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Boston Area Chapter





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NEWSLETTER



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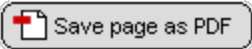
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[Return to the Table of Contents](#) | [Printing Instructions](#)



President's Message: Greetings From Incoming Chapter President, Jay Zaino



Dear Fellow Boston Area Chapter Members,

It's been another fantastic year for the Boston Area Chapter and I am proud to be President of such a great organization. I sincerely thank you all for giving me this opportunity. Our Chapter Excellence (a prestigious ISPE award we have won for three years in a row!) has been achieved through the hard work and dedication of our previous officers, board members, committee chairs, committee members and our Chapter management team at CAMI, so I would like to take this opportunity to thank all those involved. I look forward to working with our new board and committee members to further the great work done to make the Boston Area Chapter a valuable resource for all our Members.

That said, I would like to take this opportunity to introduce our new board. Without the hard work and dedication of these individuals, our membership would not be able to enjoy and benefit from all the activities and resources our Chapter has to offer:

| | | |
|----------------|----------------------|-------------------------|
| President | Jay Zaino | GxP Automation, LLC |
| Vice President | Daniel Ramsey | Commissioning Agents |
| Treasurer | Christopher Opolski | Alexion Pharmaceuticals |
| Secretary | Janet Tice | GMP Piping |
| Directors | Mert Aktar | Shire HGT |
| | Jack Campion | Genzyme |
| | Tom Choyce | Biogen Idec |
| | H. Steven Kennedy | M+W Group |
| | Dan Rufo | IPM |
| | Mark Sitcoske | High Purity New England |
| | John Spohn, CPIP | Castle Hill |
| | Jillian Willard | Genzyme |
| Past President | Brian Hagopian, CPIP | Clear Water Consulting |

Moving forward, the new board has already held our strategic planning meeting for the new year and will continue building on last year's major goals as follows:

- Membership Growth:

Our Chapter is currently the third largest in the US and fourth largest in the world. With another successful year of Chapter growth, we could hold the position of the largest ISPE Chapter in the US and maybe even the world!

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- Student Chapter Growth and Development:

Today's colleges hold the life sciences professionals of tomorrow. The Boston Area Chapter will continue to be heavily focused on developing services and activities to benefit today's students and help them prepare for entry into the industry with a goal to strategically add Student Chapters from many of the fine colleges in the Boston area.

- Educational Program Excellence:

Our Chapter has gained national recognition for our stellar educational programs. In addition, we lead the world in CPIP™ certified professionals - based in large part on the success of our CPIP study groups. For more information on the next study group, beginning September 18, consult the "Chapter Bulletin Board" [link to the article] elsewhere in this issue.

Our thanks go out to all involved in making these programs such a high-value benefit for our membership. Many Members attended our recent educational program planning meeting and helped develop a great line up of programs for the upcoming year. Keep an eye out for the topics that will benefit you and join your fellow Members for a season of networking and learning from fellow Chapter Members and industry-recognized experts.

Finally, our Chapter will continue to give back to our membership and our community through our scholarship program and charitable donations generated through our many social events and the generous contributions of our membership.

These are all very worthy goals, so I urge all Members to spread the word about the many benefits our Chapter offers and help us achieve our membership and Student Chapter growth goals. I also encourage all Members to get involved at any level - attending events, volunteering to help with specific activities or joining one of our many committees. Personally, I have been involved with the ISPE organization since 1993 - way back when I was a young professional with no idea what this industry was about and the tremendous opportunities it can offer. (Today, our Chapter leads the country with our dynamic YP organization and gives young professionals the head start they need to be successful.) The industry knowledge I have gained and the life-long friends I have met along the way have made ISPE membership a tremendous experience for me, both personally and professionally. So again, get involved and bring along anyone else you know, new to the industry or seasoned veteran, and see what the Boston Area Chapter can do for you - you will be glad you did!

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

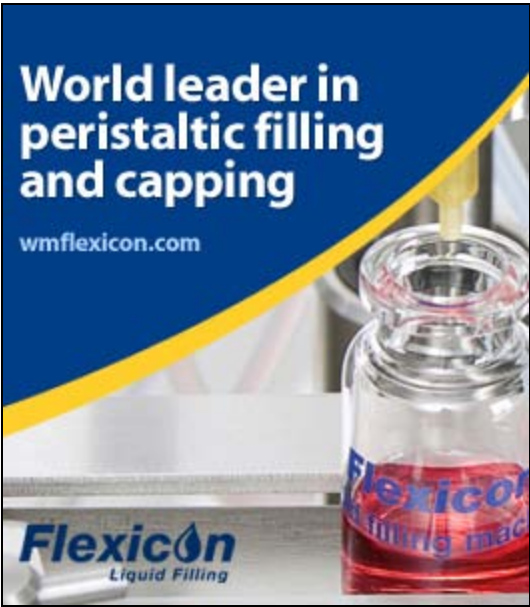
Sincerely,

Jay Zaino

Chapter Bulletin Board

Advertise on www.ISPEBoston.org and Reach Local Life Sciences Professionals

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.



Congratulations to the Six New Boston Area Chapter CPIPs!!

The Chapter's spring 2012 CPIP Study Group has resulted in six new Certified Pharmaceutical Industry Professionals™. The CPIP credential recognizes comprehensive industry knowledge; candidates are assessed through education and experience, and must also pass an exam to be awarded the credential. Please join us in congratulating our six new CPIPs:

Daniel Carpenito, CPIP
Mike Enos, CPIP
Marc Fleischman, CPIP
Brian Hagopian, CPIP
Jakub Mocny, CPIP
Brian Pochini, CPIP

The next CPIP Study Group begins on September 18th in Cambridge. Read the article below to find out how to join the Study Group and become the next Boston Area Chapter Certified Pharmaceutical Industry Professional™!!

New CPIP™ Study Group Begins September 18 at Biogen Idec in Cambridge!

The FDA approached ISPE (and only ISPE) to create the Certified Pharmaceutical Industry Professional™ (CPIP™) credential, recognizing comprehensive knowledge in the industry as well as ensuring and enhancing drug product quality. Candidates are assessed through education and experience, and must also pass an exam to be awarded the credential.

The CPIP credential is valuable to you because it:

- Establishes a global competency standard for pharmaceutical industry professionals
- Provides a professional development pathway to advance your career
- Unlocks greater career opportunities
- Recognizes your expertise in the industry and among peers
- Gives your employer the competitive advantage of a recognized credential

The Boston Area Chapter is ready to help you earn the CPIP credential. When you participate in the CPIP study group, ISPE will furnish the technical content free of charge. This saves you over \$2,500 in course costs and gives you the advantage of sharing ideas with like-minded peers seeking to further their careers. We are thrilled to have Brian Hagopian, CPIP, as our session leader. He completed the most recent study group and passed the exam, so he can share what he learned along the way to save you time and effort.

To qualify for the CPIP study group, a candidate has to meet the following requirements:


1. You must be a member of the ISPE Boston Area Chapter
2. [This requirement has changed! Please see the attached PPT presentation for more details!]
3. You must have 3 years of industry experience, or 5 years of work experience
4. You must be willing to invest \$150 in your own professional advancement (this covers the cost of food and facility)
5. You would like to save \$2,500 in course materials

This is an opportunity for ISPE Members only. To join ISPE or renew your membership, visit <http://www.ispe.org/join-or-renew>.



Location: Biogen Idec, Cambridge Center, Cambridge Mass, 02142 (exact location to be announced)

Schedule: Study group sessions run from 6 to 9pm on the following Tuesdays: September 18 & 25; October 2, 16, 23 & 30; November 6 & 27; and December 4. Dinner is provided.

Registration: There is a one-time registration fee of \$150 for the study group. Register today at www.ISPEBoston.org/Events. If you choose not to continue after the first session on September 18, your \$150 registration fee will be refunded.


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CPIP Exam: Additional fees associated with the exam are as follows: \$175 application fee to establish eligibility and \$350 to take the exam, both payable to ISPE. The exam can be taken locally whenever you feel you are ready.

Study Group Leader: Brian Hagopian, CPIP

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

Tuesday, September 18, 2012
[CPIP Study Group](#)

[Biogen Idec, Cambridge, MA](#)

Come The Certified Pharmaceutical Industry Professional (CPIP) certification demonstrates competence in pharmaceutical industry practices. The study group will prepare industry professionals to qualify for CPIP certification.

