Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

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NEWSLETTER

November 2012, Volume XXII, No. 6

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President's Message: It's Been Another Fantastic Year for the Boston Area Chapter Product Show

Dear Fellow Boston Area Chapter Members,

Last month, I started off with "It's been another fantastic year for the ISPE Boston Area Chapter," and I am going to reiterate that statement with regard to our flagship event - the Annual Product Show. Two thousand attendees and over 300 exhibitors made this year's Show the biggest in Chapter history. And the quality of the educational offerings and keynote address by Peter Moesta of Bristol-Myers Squibb made it one of the best in recent years.

I want to recognize and thank all those involved in making the Show such a resounding success. In particular, our thanks go to our hardworking committees: the Product Show Committee and Co-Chairs Laurie Masiello, Mark Sitcoske and Steve Kennedy, the Educational Program Committee, the Social Committee and the Young Professionals Committee. And special thanks to our Chapter management team at CAMI, our valued Boston Area Chapter partner.

At the Show, I had the pleasure of meeting with Nancy Berg, the new President and CEO of ISPE International. Not only did she find room for us in her busy travel schedule, she declared the Show a "world class event." I was very encouraged by our discussion and, after listening to Nancy's assessment of the current situation and gaining a little insight into her philosophy, I am convinced that ISPE made the right choice bringing her on board to lead the organization to the forefront of the industry. ISPE's new strategic plan emphasizes interaction and cooperation between pharmaceutical industry leaders and regulatory authorities, increased emphasis on product quality and patient safety, and a focus on the entire product lifecycle. With these reinforced initiatives, ISPE and the industry will continue to prosper, which in turn will help each one of us as we continue to build our careers.

While at the Show, I also had the privilege of awarding the Hank Moes Lifetime Achievement Award to Dick Priester. Please read the article in this month's newsletter to get the full picture of what this award means and why Dick is such a deserving recipient.

With the new initiatives at the national level, we are going to continue to do our part and strive to meet and hopefully exceed our goals for the upcoming year. To keep these goals in the forefront and help Members track our progress, I will make it a practice to present an update in each issue of the newsletter:

- Membership Growth

Our goal this year is to add 50 new regular Members and 15 Young Professional Members. Between August and the Product Show, we added 27 regular Members and 2 Young Professional Members. In addition, the membership drive at the Product Show added 9 regular Members - and we expect to add another 5-10 as a result of attendance at the Show. So we're already well on our way to exceeding our goals!

An important factor in membership growth is Member retention - keeping our current Members renewing their membership year after year. Our goal is to raise our retention rate from 80 to 84 percent. We are still awaiting updated membership retention data (calculated by International ISPE) which was trending upward as of August.

Retention rate is a measure of how well we are doing in regards to supporting and delivering value to our membership, so please help us help you and watch for the membership survey this month. PLEASE, PLEASE, PLEASE complete this survey to assist us in setting the course for our Chapter to deliver the benefits you all expect and deserve.

Student Chapter Growth and Development

Our goal for Student Chapters this year is 50 new Student Members. Since August, we have added only 1 additional Student Member, but this should improve dramatically now that the fall semester is underway. Plus the Student Development Committee is making great strides reaching out to all our current Student Chapters and helping them develop and prosper. We look forward to great progress against this goal in the coming months!

- Educational Program Excellence

As stated in the last newsletter, and recognized by Nancy Berg at the Product Show, our Chapter has gained national recognition for our stellar educational programs. This was demonstrated by the impressive array of programs at the Product Show. Thanks again to the Educational Program Committee Co-Chairs Sean Brown and Mike Levesque and all the committee members for yet another great event.

Together we can continue to make the ISPE Boston Area Chapter a great resource for all our Members. Again, I thank you for giving me the opportunity to help lead the way.

Sincerely,

Jay Zaino
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Congratulations to Our Newest Certified Industry Professional™ (CPIP™)

The Chapter's spring 2012 CPIP Study Group has added a total of seven new Certified Pharmaceutical Industry Professionals™ to the Chapter's CPIP roster. The latest addition to this illustrious group of Boston Area Chapter Members is Robert Snow, CPIP, of Genzyme. The CPIP credential recognizes comprehensive industry knowledge. Candidates are assessed based on both education and experience, and must also pass an exam to be awarded the credential.

The current CPIP Study Group began on September 18 at Biogen Idec in Cambridge. Plans for the future include a session combining participants from both the Boston Area and New England Chapters. Keep an eye on this space for more information.

Scholarship Application Deadline November 15 - Don't Be Late!

The ISPE Boston Area Chapter offers a scholarship program for the benefit of Members and their families who are pursuing formal education in the Life Sciences. Scholarship awards of up to $2000 are available for qualified applicants!

Who is eligible? Eligible recipients must be enrolled in an accredited College or University's Associates, Bachelors or Masters program and/or registered in a course at an accredited College or University. Three categories of individuals may apply:

- Incoming freshmen - Incoming freshmen who are the children of a Boston Area Chapter Member in good standing and are pursuing a career in the Life Sciences.
- Undergrad and grad students - Students entering their sophomore through senior years of undergraduate study or students entering or continuing post graduate study. These candidates shall be Members in good standing of the Boston Area Chapter pursuing a degree in the Life Sciences
- Continuing education - Individuals seeking continuing education as part of their career

development. These individuals shall be Boston Area Chapter Members in good standing.

The next deadline is November 15th, so apply today! Click HERE for more information and an application. If you have any additional questions call the office at (781) 647-4773 or email office@ispeboston.org .

Advertise on www.ISPEBoston.org

Did you know the Boston Area Chapter Website attracts over 8000 visits monthly from the region's life sciences professionals? Now you can reach the same audience by advertising on www.ispeboston.org. A limited number of advertising spots are now available - including some with animation - so don't delay. Ads are sold on a first-come, first-served basis. To learn more about this unique opportunity and reserve your space, contact Amy Poole, Chapter Manager, 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 at www.ispeboston.org/sponsorship containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Upcoming Chapter Events - Mark Your Calendar

Thursday, November 15, 2012
Marketing Yourself: Empowering You to Increase Your Value in the Workplace

Genzyme Corporation, Framingham, MA

Looking to be more successful in gaining new opportunities within the workplace? Or need advice for making the right impression with a potential employer? Discerning employees know there's a need to go beyond working hard and hoping someone else recognizes them for new openings or promotions. To advance in the workplace, it's critical to learn to "market yourself" and be acknowledged for your unique talents and capabilities. In the competitive world of biopharm, how do you communicate and honestly present yourself in an advantageous way? This session will examine strategies for marketing yourself from multiple perspectives within the industry. The Panelists, drawing from a wealth of experience in recruiting and developing talent in biotech, will provide key insights for boosting personal success throughout the life cycle of a working professional (from the initial interview to mid-level career).

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=189

Thursday, December 13, 2012
Serialization Regulations and Technology: Navigating the New Demands of the Distribution Chain

Hyatt Regency Hotel, Cambridge, MA

The Biopharmaceutical Industry is quickly adopting new technology to secure the drug distribution chain, help assure patient safety, comply with evolving regulations, and enhance the bottom line. Attendees at this meeting will learn from industry experts who know the regulations and the technology. Attendees will see case studies with examples that deliver real business benefits and assure compliance. If you are developing new medicines, manufacturing drug products, or distributing them, this meeting applies to you - don't miss it! Come join us and hear industry experts

describe what World-Class companies are doing now!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=190

Sneak Preview of Upcoming Events

Thursday, January 17, 2012
Educational Program focusing on Building Information Modeling (BIM)

Thursday, February 15, 2012
Joint Educational Program with the ISPE New England Chapter

Thursday, March 15, 2012
Educational Program focusing on Commissioning and Qualification

Annual Product Show Reaches New Heights in 2012

by Laurie Masiello, Masy Systems, with photos by Alastair Battson Photography

A panoramic view of Gillette greeted Product Show attendees on October 3rd.

