNC Lavalin

Mr. Peter Ferguson, Shire

Mr. James J. Gikas, Vanderweil Engineers

Mr. John Greco, Genzyme Corp

Mr. Frank R. Guardabascio, Massachusetts Biologic Laboratories

Mr. Alfonso Guarracino, ICQ Consultants

Mr. Fredric Halsall, Donnegan Systems, Inc.

Mr. Alan Karner, Shire HGT

Ms. Anna Lai, Organogenesis Inc

Dennis Lew, Biogen Idec

Mr. Russell L. Newton, Latham BioPharm Group

Mr. Joseph G. O'Brien, Pfizer

Mr. John F. Ryan, Pall Biopharmaceuticals Corp

Mr. Michael Thompson, Plastic Concepts, Inc.

Ms. Mary Valentino, Thermo Fisher

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