Come to an informational meeting to learn more about the CPIP program and the fall study group. Each class will run from 6pm-9pm and the cost includes all 9 sessions. If after the informational session you choose *not* to continue the course, we will refund your registration fee.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=299

Thursday, September 20, 2012
[This Old Plant \(even if it's new\) - Performing Retrofit Projects in an Operating Facility](#)

[Metropolitan Waterworks Museum, 2450 Beacon Street, Chestnut Hill, MA 02467](#)
5:30-8:30

From the (relatively) simple addition of a WFI drop to a major plant expansion, performing mechanical work in an operating GMP facility presents significant challenges. Often the project timeline is driven more by an absolute requirement to maintain or resume nearby manufacturing rather than traditional scope and resource loading, and in these cases it may also be more important to minimize the operational impacts than to optimize the project design. This session will first examine some of the not-so-obvious ways that facility design can impact project design in both old and relatively new plants. It will then focus on how operational considerations can constrain project execution and what planning steps can be taken to offset those constraints.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=187

Wednesday, October 3, 2012
[21st Annual Project Show](#)

[Gillette Stadium Clubhouse, Foxborough, MA](#)

10:30am - 1:15pm Educational Sessions
12:00pm - 7:30pm Exhibitor Show Floor and Career Fair Open
3:30pm Keynote Address: Peter Moesta, Senior Vice President, Biologics Manufacturing &

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Process Development, Bristol-Myers Squibb
7:30pm After Party at CBS Scene with an appearance by Jerod Mayo, New England Patriots Linebacker

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=188

Sneak Preview of Upcoming Events

Thursday, November 15, 2012

Educational Program focusing on Marketing

Thursday, December 13, 2012

Educational Program focusing on Serialization

Annual Product Show Returns to Gillette on October 3rd – Be There!

by Laurie Masiello, Masy Systems

Thirty-three states and two countries will be represented at the ISPE Boston Area Chapter Product Show at Gillette Stadium on October 3rd. Vendors signed up early to secure their spots and made this annual event a sellout in August - two months before Show time! Six vendors from Foxboro will display their products, along with companies from every New England state, the entire eastern and western seacoasts, the southwest, Midwest and Rocky Mountain area; plus Canada, our neighbor to the North, and our friends across the pond in England. It's not a local Show anymore - it's an industry blockbuster!

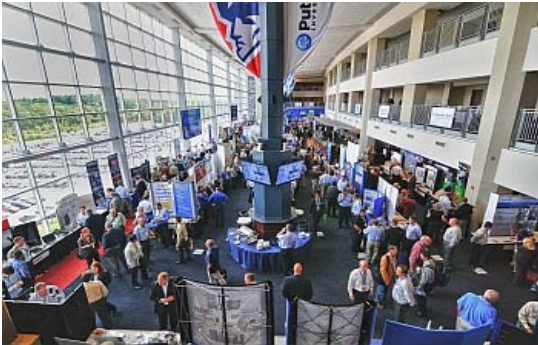


Gorgeous weather and an unbeatable view of Gillette greeted attendees at last year's Show.



Complimentary food & beverages keep attendees well-fed throughout the day.

This 21st annual event is a full-day program. Educational sessions start at 10:30am followed by 7-1/2 hours to visit with over 300 vendors and network with industry contacts. And the food never stops - nibble scrumptious appetizers, then visit the carving stations for freshly prepared sandwiches (all free, of course). Stop by the career fair and find out what hiring companies have to offer. Even if you're not interested in a new position, you may know a friend, neighbor or colleague who would be a good fit.



This year, over 300 exhibitors will display

Previous Issues

| |
|---|
| July 2012, Volume... (12) |
| May 2012, Volume XXII.... (13) |
| March 2012, Volume... (11) |
| January 2012, Volume... (10) |
| November 2011, Volume... (16) |
| September 2011, Volume... (15) |
| July 2011, Volume XXI.... (12) |
| May 2011, Volume XXI.... (16) |
| March 2011, Volume XXI.... (16) |
| January 2011, Volume... (13) |
| November 2010, Volume... (14) |
| September 2010, Volume... (16) |
| July 2010, Volume XX.... (13) |
| May 2010, Volume XX.... (16) |
| March 2010, Volume XX.... (15) |
| January 2010, Volume... (14) |
| November 2009, Volume... (11) |
| September 2009, Volume... (13) |
| July 2009, Volume XIX.... (11) |
| May 2009, Volume XIX.... (9) |
| April 2009, Volume... (11) |
| February 2009, Volume... (10) |
| December 2008, Volume... (13) |
| October 2008, Volume... (12) |
| August 2008, Volume... (10) |
| June 2008, Volume... (11) |
| April 2008, Volume... (10) |
| February 2008, Volume... (10) |
| December 2007, Volume... (13) |
| October 2007, Volume... (10) |

Newsletter Archive

[their wares in the expanded exhibit area.](#)

Take a timeout at 3:30pm and attend the keynote address given by Peter Moesta, Bristol-Myers Squibb Senior Vice President of Biologics Manufacturing and Process Development based at the Devens site, who will discuss key industry trends; and also meet new ISPE President/CEO Nancy Berg and welcome her to Boston. When the exhibitor floor closes at 7:30pm, the day isn't over. Move with us to nearby Bar Louis and meet Jerod Mayo, New England Patriots linebacker. Finally, at 9:30pm the day's activities end, whether you're tired or not!



[The exhibit area provides plenty of opportunities to network with colleagues.](#)

The ISPE Boston Area Chapter is pleased to note that the day's event continues to be offered free of charge, supported in full by our generous vendors. This includes free parking, free admission, free food, free soft drinks, free educational seminars, free keynote speaker and free autographs. If you haven't attended in the past, please let us welcome you this year! 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!

Product Show Schedule of Events

21st Annual Product Show

Wednesday, October 3, 2012

AGENDA - AT - A - GLANCE

10:30 am – 7:30 pm

Registration and Information Desks Open

10:30 am – 1:15 pm

Four Educational Programs: [See Below For Full Listing](#)

12:00 pm – 7:30 pm

Show Floor Opens

Visit over 300 Exhibitor Tables and Booths

Career Fair: Alexion Pharmaceuticals, Biogen Idec, Bristol-Myers Squibb, CRB Consulting Engineers, HireMinds LLC, Hyde Engineering + Consulting, Lonza Biologics and M+W Group

3:30 pm – 5:00 pm

Keynote Address: Turning Ideas Into Medicines – Biologics Manufacturing 2013 and Beyond

Peter Moesta, PhD, Senior Vice President, Biologics Manufacturing and Process Development, Bristol-Myers Squibb

5:00 pm – 7:00 pm

Young Professionals Equipment Showcase

7:30 pm – 9:30 pm

After Party Networking Reception

Appearance by **Jerod Mayo**, New England Patriots Linebacker and Co-Captain

Location: Bar Louie, Patriot Place

| 10:30 am to 11:45 am CONCURRENT SESSIONS | |
|--|---|
| FDA Inspection Observations - The FDA-483 and Beyond David Chesney, Vice President and Practice Lead, Strategic Compliance Services, PAREXEL Consulting | Bioprocess Engineering and the ASME Reinhard Hanselka, PhD, REA, Director of Code Compliance, M+W Group Raymond Foley, Platforms Operations Manager, M+W Group |
| 12:00 pm to 1:15 pm CONCURRENT SESSIONS | |
| The Global Hub: An overview of Massachusetts Life Science Real Estate Market Peter McManus, Principal, Murphy & McManus Timothy Stoll, Director of Leasing and Development, BioMed Realty Trust Jeremy Hood, Vice President, T3 Advisors | Integrated Commissioning and Qualification, Saving Time and Money Without compromising Quality Jack Greene, Director, Process Development and Manufacturing, Allena Pharmaceuticals |

Get Updated on Industry Trends at the Product Show Educational Program

by David Greenberg, Saint-Gobain Performance Plastics

The educational opportunities at the 2012 Product Show once again follow the Chapter’s tradition of bringing current topics and industry trends to light with presentations by engaging industry leaders. Sessions this year focus on current issues that have a direct impact on the industry and offer attendees a tremendous opportunity to learn about the latest developments. This year’s offering features four presentations, all taking place before the exhibitor area opens, with two running concurrently during each of two back-to-back sessions. Be sure to register early at www.ispeboston.org to ensure a seat at the topics of your choice:

10:30am-11:45am

FDA Inspection Observations: FDA-483 and Beyond **David Chesney** will address this topic with decades of experience, including 23 years with the FDA. He will review the history and purpose of the FDA-483, the rules FDA has established for what a reportable observation is and what it is not, and agency guidance for evaluating the significance of FDA-483 observations resulting from GMP drug inspections. The process followed internally by FDA in deciding whether or not to escalate to a Warning Letter or other follow up action will be explained. In addition, the presentation will offer tips for crafting an effective and timely written response to an FDA-483 and outline the steps to take to ensure the corrective actions were effective.

Bioprocess Engineering and the ASME The Chapter is pleased to have **Reinhard Hanselka** PhD, REA presenting on the ASME BPE 2012. Reinhard is an ASME Board Member and a very active contributor to BPE with over 35 years of industry-related project experience. The ASME BPE (Bioprocess Equipment) Standard is a comprehensive document developed for the bioprocess industry. The document was developed by bioprocess users, vendors, consulting engineers and industry experts for the purpose of setting minimum standards for safe and effective operation. It has evolved into the extremely comprehensive 2012 edition, which is now the definitive worldwide industry standard. This presentation will summarize the requirements and practices expounded by the 2012 ASME Bioprocess Equipment Standard. Questions and discussion are encouraged.