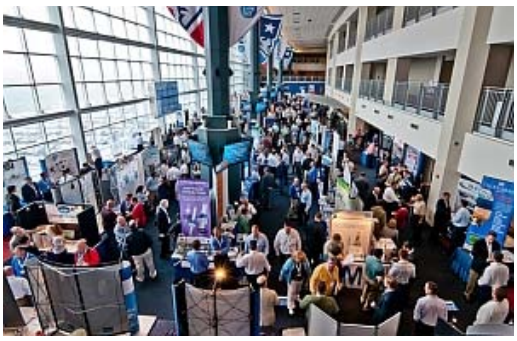
The ISPE Boston Area Chapter Product Show reached new heights in 2012. Four well-attended educational seminars presented by industry experts were enjoyed by almost 300 attendees. Keynote speaker Peter Moesta from Bristol-Myers Squibb (BMS) shared industry insights and his company's strategies for industry excellence. And to top it off, ISPE President and CEO Nancy Berg spent the day touring the exhibits and meeting with both vendors and attendees, and pronounced the Show a "world class event."

The Show opened with exciting educational seminars, including "FDA-483 and Beyond."

Two thousand attendees came to enjoy the camaraderie of over 300 vendor tables set up at Gillette Stadium. The Young Professionals were treated to a new idea - an Equipment Showcase with interactive displays by 14 vendors. Free parking, free admission and free food have been hallmarks of this event since its inception, supported in full by our generous sponsors. A new floor plan, new food choices, new advertising opportunities and a new product demonstration stage were welcome and innovative enhancements.

Exhibitors from 33 states and two countries were

Previous Issues



Over 300 exhibitors and 2000 attendees filled the Show floor to overflowing.

represented at the show. Six exhibitors had a short commute, coming from companies based in Foxboro. Exhibitors from every New England state, the entire eastern and western seacoasts, the southwestern states, the Midwest, the Rocky Mountain area, Canada - our neighbor to the North - and our friends across the pond in England all contributed to the success of this year's blockbuster.

Nine companies with job openings in the biopharmaceutical field participated in the Career Fair. Representatives from Alexion Pharmaceuticals, Biogen Idec, Bristol-Myers Squibb, CRB Consulting Engineers, HireMinds, Hyde Engineering and Consulting, Lonza, M&W Group and Shire all met with candidates about their open positions.

Wider aisles made it easy for attendees to converse with exhibitors and colleagues.

This year impromptu product demos were augmented by formal presentations in the exhibit area.

The Product Show Committee meets year round to plan all facets of the Show. Each year a survey is sent to both attendees and vendors following the Show. Committee members appreciate the candid comments and suggestions for improvements already received this year, and look forward to making next year's experience even better. If you would like to participate by joining the Product Show Committee, please contact co-chair Laurie Masiello at lmasiello@masy.com or Steve Kennedy at Steven.Kennedy@mwgroup.net.

Newsletter Archive

Networking opportunities are one of the main reasons for attending the Product Show - along with the view!

Keynote Speaker Peter Moesta of BMS Sheds Light on Industry Trends

by Shelly Henderson, Independent Consultant & former Vice President, Boston Area Chapter, with photos by Alastair Battson Photography

The Boston Area Chapter had the privilege of hosting keynote speaker, Dr. Peter Moesta, who drew a crowd of over 250 to Gillette's West Clubhouse at this year's Product Show. He described key industry trends impacting the biologics manufacturing business today and the strategy BMS has developed to capitalize on these trends. His candid answers to follow-up questions posed by audience members were an additional bonus.

Keynote Speaker Dr. Peter Moesta of BMS addressed a rapt crowd at this year's Product Show.

Dr. Moesta joined BMS in early 2011 as Senior Vice President of Biologics Manufacturing and Process Development. He leads the broad-based technical activities between R&D and Manufacturing to support the successful clinical development, registration, manufacturing and commercialization of biologics products. Prior to BMS, he served as Division Vice President, Biologics Manufacturing for Abbott Laboratories, where he guided the manufacturing process and led the CMC effort to obtain approval for HUMIRA®, with sales now approaching $10 billion annually. He also led the design, start-up and registration of the company's large scale biologics manufacturing plant in Puerto Rico.

In earlier years, Dr. Moesta was Vice President, Process Development and Operations for BASF Bioresearch Corporation in Worcester, where he planned and executed the construction of a combined research and biologics production facility, then built a successful multi-disciplinary team to develop and manufacture therapeutic proteins at that facility. Dr. Moesta earned his Master's degree in Chemistry and a Ph.D. in Biochemistry from the University of Freiburg in Germany and completed post-doctoral fellowships at the University of Freiburg and UCLA.

Dr. Moesta began by presenting the following key industry trends that are impacting the biologics manufacturing business today:

- Looking at ten of the top pharma companies, approximately 50 percent of the current market for drugs and biologics is coming off patent by 2017 - a staggering number.
- As a result, there will be increased demand in manufacturing capacity to produce generics/biosimilars.
- Also as a result, major cost reduction programs are in place at most of the top pharma companies.

Dr. Moesta's candid answers to questions from the audience made a great followup to his formal presentation

- Global mammalian production capacity is expected to stabilize at around 3 million liters by the end of 2013.
- Excess capacity, on the order of 30-50 percent, is expected to be available through 2016.

- Non-compete restrictions have prevented use of much of the existing excess capacity for biosimilar production.
- Efficiencies in pharma/medical production significantly lag other industries
- Ex-US capacity is growing due to significant tax advantages abroad in countries such as Ireland, Singapore and in Puerto Rico.
- Additional biologics manufacturing trends include:
    - Fewer blockbuster drugs, and increased niche products.
    - Increased yields, minimal changes in capacity utilization
    - Less regulatory harmonization due to increased emerging market regulations
    - Increased growth of emerging market and Asian manufacturing, and minimal growth of domestic manufacturing.

In response to these trends, BMS has developed the following strategy to adjust its biologics manufacturing to provide high quality products reliably at affordable cost to patients:

- Be prepared in the event that sharply increased capacity is required.
- Keep process development (PD) and clinical development (CD) in-house and outsource commercial production (CP) as needed to meet demand and to capitalize on excess capacity available in industry.
- Co-locate PD and CD, and to some extent CP.
- Increase the use of disposables in new facilities to provide flexibility.

In keeping with the setting, Dr. Moesta concluded by quoting New England Patriots owner, Robert Kraft, as follows: "Every crisis is an opportunity if managed properly."

Product Show Hosts ISPE President and CEO Nancy Berg

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

At this year's Product Show, the Boston Area Chapter had the privilege of hosting ISPE President and CEO Nancy Berg. Ms. Berg assumed her position with the organization in January 2012 and brings 30 years of experience in strategic leadership, organizational growth and relationship-building to her role.

Chapter President Jay Zaino and Past President Brian Hagopian had the pleasure of hosting ISPE President and CEO Nancy Berg at this year's Product Show.

At the time of her appointment, 2012 ISPE Board Chairman Randy Perez described Ms. Berg as the ideal person to drive ISPE forward. He added that her "appointment comes at a time when the global pharmaceutical industry faces increased pressure to improve productivity and control costs across their product development and manufacturing operations" and that she brings the right blend of knowledge and leadership experience to guide ISPE "in enhancing our value to our Members, our relevance to the industry, and our role as a catalyst for solutions that will positively influence global health."

Ms. Berg opened the keynote address with a few words about her vision for the future role of ISPE.

In her first months on the job, Ms. Berg has crisscrossed the country and travelled the globe, meeting with Chapters and Affiliates, regulatory agencies and industry leaders. The Boston Area Chapter is honored that she chose to include our Annual Product Show in her busy schedule. In addition to presenting opening remarks prior to the keynote address, she took the time to meet with current Chapter President Jay Zaino and Immediate Past President Brian Hagopian, CPIP, joined the Chapter's Board of Director's for a private luncheon and spent the afternoon touring the exhibits and meeting with both vendors and attendees. After her busy day at Gillette, she admitted to being extremely impressed with everything she had seen and declared the Product Show a truly "world-class event." Coming from an individual with her extensive trade show and industry background, that is a world-class compliment!

Dick Priester Receives Lifetime Achievement Award at Product Show

by Jay Zaino, GxP Automation, with photos by Alastair Battson Photography

This year, I had the distinct honor of presenting the Hank Moes Lifetime Achievement Award to Dick Priester. The award is named after Hank Moes, one of the founders of the Boston Area Chapter. Hank organized the first ISPE Boston Area Chapter steering committee meeting in Charlestown back in 1990, was one the Chapter's founding members and served as its first president. The Hank Moes Lifetime Achievement Award recognizes the contributions and dedication of key individuals who have served the Boston Area Chapter over an extended period of time and helped mold it into what it is today.

Dick Priester, one of the "founding fathers" of the Boston Area Chapter, was presented with this year's Hank Moes Lifetime Achievement Award by Chapter President Jay Zaino.

With Hank, Dick Priester was one of the original founding members of the Boston Area Chapter. He served on the first Chapter Board of Directors, followed in Hank's footsteps to become the second Chapter president and was instrumental in the early success and growth of the Chapter during its formative years. After his success with the Boston Area Chapter, Dick was nominated for and elected to the ISPE International Board of Directors where he served for several years, eventually rising to the position of Chairman. He also dedicated his time serving on the ISPE technical document steering committee and was co-chair of the Biotechnology Baseline Guide steering team.

Dick has remained very active with ISPE, helping to shape the organization at both the international and local levels. He continues to support the Boston Area Chapter by assisting with educational programs and as an active member of the past presidents' group.

Without the hard work and dedication of members like Dick, this organization would not be the success that it is today. We all owe Dick a debt of gratitude for building the foundation that has eventually led to the great success and the many achievements of the Boston Area Chapter. When you see Dick at an event, please congratulate him on winning the Hank Moes Award and join me in thanking him for all his hard work and his many contributions to ISPE and the Boston Area Chapter.

Product Show After Party Keeps the Ball Rolling

by Laurie Masiello, Masy Systems, with photos by Alastair Battson Photography

Bar Louis at Patriots Place provided an exciting venue for this year's after party.

Bar Louis was closed to the general public while the ISPE Boston Area Chapter held a private celebration after the Product Show on October 3. New England Patriots linebacker Jerod Mayo greeted a long line of enthusiastic fans and spent the evening autographing photos and mementos and posing for photos with Product Show party goers. The atmosphere was celebratory as exhibitors and attendees continued the fun and networking after the Show concluded. Sports trivia games were enjoyed along with appetizers and drinks. Tired and happy guests partied into the night, making this year's After Party another success.


Pats Linebacker Jerod Mayo signed autographs for party goers, including Product Show Committee Co-chair Laurie Masiello & husband John, & Chapter Manager Amy Poole (left) and her team.

"This Old Plant..." Educational Program Presented in a Really Old Plant

by John Spohn, CPIP, Castle Hill Technologies, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

We in the pharmaceutical industry - especially those of us who practice in "Genetown" - have a skewed idea of what constitutes an old plant. Most of us would consider a facility built in 1987 practically a museum piece. On September 20, the Chapter presented an educational program in a truly old plant: the Great Engines Hall of the Waterworks Museum in Chestnut Hill that was built back in '87 - 1887, to be exact, or 125 years ago!

The Allis "engine" moved 30 million gallons of water a day for 30 years - and provided a fitting backdrop for Rick Kotosky's excellent presentation.

"This Old Plant (Even If It's New) - Performing Retrofit Projects In An Operating Facility" began with the customary networking reception where attendees enjoyed refreshments and had the run of the Great Engines Hall, the main pumping station for the Metropolitan Waterworks which set the standard for municipal water systems for the better part of a century. The Hall houses three enormous steam engines and the pumps they drove. One, the Allis Engine, employed the same 575 horsepower unit as the eight that propelled the Titanic. This pump moved up to 30 million gallons a day at 180 psi - for nearly 60 continuous years. Try getting that kind of performance out of a CIP pump today.

The audience, nestled in between the giant machines, received welcoming greetings by Past President Brian Hagopian, CPIP, and a brief presentation on the history surrounding them by a Waterworks Museum docent. As meeting manager, I had the privilege of introducing our featured speaker for the evening, Rick Kotosky, PE, of Integrated Process Technologies. Rick has performed retrofit projects throughout his 30-year career in plants old and new.

Retrofits always involve modification of systems beyond their original specification, systems usually shared with ongoing operations. Such projects never have the luxury of shutting down the plant for the duration of project activities, so work must often be undertaken within an operating facility in spaces adjacent to those in active manufacturing use. This requires extraordinary levels of planning and coordination but, above all, the experience of those who have "been through the wringer" a few times.

Rick's presentation focused on conveying to the attendees key considerations specific to retrofit projects that they can use. Some points were illustrated with "war stories" to show how a consideration was put to good use - or discovered through hard lessons. The discussion was organized around four life cycle stages of a project: design, planning, execution and completion. A fundamental message was that all phases of retrofit projects must respond to constraints and requirements of the existing facility and

Chapter Members Gene Dennen (l) and Dan Ramsey (r) found themselves an interesting perch during the networking reception.

operations and the big question is always: "When can we return to production?"

Points from the discussion of the design stage hit upon the need to involve all key stakeholders in the concept phase, to account for all constraints from the facility and operations and hidden impacts on shared utilities. Rick recommended proactively verifying drawings and records and presented considerations for acceptance testing and the assessment of risks and regulatory impacts.

When planning a retrofit project, the watch words are to anticipate complications and expect the unexpected. System downtime for project work presents opportunity for pent-up PM but guard against over-committing utilities or resources. Careful, step-by-step planning is vital for protections against environmental and HVAC impacts for active manufacturing areas as well as developing the return-to-service plan.

Modern art? No, one of the massive pumps (called "engines") at the Waterworks Museum in Chestnut Hill, site for September's "This Old Plant..." educational program.

Rick advised that in executing a project there are obvious but important aspects like training, working clean, logistics and staffing for temporary workers, and equally important but not-so-obvious considerations like effects from vibration and noise, disruptions to normal flows of personnel and demand spikes for utilities and QC lab work for EM samples. Above all, it is crucial to maintain a manufacturing focus and literal 24/7 access to decision makers from Manufacturing, QA and Regulatory to cope with arising challenges in a timely manner.

The most vital aspect of the completion phase gets its start back in planning phase discussions with key stakeholders: defining what "done" means. Requirements and expectations of all need to be put on the table and consensus positions for each published prior to the commencement of work. Similarly, the return-to-service plan must account for contingencies like failed samples. Rick said the key in completion is the discipline to make an adequately detailed and flexible plan in advance and the discipline to stick to the plan when surprises come back from the field, as they always do.

To round out the evening, the audience took part in a lively Q&A session, building on the copious information presented by Mr. Kotosky and adding some war stories of their own for the benefit of all gathered.

The Boston Area Chapter and I would like to thank Rick Kotosky for his thorough examination of a topic of great interest and relevance to Chapter Members. Members of the audience are due some thanks for their contributions to this resoundingly successful program. Thanks also go out to the Waterworks Museum for their wonderful hospitality and a fascinating venue.

Fall Social Celebrates Universal "Day of the Dead" Holiday in True Fashion

by Fasha Onorato, R.W. Sullivan Engineering, with photo by Joyce Chiu, Honeywell Safety Products

Chapter Members brought lots of life to the "Day of the Dead" celebration at the Baseball Tavern.

On a cool November night, the Boston Area Chapter celebrated its Fall Social with the eerie theme of "Día de los Muertos" or "Day of the Dead" at the Baseball Tavern near historic Fenway Park on Thursday, November 1. The Day of the Dead is a Mexican holiday celebrated throughout Mexico and around the world in other cultures. The celebration takes place on November 1 and 2, in connection with the Catholic holidays of All Saints' Day and All Souls' Day. The Tavern was appropriately clad in traditional symbols of the holiday, including mariachi skeletons, cob webs and bones as attendees enjoyed the "traditional" Day of the Dead feast recreated by the head chef. Old silent horror films were played as members and non-members danced the night away to a deadly mix crafted by the house DJ.