Morning educational sessions feature respected subject matter experts with a wealth of knowledge and experience.

12:00pm- 1:15pm

The Global Hub: An overview of Massachusetts Life Science Real Estate Market

Peter McManus will provide insight into the Boston region real estate market and how the market dynamics can effect development in the life science sector. Ground zero for global life sciences is considered by many to be Cambridge, Massachusetts. But it is more than just the Cambridge area that makes the Boston region a focus of innovation. The presentation will focus on what is occurring in the Boston/Cambridge regional life science market as it pertains to real estate and how these market dynamics might influence future real estate endeavors at life science firms. The interactive presentation will include market lease rates/trends, build-out costs, planning considerations and future space demand.

Integrated Commissioning and Qualification: Saving Time and Money without Compromising Quality

Jack Greene will draw from his many years of industry experience to present an update on the use of Integrated Commissioning and Qualification models. Jack's hands-on practical experience will provide the basis for his presentation which will lay out a series of C&Q models, explain how they work (or do not work) and use first-hand case studies to highlight the benefits and risks of each. This workshop will present various models and chronicle their history and then address how to set up integrated C&Q programs. Bring your questions and do not hesitate to interrupt in this interactive session.

Learn more by attending these great educational programs. They are conveniently scheduled early in the day to permit plenty of time to visit the exhibit floor, network with colleagues and don't miss the keynote address and after party at Bar Louis in Patriot Place. To register online, please visit our website at www.ispeboston.org/events.

Bristol-Myers Squibb VP of Biologics Manufacturing and Process Development to Deliver 2012 Keynote Address

by Laurie Masiello, Masy Systems

The ISPE Boston Area Chapter is privileged to announce that Peter Moesta will be the keynote speaker at the 21st Annual Product Show, to be held at Gillette Stadium on October 3. Peter is Senior Vice President of Biologics Manufacturing and Process Development at Bristol-Myers Squibb (BMS) at the Devens site. He leads the broad based technical activities between R&D and Manufacturing organizations to support the successful clinical development, registration, manufacturing and commercialization of biologics products.

Peter joined BMS in early 2011 and has extensive experience in biologics manufacturing, including process development, clinical and commercial manufacturing and supply chain across global operations. Before joining BMS, he worked at Abbott Laboratories where he guided the manufacturing process and led the CMC effort to obtain approval for Humira. He also led the design, start-up and registration of the company's large-scale biologics manufacturing plant in Puerto Rico.



Keynote speaker Peter Moesta, Senior VP of Biologics Manufacturing & Process Development at Bristol-Myers Squibb.



An overflow crowd of 350 turned out for last year's keynote address.

Earlier in his career, Peter held strategic positions at BASF for 17 years in Germany and the United States. While at BASF, 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 the Worcester facility. Peter earned his Master's Degree in Chemistry and a PhD in Biochemistry from the University of Freiburg in Germany. He completed post-doctoral fellowships at the University of Freiburg and UCLA.

The Annual Product Show has been held at Gillette Stadium for the past seven years, and has been a flagship event for the ISPE Boston Area Chapter for 21 years. The Show is a full-day event offering educational sessions, a career fair, networking opportunities, over 300 vendors displaying their products and services, a lively after party at Bar

Louis featuring Patriots linebacker Jerod Mayo (autographs, anyone?), and free food and drink throughout the day and evening. The Show is expected to draw over 2000 attendees so register early and plan to stay all day!

New This Year – Young Professionals Launch “Equipment Showcase 2012”

by Jillian Willard, Genzyme

This year the YPs have decided to jazz up our Annual Product Show networking social by adding an "Equipment Showcase" designed to introduce basic concepts and provide a venue for equipment demos. Multiple vendors have already volunteered to bring in equipment and staff booths filled with opportunities for YPs to get their hands on valves, pumps, automation hardware, and more. Want to see a rupture disk rupture right in front of you? Or see how an automation system controls a valve? Stop by the Equipment Showcase and YP networking social between 5pm and 7pm at the Product Show - and bring a friend or two. Meet other YPs, have refreshments in the bar area, and learn about a range of equipment and instrumentation used throughout the biotech and pharmaceutical industries. Nothing goes better with a dismantled pump than a nice cold beer!



Young Professionals chat with Keynote Speaker, Dr. Sylvie Gregoire, in 2010.

There are still a few booths left for exhibitors interested in bringing in interactive and educational materials to familiarize YPs with their equipment. This is an especially good opportunity for YPs within exhibiting companies to teach and network with peers. If you are interested in participating, please contact the Boston Area Chapter office at office@ispeboston.org.

The Party Continues at Bar Louie with Jerod Mayo...

by Laurie Masiello, Masy Systems

Last year you came in droves to CBS Scene after the Product Show at Gillette - and the crowd overwhelmed us. This year we're moving to a new venue and made plans for a crowd even bigger than last year's. The party continues and we know you won't be disappointed! When the October 3 Product Show closes at 7:30pm, come with us to Bar Louie and relax with friends while winding down from the day's activities. Jerod Mayo, New England Patriots linebacker, will be there to sign autographs and pose for photos and free appetizers will be served until the party ends at 9:30pm.



The After Party moves to nearby Bar Louis after out-growing last year's venue.

Bar Louie is located at Two Patriot Place, a 5-minute walk from the Stadium, and specializes in "artfully created" martinis, an assortment of beers, microbrews and wines. Check them out at www.barlouieamerica.com. And mark your calendar for October 3!

The Chapter's 10th Annual Golf Tournament Shines

by Christopher Opolski, Alexion Pharmaceuticals with photos by Patty Ascanio, Mangan Biopharm; Mark Uffland, Memories in an Instant; and Christopher Opolski



On Monday, July 30th, the Boston Area Chapter hosted our Annual Golf Tournament at the Indian Pond Country Club in Kingston, MA. This was the second year the Chapter hosted our golf tournament at Indian Pond and once again the club didn't disappoint. This 18-hole championship course, which opened in 2001, measures almost 6800 yards over 160 acres of meticulously manicured grounds. The weather was gorgeous: sunny and warm. As with all our golf tournaments the event wasn't just about the golf! Some of the special "extras" of the day this year included large golf umbrellas, cigars from Gina's Cigar and liquor tastings from Firefly Sweet

Tea Vodka. Finally, over \$3,000 of proceeds from the raffle ticket sales benefited the Joel Goldenberg Memorial Scholarship Fund.

At the end of play, everyone enjoyed a cocktail reception in the clubhouse. During the reception, contestants that previously sunk a 10-foot putt during play had a chance to win \$10,000 if they first sunk a 30-foot putt and then a final 50-footer. One talented individual, Mark Tarricone, sunk the 30-foot putt. With all eyes on Mark, he bravely took his chance at immortality. Unfortunately, his putt just skipped by the hole and he was left with only the memory of a great day of golf with customers, co-workers, and friends. After the relaxing cocktail reception, a spectacular buffet dinner in the clubhouse was served followed by the presentation of awards and raffle prizes. Congratulations to all of the day's winners!



The winning teams:

| <u>First Place (55)</u> | <u>Second Place (59)</u> | <u>Third Place (59)</u> |
|-------------------------|------------------------------|-------------------------|
| The Wilkinson Companies | Middlesex Gases+Technologies | Superior Controls |
| Geoff Wilkinson Sr. | Guy Sylvester | Damon Robbins |
| Geoff Wilkinson Jr. | Ron Perry | Phil Zampatella |
| Herb Aikens | Ed Pendleton | Tim Manning |
| Paul Degnan | John Iannucci | Michael Severino |

And the individual winners:

| | <u>Men</u> | <u>Women</u> |
|-------------------|---------------------|------------------------|
| Longest Drive | Jerry Toomey | Maria Tarczuk |
| Closest to Pin | Ed Pendleton (9'7") | Meaghan O'Hara (30'8") |
| Straightest Drive | Jerry Toomey | Sylvia Beaulieu |

Many, many thanks to our Golf Tournament corporate sponsors: ahp Architects, Arion Water, AutomaTech, Commissioning Agents, DECCO, GxP Automation, Interstate Electrical Services, Leftfield Project Management, M+W Group, Mangan Biopharm, Middlesex Gases + Technologies, Neomatrix, P&IDC, R.W. Sullivan Engineering, Richard White Sons, SciTech Builders, Superior Controls, The Richmond Group, and TRG Builders, all of whom helped to make this event another big success for the Chapter.