The event also raised over $1,300 for the "We Beat Cancer" Foundation whose efforts provide assistance to Boston area cancer patients and their loved ones. For more information about this worthy nonprofit, visit http://webeatcancer.org.

A special thank you to Social Committee members Fasha Onorato (R.W. Sullivan Engineering), Paul Sullivan (R.W. Sullivan Engineering), Chris Opolski (Alexion Pharmaceuticals), and Tom Forster (Rockwell Automation) for their tireless efforts at putting together a spine-chilling event for the Chapter. In addition, thank you to event sponsors R.W. Sullivan Engineering, Perkins + Will, SciTech Builders (a Division of J.Calnan), Superior Controls, Rockwell Automation, and Tocci Building Companies. This event would not have been possible without their generous support. For additional fun photos, please visit the Chapter website at www.ispeboston.org.

Young Professionals Host New "Equipment Showcase" at Gillette

by Dave Gallagher, GxP Automation, with photos by Alastair Battson Photography

The Annual Product Show at Gillette Stadium was a great opportunity to see the new items the industry has to offer as well as catch up with old friends and acquaintances. As in past years, the Young Professionals always like to have an impact and presence at the Show that is geared toward the needs of the industry's younger professionals. Last year, the YP's hosted two morning educational events as well as a social. This year they decided to try something new and hosted the "Young Professionals Equipment Showcase" for the first time.

Instead of the traditional sales pitches and brochures typically seen at trade shows, the YPs felt it would be much more beneficial to offer hands-on product demonstrations geared to those relatively new to the industry. With a 5:00 pm start time and drinks and appetizers on hand, the event also acted as a networking social - a chance for YPs as well as students to meet fellow industry members in a relaxing environment. In the words of one of the YPs, "Nothing goes better with a dismantled pump than a nice cold beer!"

Many thanks go to the 14 vendors who brought their equipment and staffed booths filled with opportunities for YPs to get their hands on valves, pumps, automation hardware and more:

Anderson Instrument Company	GxP Automation
Burkert Fluid Control Systems	High Purity New England
Cambridge Valve and Fitting	Masy Systems
E&S Technologies	Rockwell Automation
FCx Performance	Sensitech

Fike	Spirax Sarco
GEA Tuchenhagen	Victaulic

At this year's Product Show, the Young Professionals combined their networking reception with an "Equipment Showcase" providing opportunities for informal, hands-on product demos.

The Product Show also marked the first event where the YP committee members handed out their new "YP business cards." The cards were a great way to get prospective ISPE members the information they needed to learn more about the group and upcoming events.

The Equipment Showcase was only one of several recent YP activities. YPs also hosted their annual boat cruise around Boston Harbor on September 20. Unlike the previous year, the rain held off and there was a much larger turnout than expected. This was one of the most popular events of 2012 and attracted not only young professionals but Chapter Members of all ages. With three hours out on the harbor overlooking the city, as well as a cash bar and appetizers, the cruise was a great event to kick off the YP's fall calendar.

The YPs are currently planning an array of social and educational events for the upcoming year, so stay tuned. And if you have ideas or want to help out, feel free to send us a message at YP@ispeboston.org . As always don't forget to tell your colleagues that non-members are always welcome at our events!

Industry News In Brief

by Lauren Melton, GE Healthcare

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.

Top Pharma Companies Form Nonprofit to Speed Drug Development

Ten top pharmaceutical companies from the United States and Europe have formed a nonprofit organization to accelerate the development of new drugs, a risky and expensive undertaking for companies of any size. Abbott Laboratories, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, Genentech and Sanofi SA have launched TransCelerate BioPharma Inc, headquartered in Philadelphia. Each company will contribute financial and other resources to meet specific objectives and established guidelines for sharing information and expertise. (Source: Reuters, 19 September, 2012)

Boston to Get J&J Research Unit

Johnson & Johnson says it will set up four regional ‘‘innovation centers" in life sciences hot spots around the world to speed up early research with one located in Boston. The health care giant wants to increase collaboration and investment across its businesses: prescription drugs, consumer health products, and medical devices and diagnostic equipment. Scientists, entrepreneurs, and start-up companies will get one-stop access to J&J technology and science experts who can facilitate collaborations with the company's businesses. Besides Boston, the centers will be in London, China, and California, with the latter including campuses in San Diego and San Francisco, and are expected to begin operating in the coming months. (Source: Associated Press, 19 September, 2012)

Genzyme MS Drug Gets FDA Approval

The FDA approved a Genzyme drug for patients with relapsing forms of multiple sclerosis (MS), the company has announced. Genzyme said the once-daily oral treatment Aubagio has been effective in reducing relapses, slowing the progression of physical disability and reducing the number of brain lesions as detected by MRI scans. Marketing applications for Aubagio are under review by the FDA's European counterpart, the European Medicines Agency, and other regulatory authorities.

The ongoing clinical development program of Aubagio, Genzyme's first MS treatment, involves more than 5,000 patients in 36 countries and is among the largest for any MS therapy, with some patients having been

treated for up to 10 years, Genzyme said. "Many people living with MS struggle with the additional burden of injectable therapies administered daily to weekly," said Dr. Aaron E. Miller, medical director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at Mount Sinai Medical Center. "The FDA's approval of Aubagio...is an encouraging advancement for the MS community and may be a valuable treatment for people living with this often debilitating disease."

The good news for Genzyme comes less than a month after it suffered a setback for another MS treatment, Lemtrada. The FDA had told the company that it needed data presentation to be clearer in order to be considered for a biologics license. Genzyme said it would work to address the FDA's concerns and quickly reapply. (Source: Jacquelyn Gutc, Worcester Business Journal, 13 September 2012)

Bayer Exec Warns that Push to Cut Health Care Costs Threatens Innovation

The chairman of German drug giant Bayer AG told a Boston audience recently that the global push to control health care costs threatens biopharmaceutical innovation. Because of the economic slowdown worldwide, countries are becoming more reluctant to give drug makers adequate reimbursement, Marijn Dekkers told nearly 300 people at the Boston College Chief Executives' Club of Boston luncheon at the Boston Harbor Hotel. "There is tremendous pressure all over the world in countries to bring down the price of prescription drugs," he said. "The danger of pushing prices down, down, down is that the system for developing drugs will lose its attractiveness."

Dekkers, a former chief executive of Waltham-based Thermo Fisher Scientific, said that Bayer has no plans to open operations in the Boston area. "We have a strong presence in New Jersey and San Francisco," he said. "And we have chosen in the past not to fragment this. It is not something against Boston." (Source: Robert Weisman, The Boston Globe, 19 September, 2012)

Biogen Pill Found Promising in Treatment of MS

A new oral medication to treat patients in the early stages of multiple sclerosis has shown considerable promise in two clinical trials, researchers announced on Wednesday.

The medication is on track to become just the third oral drug available to M.S. patients, and potentially the safest and most effective, experts said. The second oral drug, called Aubagio, was approved just last week.

M.S. was virtually untreatable only two decades ago, but today nine "disease modifying" drugs are available for early-stage patients; a half-dozen more are in the late stages of development. Most patients in the early stage of the disease, a form called relapsing-remitting M.S., take drugs by injection.

The two new studies, published online in The New England Journal of Medicine, found that the drug BG-12, developed by Biogen Idec, reduced relapse rates in patients with relapsing M.S. by about 50 percent. The drug also significantly reduced the frequency of new brain lesions often associated with these attacks, and slowed the progression of disease compared with a placebo. The studies were Phase 3 trials, a last step on the road to drug approval. The Food and Drug Administration is required to make a decision about the drug's approval before the end of this year. (Source: Laurie Tarkan, New York Times, 19 September, 2012)

Israeli Device Maker to Move to Massachusetts

Argo Medical Technologies, an Israeli company that makes devices enabling paraplegics to walk, said Tuesday that it will open its US headquarters in Massachusetts and expects to hire up to 40 people here within the next three to five years. The move was disclosed in dramatic fashion at the AdvaMed 2012 medical technology convention, where a US Army veteran who uses a wheelchair demonstrated Argo's ReWalk device by climbing down from a podium with crutches and ambling through the Boston Convention and Exhibition Center.