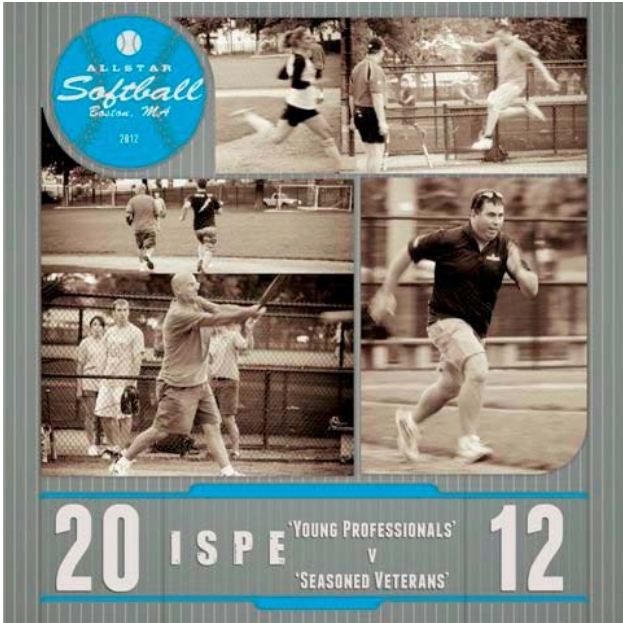
And last, but by no means least, a special thanks to the tournament committee and volunteers during the event: Fasha Onorato, Tom Forster, John Ramirez, Patty Ascanio, and Brian Hagopian whose support helped make this event another huge success.

For more photos from this event go to the ISPE Boston Area Chapter Photo Gallery on our website at <http://www.ispeboston.org/gallery/index.php?level=album&id=17>.

YPs Kick-Off the Season with the Annual Softball Showdown

by Dave Gallagher, GxP Automation

Congratulations to former Young Professionals Committee Chair Jillian Willard on her promotion to the Chapter's Board of Directors. Jillian has



been instrumental in getting the YPs to where they are today and will continue to benefit the Chapter as she serves on the board. She has been succeeded on the YPC by Andrea Massa, who is the new committee chair. Andrea is very excited about the upcoming year and has already started planning some great events for the Chapter's young professionals.

The YPs August event was their Annual Softball Showdown against the Chapter's Seasoned Veterans. The event took place at the beautiful Teddy Ebersol fields, which are located right on the Charles River in Boston. You could feel the competitive juices flowing before the event even started! Unfortunately for the YPs, the Seasoned

Vets got out to an early lead and didn't look back. The YPs posted a valiant comeback in the late innings but in the end couldn't muster up enough strength to take down the Vets. After the game, the teams convened at nearby Harvard Gardens for post-game appetizers and drinks. Overall it was a successful event and a great opportunity for the YPs to meet some "seasoned" industry professionals. Thanks to Andrea Massa of Burkert Fluid Control Systems for organizing another successful YP event!

On a less competitive note, the YPs hosted their annual cruise around Boston Harbor on September 6. This was the first social event of the new season for the YPs, and many helped us kick off the year the right way. It was another great chance to socialize with fellow industry members or maybe just an excuse to cruise the harbor and take in the beautiful scenery. Either way was a great event.

With the Annual Product Show coming up, the YPs have decided to host their own "equipment showcase" combined with a networking social during the tail end of the Show, from 5 to 7pm. Come join us to see fellow YP's equipment samples and learn firsthand from some live product demonstrations as well. And attendance at the Product Show is free, so there's no excuse not to be there and take advantage of another great opportunity to learn about your industry!



YPs lick their wounds at Harvard Gardens after their loss to the Chapter's Seasoned Veterans.

The Boston Area Chapter YPs are hoping to have another great year; which started with the Harbor Cruise on Sept 6. Stay tuned for upcoming social and educational events from the YPs and don't forget to tell your colleagues that non-members are always welcome at our events!

YPs Host the Chapter’s Annual Harbor Cruise

by Sofie Bambrick, Biogen Idec, with photos by Joyce Chiu, CPIP, Honeywell Safety Products



Don't let the fact that the Boston Harbor Cruise event was put together by the Chapter's Young Professionals Committee (YPC) fool you into thinking that you had to be a member of the Millennials generation to attend and have a great time. This was an event for all ages, as was evident by the attendees, whose time in the professional world spanned from a few months to over a few decades. "I am not young, but I still had fun!" commented Gene Dennen, a veteran ISPE member, after entertaining a small crowd with witty songs and stories.

The three-story boat left from Rowes Wharf in Boston. Upon boarding, we were all personally greeted by Captain Mike and encouraged to mingle over sandwiches and drinks (which were served by Captain Mike himself). All the while, members of the YPC and some lucky volunteers were blowing up the inflatable party favors, including guitars, saxophones and microphones. The latter came in handy for the improv karaoke that took place later in the night. Despite the poor.



weather leading up to the event, we were fortunate to have clear skies during the evening, allowing attendees to take full advantage of the deck on the top floor of the boat. The panoramic views of Boston were visible during the entire cruise, making for a lovely background, especially after sundown when all the buildings were lit up.



The overall atmosphere of the event was great for meeting new people and making new connections. Attendees represented a very diverse professional network, including pharmaceutical companies as well as other fields supporting the pharmaceutical industry, such as construction, instrumentation, software automation, etc. "There are a lot of networking opportunities," said John, who was attending his first Boston Area Chapter social event, "and the fact that we're on a sailing boat having fun just makes it all the more enjoyable!"

Major kudos go to the event's organizer, Chiderah Okoye of Rockwell Automation, and other members of the YPC for taking care of all the details (including the beautiful weather!) and putting together a great event. See you next year!

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.

Genzyme MS Drug Has Setback

Genzyme has suffered a setback in its plans to sell its multiple sclerosis (MS) drug in the United States. According to Genzyme, it received a letter from the FDA in response to its biologics license application it filed in June for Lemtrada, which would be used for the treatment of relapsing MS. Genzyme said that, in the

"refuse to file" letter, the FDA has requested that the firm modify the presentation of its data sets "to enable the agency to better navigate the application" but said the FDA had not asked for additional data or further studies. Genzyme said it will work with the FDA to meet its requests in the coming weeks and hopes to resubmit the application as soon as possible.

Lemtrada is being developed in collaboration with Bayer HealthCare. A marketing authorization application for the drug was also submitted to the European Medicines Agency, roughly the European Union's FDA equivalent, in June. That application has been accepted and the review process is underway. (Source: [Jacquelyn Gutc](#), Worcester Business Journal Online, 27 August, 2012)

Vertex Receives European Approval for Cystic Fibrosis Drug

Vertex Pharmaceuticals has announced that the European Commission has approved Kalydeco (ivacaftor) for people with cystic fibrosis (CF) ages 6 and older who have at least one copy of the G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Kalydeco is the first medicine to target the underlying cause of the disease in these patients. Cystic fibrosis is a rare genetic disease caused by defective or missing CFTR proteins resulting from mutations in the CFTR gene. In people with the G551D mutation, Kalydeco helps the defective CFTR protein function more normally. An estimated 1,100 people in Europe have the G551D mutation.

"Cystic fibrosis is a life-threatening genetic disease that causes devastating effects, particularly in the lungs, including the build up of thick, sticky mucus which becomes infected and severely limits normal breathing," said Stuart Elborn, M.D., Kalydeco investigator and President of the European Cystic Fibrosis Society. "Kalydeco is one of the most important advances in the treatment of cystic fibrosis since the discovery of the CF gene in 1989. By treating the underlying cause of the disease in people with the G551D mutation, Kalydeco helped them breathe more easily, gain weight and resulted in certain improvements in quality of life."

"Kalydeco is an exciting new beginning in the treatment of cystic fibrosis, but we're not finished," said Peter Mueller, Ph.D., Chief Scientific Officer and Executive Vice President of Global Research and Development at Vertex. "The scientists at Vertex, in collaboration with doctors, patients and advocates around the world, are working hard to develop additional new medicines to treat the underlying cause of the disease in many more people with cystic fibrosis."

Kalydeco was discovered as part of a collaboration with Cystic Fibrosis Foundation Therapeutics, Inc., the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation and was first approved by the FDA in January 2012 for use in people with CF ages 6 and older who have at least one copy of the G551D mutation in the CFTR gene. (Source: Vertex Pharmaceuticals Website, 27 July, 2012)

Advanced Cell Technology Praises Stem Cell Decision

Marlborough-based Advanced Cell Technology (ACT), which is developing stem cell treatments for eye diseases, praised a court ruling that it said will eliminate "major speed bumps" to getting federal funding. Such funding has been permitted, with some restrictions, since President Obama issued an executive order in 2009 overturning a ban put in place by President George W. Bush. Obama's order drew a legal challenge at the time, which resulted in a federal judge issuing a preliminary injunction in 2010. That injunction was overturned by the U.S. Court of Appeals in Washington, D.C. on August 24. "We expect that a number of our embryonic stem cell lines will be approved for funding in the coming months," ACT CEO Gary Rabin said in a statement.