"I am standing, and the doctors told me I would never stand again," said Theresa Hannigan, an Army sergeant who must use a wheelchair because of an autoimmune disease contracted during her Vietnam-era service. "This is life altering. It gives me independence."

Argo's chief executive, Larry Jasinski, who spent more than a decade at Boston Scientific, said the 11-year-old Israeli company has chosen Marlborough for its American operations base and will increase hiring there if ReWalk wins approval from the FDA next year for use in the United States. The mobility device was approved by European regulators last month and Argo plans to file its US application with the FDA later this month. (Source: Robert Weisman, The Boston Globe, 03 October, 2012)

RXi Awarded Funding for Cancer Therapy

Westborough-based RXi Pharmaceuticals Corp. has been awarded a $300,000 grant from the National Institutes of Health to fund development of a treatment for retinoblastoma, a rare form of eye cancer. The Small Business Innovation Research grant, by the National Cancer Institute, will provide six months of funding

for the discovery and preclinical development of the therapy, sd-rxRNA, through a collaborative project between RXi and Memorial Sloan-Kettering Cancer Center. Through the project, compounds will be developed to stop targets that are critical to the growth and survival of the cancer cells.

"We are honored to have the opportunity to collaborate with the team at Memorial Sloan-Kettering, and are very pleased to have received financial support from the NCI to further the development of our novel RNAi compounds as potential therapeutics for ocular cancer," said RXi Chief Development Officer Pamela Pavco. "The grant process is highly competitive, and this award serves to recognize and support the therapeutic potential of RXi's proprietary RNAi platform." (Source: Jacquelyn Gutc, Worcester Business Journal, 05 October, 2012)

Study Says Angel Investor Market Recovering

Angel investors inked more deals and the number of active investors climbed in the first half of 2012 compared to the first half of 2011, according to the Center for Venture Research at the University of New Hampshire. Total angel investments nationwide in the first and second quarters of the year totaled $9.2 billion, an increase of 3.2 percent over the first half of last year. There were 27,280 businesses that received angel funding, an increase of 3.7 percent. The average deal size fell slightly, from $338,400 to $336,390. And investments created more than 106,000 jobs, the center said.

"While the market exhibited a stabilization from the first and second quarters of 2011, when compared to the market correction that occurred in 2008, these data indicate that the angel market has demonstrated a steady recovery since 2008," said Jeffrey Sohl, director if the center. Seed and start-up-level funding represented 40 percent of angel activity, down from a pre-2008 peak of 55 percent.

Expansion stage financing saw a significant bump, from 13 percent of all angel investments in the first half of 2011 to 22 percent in the first half of this year. Sohl said that indicates that more angels are positioning their investments for exits in 2013. (Source: Matt Pilon, Worcester Business Journal, 10 October, 2012)

Biotech Group Opposes Cambridge Rezoning

The state's largest biotechnology trade group has sent a letter to Cambridge city officials opposing a proposal by neighborhood activists that would change zoning in an area around Central Square, potentially blocking large-scale development or expansion plans for life sciences companies. In the letter, sent to the chairmen of the City Council's ordinance committee and the Planning Board, Robert K. Coughlin, president of the Massachusetts Biotechnology Council, noted the city is home to more than 110 life sciences companies that were drawn to nearby research universities and hospitals.

"The life sciences industry has always sought to be a good neighbor and active corporate citizen in the life of Cambridge," Coughlin wrote. "With this commitment in mind, we encourage you to defeat the downzoning proposal. We feel that it would restrict the kind of sustainable development that brings tremendous benefits to the people of Cambridge." (Source: Robert Weisman, The Boston Globe, 01 October, 2012)

Hepatitis C Results Boost Two Firms

Abbott Laboratories has said that its experimental hepatitis C drug regimen cured 99 percent of patients in a midstage study with the most common and hardest-to-treat type of the disease. Patients who took a three-drug regimen and the drugs Ritonavir and ribavirin had undetectable virus levels after 12 weeks of treatment. The company says it observed a 93 percent cure rate in a group of patients who were not helped by other treatments.

Patients in the trial had genotype 1 hepatitis C, which is the most common type in the Western world and the hardest to treat. The regimen did not include interferon, a standard component of hepatitis C therapy that causes flu-like side effects that can last for months. (Source: The Boston Globe, 16 October, 2012)

Vaccine Company Genocea Biosciences Raises $30 Million

Cambridge-based Genocea Biosciences, a clinical-stage company advancing innovative T cell vaccines for infectious diseases, has raised $30 million in a Series C financing round. The Bill & Melinda Gates Foundation and CVF, LLC, an affiliate of Henry Crown and Company, are participating alongside all of Genocea's existing investors. With the close of this financing round, Genocea has raised a total of $76 million in equity financing to date.

"We have made strong progress in our effort to create a new class of vaccines capable of combating serious infectious diseases that current vaccine discovery technologies cannot address," said Chip Clark, chief executive officer at Genocea. "Completion of this financing round is a powerful vote of confidence from the financial community that will enable us to move aggressively to create new vaccines that will improve the health of patients around the world."

Funds raised will support the continued development of Genocea's two lead programs: GEN-003, a clinical-

stage therapeutic vaccine candidate designed to reduce the frequency and severity of clinical outbreaks associated with moderate-to-severe Herpes Simplex Virus type 2 (HSV-2), and GEN-004, a preclinical vaccine candidate to prevent infections caused by Streptococcus pneumoniae. In addition Genocea will expand its malaria program in collaboration with The Foundation, using Genocea's proprietary ATLAS™ platform to profile the immune response of volunteers participating in Foundation-sponsored malaria vaccine trials, to identify antigens for potential inclusion in a protein subunit vaccine.

The Bill & Melinda Gates Foundation made this equity investment as part of an initiative that commits $1 billion to program-related investments to deepen the impact of The Foundation's work. "We are excited about the potential of the partnership with Genocea to further our global health priorities," said Trevor Mundel, president of Global Health at the Bill & Melinda Gates Foundation. "T cell innovation of this kind presents an intriguing opportunity to advance our global health mission through development of a new class of vaccines."

Genocea is currently enrolling a Phase 1/2a study of GEN-003 and expects to report preliminary data in the second half of 2013. The company anticipates beginning clinical trials in late 2013 for GEN-004, a next-generation vaccine to address Pneumococcal infections, which currently drives the largest global vaccine market, by value. GEN-004 is designed to cover all serotypes of Pneumococcus, rather than the select strains addressed by existing vaccines, and to affect nasopharyngeal colonization caused by Pneumococcus via a TH17 mediated mechanism of action which complements the B cell-mediated effect of existing vaccines. (Source: Genocea Biosciences Website)

Alnylam and Genzyme Form Alliance to Develop and Commercialize RNAi Therapeutics in Asia

Alnylam Pharmaceuticals and Genzyme, a Sanofi company, have announced that they have formed an exclusive alliance to develop and commercialize RNAi therapeutics targeting transthyretin (TTR) for the treatment of transthyretin-mediated amyloidosis (ATTR) in Japan and other Asia-Pacific countries. ATTR is a rare, debilitating, hereditary disease that damages the nervous system and heart, resulting in a life expectancy of 5 to 15 years.

"Our ALN-TTR program holds promise as a breakthrough therapy for the treatment of ATTR, a debilitating orphan disease. As the lead program in our 'Alnylam 5x15' product strategy, we also view this program as a key part of building Alnylam for the future," said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. "In this important collaboration, Genzyme will advance our ALN-TTR program with their proven capabilities in the Japanese and broader Asian market, while we maintain our plans to develop and commercialize this potential breakthrough medicine in the U.S., Europe, and rest of world. In addition, a key part of the value proposition in this alliance for Alnylam is the potential for significant royalty payments on sales of products."

ATTR is an endemic disease in Japan, with a significant number of patients carrying the V30M TTR mutation which leads to onset of a severe form of ATTR known as familial amyloidotic polyneuropathy (FAP). Together, Alnylam and Genzyme intend to maximize the value of ALN-TTR worldwide by developing the program in FAP and other ATTR indications, such as familial amyloidotic cardiomyopathy (FAC) and senile systemic amyloidosis (SSA). Alnylam's ALN-TTR program currently includes ALN-TTR02, which is in a Phase II clinical trial, and ALN-TTRsc, a subcutaneously administered RNAi therapeutic in late stage pre-clinical development.

Under the terms of the agreement, Genzyme will make an upfront cash payment of $22.5 million to Alnylam. The agreement also includes development milestone payments and tiered royalties expected to yield an effective rate in the mid-teens to mid-twenties on Genzyme's sales of ALN-TTR products in their territory. In addition, each party will be responsible for the development and commercialization activities in their respective territories.

Recently, Alnylam presented positive clinical results from its ALN-TTR02 Phase I trial demonstrating robust and unprecedented knockdown of serum TTR protein levels of up to 94%; the overall results were highly significant ($p<0.00001$ by ANOVA). Suppression of TTR, the disease-causing protein in ATTR, was found to be rapid, dose dependent, durable, and specific after just a single dose. The drug was generally safe and well tolerated in this Phase I study. Alnylam is currently enrolling patients in a Phase II multi-dose study of ALN-TTR02 in ATTR patients and aims to initiate a Phase III pivotal study of ALN-TTR02 by the end of 2013. (Source: Alnylam Pharmaceuticals Website, 22 October, 2012)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

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

FDA Approves Gilead Sciences Combination Pill for HIV Treatment

The FDA has approved Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate), a new once-a-day combination pill to treat HIV-1 infection in adults who have never been treated for HIV infection.

Stribild contains two previously approved HIV drugs plus two new drugs, elvitegravir and cobicistat. Elvitegravir is an HIV integrase strand transfer inhibitor, a drug that interferes with one of the enzymes that HIV needs to multiply. Cobicistat, a pharmacokinetic enhancer, inhibits an enzyme that metabolizes certain HIV drugs and is used to prolong the effect of elvitegravir.

The combination of emtricitabine and tenofovir disoproxil fumarate, approved in 2004 and marketed as Truvada, blocks the action of another enzyme that HIV needs to replicate in a person's body. Together, these drugs provide a complete treatment regimen for HIV infection.

Like labels of many other drugs used to treat HIV, Stribild's label carries a Boxed Warning alerting patients and health care professionals that the drug can cause a build up of lactic acid in the blood and severe liver problems, both of which can be fatal. The Boxed Warning also states that Stribild is not approved to treat chronic hepatitis B virus infection.

Gilead Sciences, Stribild's manufacturer, is required to conduct additional studies to help further characterize the drug's safety in women and children, how resistance develops to Stribild, and the possibility of interactions between Stribild and other drugs. (Source: FDA Website, 27 August, 2012)

FDA Approves First Drug Formulated For Children with Rare Brain Tumor

The FDA has approved Novartis' Afinitor Disperz (everolimus tablets for oral suspension), a new pediatric dosage form of the anti-cancer drug Afinitor (everolimus) used to treat a rare brain tumor called subependymal giant cell astrocytoma (SEGA). Afinitor Disperz is the first approved pediatric-specific dosage form developed for the treatment of a pediatric tumor.

Afinitor Disperz is recommended to treat patients ages one year and older with tuberous sclerosis complex (TSC) who are diagnosed with SEGA that cannot be treated with surgery. Prior to approval of this new dosage form, Afinitor was recommended for use only in patients ages three years and older. Afinitor was granted accelerated approval in 2010 to treat SEGA in patients with TSC. Afinitor Disperz is available in smaller dose increments than the adult dosage form and also dissolves easily in a small volume of water, making it easy to administer to patients who are unable to swallow whole tablets to take their medication.

TSC is a rare genetic disease that causes tumors to grow in the brain and other vital organs. SEGA is a slow-growing tumor that can cause life-threatening complications by blocking the flow of fluid in the brain. It is considered a major diagnostic feature of TSC and is seen in 6 percent to 9 percent of patients, generally pediatric and young adult patients. (Source: FDA Website, 29 August, 2012)

FDA Approves New Treatment for Severe Neutropenia in Certain Cancer Patients

The FDA has approved Sicor Biotech's tbo-filgrastim to reduce the time certain patients receiving cancer chemotherapy experience severe neutropenia, a decrease in infection-fighting white blood cells called neutrophils. Tbo-filgrastim is intended for use in adults who have cancers other than blood or bone marrow cancers (non-myeloid malignancies) and are taking chemotherapy drugs that cause a substantial decrease in the production of neutrophils in the bone marrow. This reduction in neutrophils may lead to infection and fever (febrile neutropenia).

Tbo-filgrastim stimulates the bone marrow to increase the production of neutrophils. It is administered as an injection beginning 24 hours after chemotherapy treatment. Tbo-filgrastim was approved in an original biologics license application (BLA). FDA has not approved tbo-filgrastim as a biosimilar to Neupogen (filgrastim), which is a previously licensed biological product that contains a related drug substance. Tbo-filgrastim is manufactured by Sicor Biotech UAB, a member of Teva Corporation. (Source: FDA Website, 29 August, 2012)

FDA Approves Linzess to Treat Irritable Bowel Syndrome and Constipation

The FDA has approved Linzess (linaclotide) to treat chronic idiopathic constipation and to treat irritable bowel syndrome with constipation (IBS-C) in adults. Linzess is a capsule taken once daily on an empty stomach, at least 30 minutes before the first meal of the day. Linzess helps relieve constipation by helping bowel movements occur more often. In IBS-C, it may also help ease abdominal pain. Linzess is approved with a Boxed Warning to alert patients and health care professionals that the drug should not be used in patients 17 years of age and younger.

Linzess is co-marketed by Cambridge-based Ironwood Pharmaceuticals and Forest Pharmaceutical of St. Louis, Missouri. (Source: FDA Website, 30 August, 2012)

FDA Approves New Treatment for Late Stage Prostate Cancer

The FDA has approved Xtandi (enzalutamide) to treat men with late-stage (metastatic) castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone. Approved for prostate cancer patients previously treated with docetaxel, another anti-cancer treatment, Xtandi

was reviewed under the FDA's priority review program. The program provides for an expedited six-month review for drugs that may offer major advances in treatment or that provide a treatment when no adequate therapy exists. Xtandi received FDA approval three months ahead of the product's prescription drug user fee goal date.

Prostate cancer forms in a gland in the male reproductive system found below the bladder and in front of the rectum. The male sex hormone testosterone stimulates the prostate tumors to grow. According to the National Cancer Institute, an estimated 241,740 men will be diagnosed with prostate cancer and 28,170 will die from the disease in 2012.

Xtandi will be co-marketed by Astellas Pharma U.S. of Northbrook, Illinois and Medivation of San Francisco, California. (Source: FDA Website, 31 August, 2012)

FDA Approves New Pfizer Orphan Drug For Chronic Myelogenous Leukemia

The FDA has approved Pfizer's Bosulif (bosutinib) to treat chronic myelogenous leukemia (CML), a blood and bone marrow disease that usually affects older adults. An estimated 5,430 men and women will be diagnosed with CML in 2012.

Most people with CML have a genetic mutation, called the Philadelphia chromosome, which causes the bone marrow to make an enzyme called tyrosine kinase. This enzyme triggers the development of too many abnormal and unhealthy white blood cells called granulocytes. Granulocytes fight infection.

Bosulif is intended for patients with chronic, accelerated or blast phase Philadelphia chromosome positive CML who are resistant to or who cannot tolerate other therapies, including imatinib. Bosulif works by blocking the signal of the tyrosine kinase that promotes the development of abnormal and unhealthy granulocytes. (Source: FDA Website, 04 September, 2012)

FDA Approves Production of Imaging Agent that Helps Detect Prostate Cancer

The FDA has approved the production and use of Choline C 11 Injection, a Positron Emission Tomography (PET) imaging agent used to help detect recurrent prostate cancer. Choline C 11 Injection is administered intravenously to produce an image that helps to locate specific body sites for follow-up tissue sampling and testing in men with recurrent prostate cancer.