ACT has Phase I trials underway for stem cell treatments it has developed for Stargardt's Macular Dystrophy and Dry AMD, which lead to blindness. Rabin wrote in his blog that "myths and misunderstanding" still permeate the stem cell research discussion, though 12 years have passed since the first human embryonic stem cell (hESC) line was derived. He noted that ACT derives hESCs through a patented technique that removes a single cell from an embryo without damaging or destroying it, which eliminates many of the ethical and religious arguments against embryonic stem cell research.

Francis Collins, the director of NIH, issued a statement on the court ruling that said it affirms the agency's commitments to patients afflicted by diseases that may one day be treatable using stem cell therapies. "NIH will continue to move forward, conducting and funding research in this very promising area of science," Francis said. (Source: Matt Pilon, Worcester Business Journal Online, 28 August, 2012)

Biogen & Isis Announce Drug Collaboration

Biogen Idec and Isis Pharmaceuticals announced a second collaboration agreement under which both companies will develop and commercialize a novel antisense drug for the treatment of a type of myotonic

dystrophy known as Steinert disease. The companies previously announced collaborative efforts in January to develop and commercialize an Isis antisense investigational drug designed to treat spinal muscular atrophy.

Isis, based in Carlsbad, California, will receive an upfront payment of \$12 million and is responsible for the discovery of a lead antisense drug candidate targeting the dystrophia myotonica-protein kinase gene for treating the disease. Isis is eligible to receive up to \$59 million in milestone payments associated with the clinical development of the DMPK-targeting drug prior to licensing, and could receive up to another \$200 million in a license fee and regulatory milestone payments. Biogen Idec has the option to license the drug from Isis up through the completion of a Phase 2 trial, both companies said. (Source: Ira Kantor, The Boston Herald, 29 June, 2012)

Bristol-Myers Squibb and AstraZeneca Expand Diabetes Alliance via Bristol-Myers Squibb's Acquisition of Amylin

Bristol-Myers Squibb and AstraZeneca have announced that following the successful completion of the acquisition of Amylin Pharmaceuticals by Bristol-Myers Squibb, AstraZeneca has made an initial payment of approximately \$3.2 billion to Amylin Pharmaceuticals, now a wholly-owned subsidiary of Bristol-Myers Squibb. As previously disclosed, the payment is being made in connection with the expansion of the diabetes alliance between AstraZeneca and Bristol-Myers Squibb to incorporate the development and marketing of Amylin's portfolio of diabetes products, and profits and losses arising from the collaboration will be shared equally.

AstraZeneca has also informed Bristol-Myers Squibb of its intention to exercise its option to acquire certain additional governance rights over key strategic and financial decisions regarding Amylin's portfolio. The right to exercise this option will become effective once applicable anti-trust and competition approvals are received by AstraZeneca. Upon the exercise of the option an additional payment of \$135 million will be made to Bristol-Myers Squibb.

"The completion of our acquisition of Amylin and the expansion of our diabetes alliance with AstraZeneca will increase and strengthen our innovative portfolio of diabetes medicines, extending its reach across the spectrum of treatment options," said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. "We are pleased to have the opportunity to work together to build on the innovative portfolio, state-of-the art manufacturing facilities and dedicated customer focus that the talented people at Amylin have created."

Simon Lowth, interim chief executive officer, AstraZeneca, said: "We are delighted to have successfully completed the expansion of our diabetes alliance with Bristol-Myers Squibb through the addition of Amylin's GLP-1 franchise, creating a broader disease management platform for patients, physicians and payers. We are looking forward to working with the team at Amylin to build on their success and maximize AstraZeneca's and Bristol-Myers Squibb's combined capabilities to make these innovative treatments available to many more diabetes patients across the world." (Source: Bristol-Myers Squibb Website, 09 August, 2012)

Masy Systems Breaks Ground on New -75°C Storage Facility

Masy Systems, headquartered in Pepperell, held an official groundbreaking celebration on July 17 to officially begin work on a new 6,200 cu. ft. -75°C storage facility. The new storage space is needed to meet customer demands in response to the success of a 1,000 cu. ft. -75°C storage facility that Masy opened just over two years ago. The planned opening of the new storage facility is scheduled for late fall of 2012.

The financing of the cold space as well as the building where this new endeavor will be housed was all made possible with the help of a number of groups, all in attendance at the celebration. State Treasurer Steven Grossman said, "Through our Small Business Banking Partnership we are seeing innovative companies like Masy Systems put their entrepreneurial spirit to work and expand their business."

"We are excited to partner with the State Treasurer and North Middlesex Savings Bank to finance our growth," said Laurie Masiello, Masy Systems' President. "In addition to real estate expansion and job growth, their support has enabled our company to add equipment for our biorepository and invest in wireless sensors for our validation and rental business."

Masy provides validation services for sterilizers, chambers and warehouses for numerous clients in North America. The company is NVLAP accredited to ISO 17025 for calibration services, and ISO 9001 certified. Masy provides validation and calibration services, equipment rentals, and GMP storage for the pharmaceutical and biotech industries. (Source: Masy Systems Press Release, 17 July, 2010)

Cubist Launches Phase 3 Trials for CDAD Medication

Cubist Pharmaceuticals has launched a Phase 3 clinical trial for its potential therapy for the sometimes-deadly

Clostridium difficile-associated diarrhea (CDAD). Cubist's candidate will be tested against the FDA-approved oral vancomycin. Cubist Chief Scientific Officer Steve Gilman said in a statement, "We are very excited to be able to advance CB-315 as a potential therapy, and today's announcement marks an important milestone as we continue to build a portfolio of potential new therapies for acutely ill patients." (Source: Julie M. Donnelly, The Boston Business Journal, 13 July, 2012)

AstraZeneca Advances Neurological Research, Phase 3 Projects

AstraZeneca has recently signed two new agreements in the neuroscience field to look for compounds to treat Alzheimer's, Parkinson's, and various other brain afflictions. Reuters also reports that they have signed a deal with US scientists to study apolipoprotein E4, a gene that is believed to increase the risk of Alzheimer's. Bloomberg News quotes Menelas Pangalos, AstraZeneca's executive vice president of Innovative Medicine Research, saying, "We've set our R&D organization a goal of delivering eight to 11 Phase 3 projects. ... That's more than we've ever done." (Source: Ben Hirschler, Reuters, 13 July, 2012)

Sanofi Signs Diabetes Research Agreement with Brigham & Women's Hospital

Sanofi SA, the French drug giant that bought Cambridge-based Genzyme Corp. for \$20.1 billion last year, has announced a new research collaboration with Brigham and Women's Hospital, a teaching and research affiliate of Harvard Medical School. Under the terms of the agreement, researchers from both organizations will undertake studies for a novel approach to treat type 1 diabetes. Sanofi has an option to exclusively license intellectual property emerging from this collaboration.

Sanofi has been using its newly expanded presence in the Boston area to pioneer a research model that relies more on partnerships with outside innovators and less on its in-house efforts.

In a March speech to the Boston College Chief Executives' Club, Sanofi chief executive Christopher A. Viehbacher said that the area's focus on innovation makes it a perfect location to collaborate on drug development with academic researchers and biotech start-ups. Sanofi has made the Boston area its top US research hub. (Source: Chris Reidy, Boston Globe, 19 July, 2012)

Bristol-Myers Drug Fails Liver Cancer Trial

Bristol-Myers Squibb said its experimental drug brivanib failed in a late-stage trial to match Nexavar, a cancer treatment sold by Bayer AG and Onyx Pharmaceuticals in prolonging the lives of patients with advanced liver cancer. The Bristol-Myers drug is an oral once-daily treatment that blocks receptors to VEGF, a protein involved in many cancers, and also blocks enzymes called FGFR tyrosine kinases that have been linked to cancer. The company said it will continue other trials of the medicine in kidney cancer and against other tumor types. (Source: Ransdell Pierson, Reuters, 19 July, 2012)

Tax Incentives for Life Science Companies Announced by MLSC

The Massachusetts Life Sciences Center (MLSC) is looking to give away up to \$25 million in tax incentives to companies that plan to expand and create jobs within the state. The center, a quasi-public agency headquartered in Waltham that was established in 2006 and affiliated with, but not directly overseen by, the Executive Office of Housing and Economic Development, has announced that applications are now being accepted for the fourth round of the program. In the previous three rounds, the center has granted 57 awards totaling \$56.7 million for companies that have created or are promising to create more than 2,000 jobs.

"Our Tax Incentive Program has provided a solid return on investment for the taxpayers by incentivizing job creation, and holding the companies involved accountable for their job creation commitments," said Susan Windham-Bannister, MLSC president and CEO, in a statement. "In keeping with our mandate, the center is utilizing our tax incentives to stimulate the state's economy by creating jobs in industry sectors where Massachusetts is a global leader and where jobs pay far more than the average salary in Massachusetts." Waltham-based Nova Biomedical Corporation, for example, has received tax incentives over the past three years to support its new 80,000 square foot manufacturing facility in Billerica. Nova Biomedical now employs nearly 700 full-time employees in Massachusetts and more than 900 worldwide.