PET imaging with Choline C 11 Injection is performed in patients whose blood prostate specific antigen (PSA) levels are increasing after earlier treatment for prostate cancer. An elevated PSA result suggests that prostate cancer may have returned, even though conventional imaging tests, such as computerized tomography (CT), have not shown any signs of cancer. PET imaging is not a replacement for tissue sampling and testing.

Choline C 11 Injection must be produced in a specialized facility and administered to patients shortly after its production. While PET imaging with Choline C 11 Injection has been performed at a few facilities over the past several years, none of these facilities were approved by the FDA to manufacture the agent. The FDA Modernization Act directed the agency to establish appropriate approval procedures and current good manufacturing practice requirements for all PET products marketed and used in the United States. The Mayo Clinic PET Radiochemistry Facility in Rochester, Minnesota is now the first FDA-approved facility to produce Choline C 11 Injection. (Source: FDA Website, 12 September, 2012)

FDA Approves Sanofi Aventis' Aubagio for Treatment of Multiple Sclerosis

The FDA has approved the Sanofi Aventis drug Aubagio (teriflunomide), a once-a-day tablet for the treatment of adults with relapsing forms of multiple sclerosis (MS).

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. It is among the most common causes of neurological disability in young adults and occurs at least twice as frequently in women as in men. For most people with MS, episodes of worsening function (relapses) are initially followed by recovery periods (remissions). Over time, recovery periods may be incomplete, leading to progressive decline.

The drug contains a Boxed Warning to alert prescribers and patients to the risk of liver problems, including death, and a risk of birth defects. Physicians should do blood tests to check liver function before a patient starts taking Aubagio and periodically during treatment. (Source: FDA Website, 12 September, 2012)

New FDA Task Force Will Support Innovation in Antibacterial Drug Development

The FDA has announced the formation of an internal task force that will support the development of new antibacterial drugs, a critical public health care goal and a priority for the agency. As part of its work, the Antibacterial Drug Development Task Force will assist in developing and revising guidance related to antibacterial drug development, as required by the Generating Antibiotic Incentives Now (GAIN) Title of the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012.

Research and development for new antibacterial drugs has been in decline in recent decades, and the number of new FDA-approved antibacterial drugs has been falling steadily since the 1980s. During this time, the persistent and sometimes indiscriminate use of existing antibacterial drugs worldwide has resulted in a decrease in the effectiveness of these drugs. This phenomenon, known as antibacterial drug resistance or antibiotic resistance, has become a serious issue of global concern.

The task force is part of FDA's efforts to promote antibacterial drug development and combat antibiotic resistance. Over several years, the agency has provided guidance to industry and hosted public workshops and meetings to address and discuss scientific challenges in the field of antibacterial drug development. The FDA also plays a key role in working with other federal agencies to implement a national plan to address antibiotic resistance. (Source: FDA Website, 24 September, 2012)

FDA Approves New Treatment for Advanced Colorectal Cancer

The FDA approved Stivarga (regorafenib) to treat patients with colorectal cancer that has progressed after treatment and spread to other parts of the body (metastatic). Stivarga is a multi-kinase inhibitor that blocks several enzymes that promote cancer growth. The drug was reviewed under the FDA's priority review program that provides an expedited six-month review for drugs that offer major advances in treatment or that provide treatment when no adequate therapy exists.

Stivarga is being approved one month ahead of the product's prescription drug user fee goal date with a Boxed Warning alerting patients and health care professionals that severe and fatal liver toxicity occurred in patients treated with Stivarga during clinical studies.

In August 2012, the FDA approved Zaltrap (ziv-aflibercept) for use in combination with a FOLFIRI (folinic acid, fluorouracil and irinotecan) chemotherapy regimen to treat adults with metastatic colorectal cancer.

Stivarga is marketed by Bayer HealthCare Pharmaceuticals, based in Wayne, New Jersey. Zaltrap is marketed by Bridgewater, New Jersey-based sanofi-aventis. (Source: FDA Website, 27 September, 2012)

FDA Approves Abbott Laboratories' Humira to Treat Ulcerative Colitis

The FDA has expanded the approved use of Humira (adalimumab) to include treatment of moderate-to-severe ulcerative colitis in adults. Humira is approved to control ulcerative colitis when immunosuppressant medicines like corticosteroids, azathioprine, and 6-mercaptopurine have not worked. The drug is an anti-tumor necrosis factor (TNF) that blocks proteins that play an important role in abnormal inflammatory and immune responses.

The FDA previously approved Humira to treat rheumatoid arthritis (2002), psoriatic arthritis (2005), ankylosing spondylitis (2006), Crohn's disease (2007), plaque psoriasis (2008) and juvenile idiopathic arthritis (2008).

The FDA-approved dosing regimen for Humira for ulcerative colitis begins with an initial dose of 160 milligrams, a second dose two weeks later of 80 mg, and a maintenance dose of 40 mg every other week, thereafter. The drug should only continue to be used in patients who have shown evidence of clinical remission by eight weeks of therapy. No new side effects were identified during clinical studies. Common side effects of Humira include infections, reactions at the injection site, headache, and rash. (Source: FDA Website, 28 September, 2012)

FDA Approves Vaccines for 2012-2013 Flu Season

The FDA has announced that it has approved the 2012-2013 influenza (flu) vaccine formulation for all six manufacturers licensed to produce and distribute the vaccines in the United States.

Each year experts from the FDA, the World Health Organization, the Centers for Disease Control and Prevention (CDC), and other public health experts study influenza virus samples and global disease patterns to identify virus strains likely to cause the most illness during the upcoming flu season. While the H1N1 virus is the same as what was included in the 2011-2012 influenza vaccines, this year's influenza H3N2 and B viruses differ from those in the 2011-2012 influenza vaccines.

Vaccination remains the cornerstone of preventing influenza, a contagious respiratory disease caused by different influenza viruses infecting the nose, throat and lungs. This year's seasonal vaccines will provide protection against the three influenza virus strains that global surveillance indicates are likely to be the most common strains circulating during the upcoming season. (Source: FDA Website, 13 August, 2012)

FDA Approves First Generic Actos to Treat Type 2 Diabetes

The FDA has approved the first generic version of Actos (pioglitazone hydrochloride) tablets. Along with diet and exercise, pioglitazone is used to improve blood glucose control in adults with type 2 diabetes. Mylan Pharmaceuticals, based in Morgantown, West Virginia, gained FDA approval for 15 milligram, 30 mg and 45 mg pioglitazone tablets.

Generic drugs approved by FDA are of the same high quality and strength as brand-name drugs. The generic

manufacturing and packaging sites must pass the same quality standards as those for brand-name drugs. (Source: FDA Website, 17 August, 2012)

FDA Withdraws Approval of a Generic Wellbutrin

The FDA has reviewed new data that indicate Budeprion XL 300 mg (bupropion hydrochloride extended-release tablets), manufactured by Impax Laboratories and marketed by Teva Pharmaceuticals USA is not therapeutically equivalent to GlaxoSmithKline's Wellbutrin XL 300 mg.

Impax has requested that the Agency withdraw approval of budeprion XL 300 mg extended-release tablets. Impax and Teva have stopped shipping the product and are issuing detailed information to their customers. This announcement relates only to Budeprion XL 300 mg manufactured by Impax and marketed by Teva. It does not affect the Impax/Teva Budeprion 150 mg product or generic bupropion products made by other manufacturers.

FDA has approved five generic versions of Wellbutrin XL 300 mg. Each of these generics was approved based on bioequivalence studies comparing the 150 mg strength of the products to Wellbutrin XL 150 mg. Studies were not performed directly on the 300 mg strength of the products. Rather, the bioequivalence studies were performed using the 150 mg strength, and the results were extrapolated to establish bioequivalence of the 300 mg product. This methodology was based on FDA's guidance at the time the products were approved. FDA has determined that this approach is no longer appropriate to establish bioequivalence of 300 mg bupropion hydrochloride extended-release tablets to Wellbutrin XL 300 mg, and the Agency is revising its guidance to industry for how to conduct premarket bioequivalence studies in generic bupropion products. (Source: FDA Website, 03 October, 2012

White House Advisory Body Urges FDA to Speed Approval of Drugs

The U.S. should set a goal of doubling the output of innovative new medicines that meet critical public health needs over the next 10 to 15 years, while continuing to increase drug safety, a presidentially appointed council of experts advised in a report released today. The council recommends a number of actions involving industry, academia, and the Federal Government.

While basic biomedical sciences have seen stunning progress in past decades, challenges remain in translating those scientific advances into practical solutions, according to the report produced by the President's Council of Advisors on Science and Technology (PCAST). The report assesses the reasons for that long-term trend.

To support innovation and accelerate the development of new therapies, the report makes a number of detailed recommendations aimed at bolstering the discovery and development of new therapeutic compounds; optimizing processes used by the FDA to evaluate the safety and efficacy of candidate drugs; enhancing long-term monitoring of approved medicines; and enhancing public understanding about the benefits and risks of medicines. "With improved collaboration among all the participants in the drug development ecosystem and optimization of drug-evaluation pathways, American researchers and companies should be able to accelerate the development of safe and effective drugs while also strengthening the U.S. economy," said Eric Lander, who co-chairs PCAST.

The report concludes there are two critical needs related to drug discovery and development that must be addressed to advance innovation:

(1) Scientists need better methodologies and tools for translating basic biological insights into validated therapeutic targets and leads-a gap in the drug discovery and development pipeline that academic scientists often view as "too applied" and pharmaceutical companies often eschew as "too basic" to justify private investment.

(2) Pharmaceutical developers and regulators need to incorporate new efficiencies into clinical trials of candidate medicines-complex and costly human studies that today constitute fully 40 percent of the biopharmaceutical industry's R&D budget.

To achieve some of the report's broader goals, PCAST recommends the creation of a public-private "Partnership to Accelerate Therapeutics," involving representatives from the bio-pharmaceutical industry; the academic biomedical research and ethics community; physician societies and pharmacists; patient-focused research foundations and advocacy groups; healthcare providers and insurers; and the Federal Government. The Partnership would help identify and plan collaborative actions to speed drug development while balancing competing stakeholder interests and minimizing duplication of efforts.

In addition, the report concludes that the return on investment in certain disease domains may be too low to justify their pursuit by companies, even though the potential benefits for public health in these domains may be large. It recommends that the Department of Health and Human Services commission a study to assess potential mechanisms to encourage companies to tackle important medical challenges that may be financially unattractive. "There is a tremendous need for new antibiotics, for example, but the potential market share for such medicines is typically small and their duration of use is typically short," said PCAST member Christine Cassel, a physician who-with Lander and PCAST members Ed Penhoet and Rick Levin-oversaw a group of 30 outside experts who helped inform PCAST in its work. (Source: President's Council of Advisors on Science

and Technology Website, 25 September, 2012)

FDA Approves First Subcutaneous Heart Defibrillator

The FDA has approved a heart defibrillator that helps to restore regular heart rhythms with leads that can be implanted just under the skin (subcutaneously) instead of connected directly into the heart. An implantable defibrillator is a small battery-powered device that constantly monitors a person's heart rhythm and can deliver a therapeutic dose of electricity to restore the rhythm when it senses the heart is beating dangerously fast (tachycardia) or chaotically (sudden cardiac arrest). The S-ICD System is manufactured by Cameron Health of San Clemente, California.

Other implantable defibrillators on the market require a physician to insert one or more electrical conductor wires, called "leads," into a vein in the upper chest and guide them into the patient's heart. X-ray fluoroscopy, a real-time imaging method, helps the physician to visualize the heart and blood vessels to guide the leads to the correct position. The Subcutaneous Implantable Defibrillator (S-ICD) System uses a lead that is implanted just under the skin along the bottom of the rib cage and breast bone. Because the lead is placed under the skin rather than through a vein into the heart, a physician can implant the device without accessing a patient's blood vessels or heart and without the need for fluoroscopy.

As part of the approval, the FDA is requiring the manufacturer to conduct a postmarket study to assess the long-term safety and performance of the device and to assess differences in effectiveness across genders. The study will follow 1,616 patients for five years. (Source: FDA Website, 28 September, 2012)

New Members

Natalya Alekseyeva, *Manager, Shire HGT*

Mr. John D. Allemeier, *General Manager,* DECCO

Mr. Erik Ashby, *Process Engineer*

Mr. Michael P. Barnes, *Publisher,* High-Profile Monthly

Mr. Youssef Benchekroun, *Product Manager*

Dr. Thomas J. Bohnert, *R&D Director,* Mill Creek Life Sciences

Richard H. Bonnin, *Mechanical Engineer,* M+W US, Inc.

Mr. Michael W. Burnsh, *Senior Associate Scientist,* Amgen

Mr. Min Jae Byun, *Student,* University of Massachusetts Amherst

Mr. Daniel Carson, *Account Manager,* Pond Technical Sales, inc

Mr. Toji Chacko, *Facilities Manager*

Mr. Rui FW Coelho, *Assoc Director Operational Excellence,* Biogen Idec

Mr. Michael Comtois, *Marketing Coordinator,* RDK Engineers

Mr. Stephen P. Crimlisk, *QC Professional,* Sanofi Pasteur Biologics, LLC

Elvin K. Eng, *Validation Associate,* Biogen Idec

Ms. Katherine C. Faria, *Dir Process Development,* Organogenesis Inc

Mr. Antonio J. Fernandez, *Principal Consultant/ Director,* Biopharma Consulting JAD Group Inc

Mr. Dickson Fong, *Engineer,* Genzyme Corporation

Mr. Xavier Glardon, *Assoc Director Capital Project,* Genzyme

Xuan He, *Student,* Worcester Polytechnic Institute

Ankita K. Jaipuria, *Graduate Student,* Northeastern University

Beatrice O. Johnson, *Senior Engineer,* Abbott Bioresearch Center

Peggy S. Johnson, *Director Business,* Sensitech Inc

Mr. Gaurav Kapila, *Student,* Northeastern University

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Daniel Kenny, *Applications Engineer,* Northeast Engineering, Inc

Martin Kimani, *Process Engineer,* Genzyme Corporation

Stephen Ladd, *VP of Manf,* Steel-Pro Inc

Nicholas S. Lagasse, *Student,* University of Masachusetts Amherst

Mr. Robert Langevin, *Manufacturing Manager,* Microtest Laboratories

Mr. Jeremiah Lechleiter, *Process Engineer,* Process Design Solutions

Kaitlin Lesiczka, *MFG Operator,* Lonza Biologics

Mr. Travis P. Maiderd, *Student,* Ursinus College

Mr. Christos Maravelias, *Sr. Project Manager,* Novartis Institutes for BioMedical Research, Inc

Andrew Martuscellos, *Technical Sales Rep.,* Sentinel Process Systems, Inc.

Mr. Alex McKinnon, *Senior Account Executive,* RCM Technologies

Ann J. Montgomery, *Sr. Manager,* Cubist

Mrs. Valerie Montgomery, *Manager, Environmental Services,* Microtest Laboratories Inc

Ms. Deanna E. Oliveirai, *Student,* Umass Amherst

Joseph Ramoutar, Organogenesis Inc.

Ms. Janani Ravindhar, *Engineer I,* Biogen Idec

Mr. Thomas L. Robicheau, *Facilities Technician,* Lyophilization Services of New England

Michael Schmidt, *Director,* Pfizer

Ms. Bonnie K. Shum, *Process Engineer,* Genzyme

Mr. Thomas F. Struble, *Validation Engineer,* Commissioning Agents Inc

Ms. Samantha Szatek, *Business Associate-PSS,* New England Controls Inc

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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!

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