Companies have until October 25 to submit applications, which can be submitted online. Information sessions will be held in various locations for potential applicants, with dates and locations on the MLSC website. The program is meant to help with the money needed to translate life science research into commercially viable products. To qualify, companies must be certified from the center and must demonstrate scientific and economic merit of their expansion plans. The goal is to create new long-term jobs in Massachusetts. (Source: Don Seiffert, Mass High Tech Online, 23 July, 2012)

Bluebird Bio Raises \$60M for Gene Therapies

Cambridge-based bluebird bio, a leader in the development of innovative gene therapies for severe genetic disorders, has announced the successful completion of a \$60 million Series D financing. In this round, new investors Deerfield Partners, RA Capital, Ramius Capital Group, and two undisclosed blue chip public investment funds joined existing investors ARCH Venture Partners, Third Rock Ventures, TVM Capital, and Forbion Capital Partners. In addition, Shire plc joined the round as a strategic investor.

Proceeds will be used to advance the company's clinical programs in severe genetic disorders, including childhood cerebral adrenoleukodystrophy (CCALD), beta-thalassemia and sickle cell disease. With the proceeds from this financing and based on promising early clinical proof-of-concept results, bluebird bio plans to initiate a Phase 2/3 clinical study in CCALD in both the United States and Europe in 2013, as well as a second U.S.-based Phase 1/2 study in beta-thalassemia in 2013. In addition, the company expects to initiate a more extensive sickle cell disease development program and invest in manufacturing, clinical and commercial infrastructure to support the upcoming clinical trials and pre-commercial launch activities. (Source: bluebird bio Website, 25 July, 2012)

Millennium to Anchor Complex in Cambridge

Cancer drug developer Millennium has agreed to lease about 230,000 square feet of office and lab space and become the anchor tenant in a new mixed-use building planned for 300 Mass Ave. in Cambridge, a move that would significantly expand the company's local footprint while extending the University Park at MIT life sciences cluster. The Cambridge City Council is set to vote on zoning approval for the proposed six-story structure, which would be developed by Cleveland-based Forest City Enterprises and include shops and restaurants on the ground floor. If the parties finalize their deal, the rest of the building would be occupied by Millennium, which has hired 400 employees and boosted its workforce to 1,200 since it was bought by Japan's Takeda Pharmaceutical four years ago. (Source: Robert Weisman, The Boston Globe, 27 July, 2012)

Boston Scientific Attains Expanded EU Approval for Pacemaker

Boston Scientific Corp. has received an "expanded approval in Europe" for its "implantable pacemaker called Ingenio," which is the "first new pacemaker platform" the company has launched in 10 years. European regulators approved the device in April and FDA approved it in May; the expanded EU approval allows "European patients with the pacemaker to undergo MRI scans." The Journal points out that "earlier this year, incoming Boston Scientific CEO Michael Mahoney said increasing the company's market share in the pacemaker market, which now stands at 15 percent of the \$4 billion market, is an important goal for the company." (Source: Julie M. Donnelly, Boston Business Journal, 28 July, 2012)

Dendreon Reports Another Loss & 600 More Job Cuts

Seattle-based Dendreon has unveiled restructuring plans that include cutting more than 600 jobs over the next year as the pharmaceutical company continues to lose money due to slow sales of its prostate-cancer treatment. Dendreon said it will reconfigure its manufacturing model and close its Morris Plains, New Jersey manufacturing facility. The restructuring efforts, implemented immediately, will reduce the company's costs by about \$150 million annually. Dendreon expects benefits from these efforts as early as the first half of 2013.

Dendreon's Provenge was approved in 2010 after a lengthy review process and is seen as the first of a new class of drugs to battle cancer using a patient's own cells to stimulate the body's immune system and fight the disease. Dendreon continues to face reimbursement issues with Provenge, however, as some doctors aren't comfortable with the complex task of getting reimbursed for the expensive drug. (Source: Nathalie Tadena, Wall Street Journal Online, 30 July 2012)

Ariad Seeks Quick Approval of Leukemia Drug

Cambridge-based Ariad Pharmaceuticals has filed a long-awaited new drug application, asking the FDA for priority review and accelerated approval of a treatment for chronic myeloid leukemia. The massive filing came more than a month earlier than expected and was the electronic equivalent of "700 bound volumes, each two and a half inches thick," Ariad chief executive Harvey J. Berger said. If the FDA grants Ariad's request for accelerated approval of the leukemia drug - to be used in patients for whom other treatments haven't worked - it could be on the market by the first quarter of next year, Berger said.

Berger said the Cambridge company received "fast-track" designation from the FDA two years ago, enabling it to use a rolling submission process, something the agency permits for potentially breakthrough drug candidates in areas of high medical need. That process allowed Ariad to submit more than 99 percent of the

application so regulators can begin reviewing it even before the remaining information - mostly chemical and manufacturing data - is filed by Sept. 30. (Source: Robert Weisman, The Boston Globe, 31 July, 2012)

Idenix & Novartis Restructure Development & Commercialization Collaboration

Cambridge-based Idenix Pharmaceuticals has announced that Idenix and Novartis entered into a termination and revised relationship agreement that restructures the development and commercialization collaboration that was established in May 2003. Under the new agreement, among other changes, Novartis' option right to license Idenix's current and future development-stage drug candidates in any therapeutic area has terminated. In exchange, Idenix has agreed to pay Novartis a royalty based on worldwide product sales of Idenix's future hepatitis C virus (HCV) drugs, unless they are used in combination with drugs from Novartis. The royalty percentage will vary based on the commercialized Idenix HCV drug.

"This agreement affords Idenix increased flexibility to optimize the value of our pipeline for the benefit of Idenix, our shareholders and ultimately HCV patients. By regaining the worldwide rights to develop, commercialize and license all of our drug candidates, we believe Idenix will be well-positioned to develop pan-genotypic all-oral direct-acting antiviral combination treatments with potential collaborators," said Ron Renaud, Idenix's President and Chief Executive Officer. (Source: Idenix Pharmaceuticals Website, 31 July, 2012)

Idenix Shares Sink on FDA Setback for Hep C Drug

Idenix Pharmaceuticals Inc. saw its shares fall 28 percent, after the biotech company disclosed that the FDA has temporarily delayed development of its experimental therapy for hepatitis C. Idenix said the FDA's decision was based on a serious cardiac side effect reported earlier this month by rival Bristol-Myers Squibb, which is developing a similar drug candidate.

BMS, Idenix and Vertex Pharmaceuticals are in a race with a number of other drug makers to be the first to market with a hepatitis C drug cocktail that does not include interferon. Patients taking interferon experience a number of side effects, including flu-like symptoms, so an interferon-free drug regimen would improve patients' quality of life.

Idenix said the FDA put a "partial clinical hold" on its potential hepatitis C therapy because it wants to further review the safety of the drug candidate, called IDX184. The regulatory agency has requested additional safety data from the company. The company cannot enroll any new patients in trials until an agreement is reached with the FDA. "Patient safety is our main concern and Idenix will immediately begin work to comply with the FDA request and expects to submit these data to the FDA in the coming weeks. The Company intends to have an ongoing discussion with the FDA following the submission of this data," Idenix executives wrote in a statement.

The company said so far there has been no evidence of increased cardiotoxicity from IDX184, and that currently no patients are being dosed with the experimental medication. The company reported interim data from its ongoing phase 2B trial this past June." (Source: Julie M. Donnelly, The Boston Business Journal, 16 August, 2012)

Haemonetics Completes Acquisition of Pall's Transfusion Medicine Business

Braintree-based Haemonetics Corp. has announced that it has completed the acquisition of the business assets of the blood collection, filtration and processing product lines of Pall Corp. The acquired business has approximately 1,300 employees and provides Haemonetics with commercial presence in all aspects of the whole blood collection market. The combined company is expected to generate greater than \$1 billion of revenue in its full fiscal year 2014. (Source: Haemonetics Website, 01 August, 2012)

Hologic Completes Acquisition of Gen-Probe

Bedford-based Hologic has announced that it has successfully completed its acquisition of Gen-Probe Inc. for a total net purchase price of approximately \$3.8 billion. Gen-Probe is now a wholly-owned subsidiary of Hologic. Rob Cascella, President and Chief Executive Officer of Hologic said, "We are pleased to complete this acquisition and welcome Gen-Probe into the Hologic family. I am excited to work with Carl Hull to capitalize on the many opportunities ahead for our Diagnostics business and for our company. With Gen-Probe's suite of technologies, Hologic is now firmly established as a premier provider of diagnostic solutions. We are poised to leverage our established global infrastructure with an impressive new product pipeline, and to capitalize on the fast-growing molecular diagnostics market. We are committed to a seamless integration of Gen-Probe and look forward to delivering on the synergies and growth potential presented by this combination." (Source: PRNewswire, 01 August, 2012)

Pfizer, J&J End Development of Alzheimer's Drug; Lilly Continues Its Program

For millions of people suffering from Alzheimer's disease, an experimental drug from Eli Lilly and Co. may now be their last hope for treatment. Pharmaceutical giants Pfizer Inc. and Johnson & Johnson pulled the plug Monday on their joint development of a similar Alzheimer's therapy, after that drug failed to show any benefit in two late-stage studies. Lilly has said it will release its findings by the end of September.

Lilly could use a big win. It is facing the loss of \$7 billion in sales over the next five years from generic competition to its two best-selling medicines. Lilly has spent more than a decade, and perhaps \$1 billion or more, studying the drug. Yet after Pfizer and J&J pulled out, investors give the Lilly drug a less than 20 percent chance of success. Meanwhile, newer treatments in development by other companies are still years away.

The Pfizer-J&J drug that failed, called bapineuzumab, and Lilly's both target plaque that builds up in the brains of Alzheimer's patients, which some believe may be the cause of the disease. Lilly's drug targets the floating plaque while the Pfizer-J&J drug goes after the deposits of plaque. Lilly remains far more vulnerable to a failure on Alzheimer's than its larger competitors. Pfizer, with a market value of \$178 billion, and J&J, at \$188 billion, have made big acquisitions to help them overcome generic competition to their top drugs. The much-smaller Lilly, with a \$50 billion market capitalization, has yet to do a large deal to shore up its pipeline of experimental drugs. (Source: Shannon Pettypiece, Bloomberg News, 09 August, 2012)

Biogen Idec and Regulus Therapeutics Cut Deal to Monitor MS

San Diego-based Regulus Therapeutics, a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, announced that it has entered into a collaboration with Biogen Idec to identify microRNAs as biomarkers for multiple sclerosis (MS). Under the transaction, Biogen Idec will make an investment in Regulus in addition to upfront and milestone payments. The key objective of the collaboration is to identify microRNA biomarkers in the blood of patients with MS. Regulus believes that microRNA biomarkers may be used to select optimal patient segments in clinical trials, to develop companion diagnostics, and to monitor disease progression or relapse.

"Utilizing innovative technology such as biomarkers can help us make more informed decisions earlier in clinical development and is key to our overall company strategy to enhance early-stage discovery efforts," said Steven Holtzman, Executive Vice President, Corporate Development of Biogen Idec. "We're excited to collaborate with Regulus to seek to identify biomarkers in MS patients, and are hopeful it can speed the work we're doing to bring new, effective treatments to market for patients with MS."

"Regulus is delighted to form a collaboration with Biogen Idec, a biotechnology pioneer with more than thirty years of innovative contributions to the industry," said Garry E. Menzel, Ph.D., Chief Operating Officer and Executive Vice President of Finance at Regulus. "This collaboration allows us to further explore our proprietary microRNA biomarker platform with Biogen Idec's additional resources and expertise." (Source: PRNewswire, 16 August, 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.

Court of Appeals Upholds Myriad's Gene Patents for BRCA 1 and BRCA 2

Myriad Genetics of Salt Lake City, Utah has reported that the US Court of Appeals for the Federal Circuit declared that the company's composition of matter claims covering isolated DNA of the BRCA 1 and BRCA 2 genes are patent-eligible material under Section 101 of the United States Patent Act. This decision reinstates the prior decision by the Court on July 29, 2011.

"We are very pleased with the favorable decision the Court rendered today which again confirmed that isolated DNA is patentable," said Peter Meldrum, President and CEO of Myriad Genetics. "Importantly, the Court agreed with Myriad that isolated DNA is a new chemical matter with important utilities which can only exist as the product of human ingenuity."

Myriad's portfolio of molecular diagnostic tests are based on an understanding of the role genes play in human disease and were developed with a commitment to improving an individual's decision making process for monitoring and treating disease. Myriad is focused on strategic directives to introduce new products,

including companion diagnostics, as well as expanding internationally. (Source: Myriad Genetics Website, 16 August, 2012)

FDA Approves New Vaccine to Protect Children Against Two Bacterial Diseases

The FDA has approved Menhibrix, a combination vaccine for infants and children ages 6 weeks through 18 months, for prevention of invasive disease caused by *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b. Menhibrix is manufactured by GlaxoSmithKline Biologicals, based in Rixensart, Belgium.

Diseases caused by the bacteria *Neisseria meningitidis* (meningococcal disease) and *Haemophilus influenzae* type b (Hib disease) can be life-threatening. These bacteria can infect the bloodstream causing sepsis; and the lining that surrounds the brain and spinal cord causing meningitis. In young children, *Neisseria meningitidis* and *Haemophilus influenzae* type b are important causes of bacterial meningitis.

Without vaccination, children younger than two years are susceptible to these serious illnesses. Meningococcal and Hib diseases are particularly dangerous because both diseases often progress rapidly and can cause death or serious, long-lasting health consequences such as blindness, mental retardation, or amputations. Early symptoms for both diseases often are difficult to distinguish from other common childhood illnesses. (Source: FDA Website, 14 June, 2012)

FDA Allows Marketing of First Nucleic Acid Test for Bacteria Associated with Bloodstream Infections

The FDA has allowed marketing of the first nucleic acid test that can identify 12 different bacterial types known to cause bloodstream infections. The test, manufactured by Nanosphere of Northbrook, Illinois, allows for simultaneous identification of the bacteria and three associated resistance genes in just a few hours after the first sign of bacterial growth. Traditional methods may require two to four days to produce bacterial identification and resistance results. The Verigene GP Blood Culture Nucleic Acid Test (BC-GP) can identify different types of Staphylococcus, (including methicillin-resistant Staphylococcus aureus or MRSA), Streptococcus, Enterococcus (including vancomycin-resistant Enterococci or VRE), and Listeria.

Bloodstream infections are one of the most common and serious illnesses found in U.S. hospitals. Bacteria entering the bloodstream can cause severe illness, including infections of the heart, kidney, and other vital organs. Without treatment, infection of vital organs can result in serious consequences, including death. (Source: FDA Website, 27 June, 2012)

FDA Approves Belviq to Treat Some Overweight or Obese Adults

The FDA has approved Belviq (lorcaserin hydrochloride), as an addition to a reduced-calorie diet and exercise, for chronic weight management. The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese), or adults with a BMI of 27 or greater (overweight) and who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia). BMI, which measures body fat based on an individual's weight and height, is used to define the obesity and overweight categories. According to the CDC, more than one-third of adults in the United States are obese.

The drug's manufacturer will be required to conduct six postmarketing studies, including a long-term cardiovascular outcomes trial to assess the effect of Belviq on the risk for major adverse cardiac events such as heart attack and stroke. Belviq is manufactured by Arena Pharmaceuticals GmbH of Zofingen, Switzerland, and distributed by Eisai Inc. of Woodcliff Lake, N.J. (Source: FDA Website, 27 June, 2012)

FDA Approves First Over-The-Counter Rapid HIV Test for Home Use

The FDA has approved the OraQuick In-Home HIV Test, the first over-the-counter, home-use rapid HIV test kit to detect the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). The test is manufactured by OraSure Technologies, headquartered in Bethlehem, Pennsylvania. A version of this test for use by trained technicians in clinical settings was approved in 2004.

The OraQuick In-Home HIV Test is designed to allow individuals to collect an oral fluid sample by swabbing the upper and lower gums inside of their mouths, then place that sample into a developer vial, and obtain test results within 20 to 40 minutes. A positive result with this test does not mean that an individual is definitely infected with HIV, but rather that additional testing should be done in a medical setting to confirm the test result.

The CDC estimates that 1.2 million people in the United States are living with HIV infection. About one in five are not aware they are infected. There are about 50,000 new HIV infections every year. Many of these new infections are transmitted from people who are unaware of their HIV status. (Source: FDA Website, 03 July, 2012)

FDA Approves First DNA Test to Help Manage CMV Infection in Transplant Patients

The FDA has approved the first DNA test to help health care professionals gauge the progress of anti-viral treatment in solid organ transplant patients undergoing cytomegalovirus (CMV) antiviral therapy. The COBAS AmpliPrep/COBAS TaqMan CMV Test, manufactured by Roche Molecular Systems in Somerville, New Jersey, is a viral load test that can help determine the amount of CMV nucleic acid present in a sample of a patient's blood plasma.

While a patient is undergoing anti-CMV therapy, a clinician can use the device to perform a series of tests to look for changes in a patient's CMV viral load. A significant decrease in viral load from one test to the next may indicate that a particular therapy is effective, while an increase or no change may indicate the need for a different therapy. When used along with other clinical and laboratory data, this information can aid clinicians to manage and optimize patient care.

CMV is a common virus that can cause severe diseases such as pneumonia or colitis in people with weakened immune systems, including solid organ transplant patients. Solid organ transplants include heart, lung, pancreas, kidney, or small intestine transplants. Transplants of tissue or cells, such as bone marrow, skin, or muscle, are not included. (Source: FDA Website, 05 July, 2012)

FDA Approves Genetic Test to Help Determine Effectiveness of Erbitux Therapy

The FDA has approved the first genetic test that can help some colorectal cancer (CRC) patients and their doctors determine if the drug Erbitux (cetuximab) would be an effective treatment based on the absence of a gene mutation. The *therascreen* KRAS RGQ PCR Kit, developed by QIAGEN Manchester Ltd., of Manchester, England, can provide information about the KRAS gene mutation in patients whose CRC has spread to other parts of their body (metastasized). Studies have found that Erbitux, co-marketed by New York City-based Bristol-Myers Squibb and Eli Lilly and Company of Indianapolis, is not effective in those who have the mutation.

CRC is the third leading cause of cancer death in the United States. According to the American Cancer Society, there were more than 141,000 new CRC cases in 2011, and nearly 50,000 deaths resulted from CRC. Erbitux targets the epidermal growth factor receptor (EGFR) on the surface of CRC cells. When certain chemicals in the body bind to EGFR, the receptor starts a complex chain of biochemical reactions inside the cell that signals the cancer cell to reproduce. Erbitux blocks EGFR, interrupting a signal to reproduce which can stop the growth of CRC cells. However, when CRC cells have a mutation in the KRAS gene, they continue to reproduce even when Erbitux blocks EGFR. (Source: FDA Website, 06 July, 2012)

FDA Outlines Plans to Provide Earlier Feedback on Device Product Submissions

The FDA issued a draft guidance that outlines the agency's recommendations and procedures for medical device manufacturers and researchers who want early feedback and advice before submitting a product- or research-specific application. The draft guidance expands on the agency's existing pre-Investigational Device Exemption (pre-IDE) program, which allows companies to obtain feedback on a product during the investigational stage and prior to the formal application process.

The new program will be referred to as the Pre-Submission or "Pre-Sub" program. It will operate within the FDA's existing medical device premarket regulatory pathways: IDE, Premarket Approval (PMA), Humanitarian Device Exemption (HDE), Premarket Notification (510(k)), and de novo. It is intended to foster innovation by helping medical device developers identify the regulatory requirements early in the device development process.

The Pre-Sub program is part of the FDA's ongoing commitment to facilitate earlier, more transparent, and more predictable interactions between the agency and innovators during the earliest stages of product development. The FDA is seeking public comment on the draft guidance. Instructions for submitting a comment are available in a Federal Register notice published today. (Source: FDA Website, 12 July, 2012)

FDA Approves First Drug for Reducing Risk of Sexually-Acquired HIV Infection

The FDA has approved Truvada (emtricitabine/tenofovir disoproxil fumarate), the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in

sexual activity with HIV-infected partners. Truvada, taken daily, is to be used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at high risk. The FDA previously approved Truvada to be used in combination with other antiretroviral agents for the treatment of HIV-infected adults and children 12 years or older. Truvada is manufactured by Gilead Sciences of Foster City, California.

As part of PrEP, HIV-uninfected individuals who are at high risk will take Truvada daily to lower their chances of becoming infected with HIV should they be exposed to the virus. A PrEP indication means Truvada is approved for use as part of a comprehensive HIV prevention strategy that includes other prevention methods, such as safe sex practices, risk reduction counseling, and regular HIV testing.

As a part of this action, the FDA is strengthening Truvada's Boxed Warning to alert health care professionals and uninfected individuals that Truvada for PrEP must only be used by individuals who are confirmed to be HIV-negative prior to prescribing the drug and at least every three months during use. The drug is contraindicated for PrEP in individuals with unknown or positive HIV status. The FDA strongly recommends against such use. (Source: FDA Website,16 July, 2012)

FDA Approves Gilead's Stribild for HIV

The FDA has approved Stribild, a complete once-daily single tablet regimen for HIV-1 infection for treatment-naïve adults. Stribild, referred to as "Quad" prior to FDA approval, combines four compounds in one daily tablet: elvitegravir, an integrase inhibitor; cobicistat, a pharmacoenhancing agent; emtricitabine and tenofovir disoproxil fumarate.

"Over the past decade, co-formulated HIV medicines have simplified therapy for many patients and have become standard of care," said Paul Sax, MD, Clinical Director of the Division of Infectious Diseases at Brigham and Women's Hospital, Boston, Professor of Medicine at Harvard Medical School, and principal investigator of one of the Stribild pivotal studies. "Today's approval of Stribild will provide physicians and their patients an effective new single tablet treatment option for individuals starting HIV therapy for the first time."

Stribild is the third single tablet HIV regimen developed by Gilead. The first, Atripla, was approved in 2006 and is marketed by Gilead and Bristol-Myers Squibb in the United States. The second single tablet regimen, Complera® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), which combines Gilead's Truvada and Janssen R&D Ireland's rilpivirine, was approved in 2011.

Applications for marketing approval of Stribild are also pending in Australia, Canada and the European Union. In the developing world, Gilead has granted multiple Indian manufacturing partners and the Medicines Patent Pool the right to develop generic versions of Stribild and distribute them to 100 developing countries. These agreements include a complete technology transfer of the manufacturing process for the single tablet regimen. (Source: Gilead Sciences Website, 27 August, 2012)

FDA Approves Weight-Management Drug Qsymia

The FDA approved Qsymia (phentermine and topiramate extended-release) as an addition to a reduced-calorie diet and exercise for chronic weight management. The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese) or adults with a BMI of 27 or greater (overweight) who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia). Qsymia is marketed by Vivus Inc. of Mountain View, California.

Qsymia is a combination of two FDA-approved drugs, phentermine and topiramate, in an extended-release formulation. Phentermine is indicated for short-term weight loss in overweight or obese adults who are exercising and eating a reduced calorie diet. Topiramate is indicated to treat certain types of seizures in people who have epilepsy and to prevent migraine headaches.

Vivus Inc. will be required to conduct 10 postmarketing requirements, including a long-term cardiovascular outcomes trial to assess the effect of Qsymia on the risk for major adverse cardiac events such as heart attack and stroke. (Source: FDA Website, 17 July, 2012)

FDA Approves Kyprolis for Some Patients with Multiple Myeloma

The FDA approved Kyprolis (carfilzomib) to treat patients with multiple myeloma who have received at least two prior therapies, including treatment with Velcade (bortezomib) and an immunomodulatory therapy. Kypolis is marketed by Onyx Pharmaceuticals of South San Francisco, California.

A form of blood cancer that arises from plasma cells, multiple myeloma usually grows in bone marrow, the soft, spongy tissue found inside most bones. The bone marrow is where normal blood cells are produced. In

2012, an estimated 21,700 people will be diagnosed with multiple myeloma and 10,710 will die from the disease, according to the American Cancer Society. The drug is being approved under the FDA's accelerated approval program. (Source: FDA Website, 20 July, 2012)

FDA Approves Afinitor for Advanced Breast Cancer

The FDA has approved Afinitor (everolimus) for use in combination with Aromasin (exemestane) to treat certain postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer. The drug combination is intended for use in women with recurrence or progression of their cancer after treatment with Femara (letrozole) or Arimidex (anastrozole). Afinitor is marketed by Novartis Pharmaceuticals Corporation based in East Hanover, New Jersey.

The FDA has previously approved Afinitor to treat patients with advanced renal cell carcinoma that has progressed after treatment with other cancer therapies, in adult patients with progressive advanced neuroendocrine tumors of pancreatic origin, for patients with renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, and for adults and children with subependymal giant cell astrocytoma associated with TSC who require treatment but are not candidates for curative surgery.

Breast cancer is the second leading cause of cancer-related death among women. This year an estimated 226,870 women will be diagnosed with breast cancer, and 39,510 will die from the disease. (Source: FDA Website, 20 July, 2012)

FDA Approves Tudorza Pressair to Treat COPD

The FDA has approved Tudorza Pressair (acclidinium bromide) for the long-term maintenance treatment of bronchospasm (narrowing of the airways in the lung) associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

COPD is a serious lung disease that makes breathing difficult. Cigarette smoking is the leading cause of COPD, according to the National Heart, Lung, and Blood Institute. COPD is the fourth leading cause of death in the United States. Symptoms can include chest tightness, chronic cough, and excessive phlegm.

Tudorza Pressair, a dry powder inhaler used twice daily, is a long-acting antimuscarinic agent that helps muscles around the large airways of the lungs stay relaxed to improve airflow. Tudorza Pressair is distributed by St. Louis-based Forest Pharmaceuticals, a subsidiary of Forest Laboratories. (Source: FDA Website, 23 July, 2012)

FDA Approves Zaltrap for Metastatic Colorectal Cancer

The FDA approved Zaltrap (ziv-aflibercept) for use in combination with a FOLFIRI (folinic acid, fluorouracil and irinotecan) chemotherapy regimen to treat adults with colorectal cancer. Zaltrap is an angiogenesis inhibitor that inhibits the blood supply to tumors. It is intended for patients whose cancer has spread to other parts of the body (metastatic) and whose tumors are resistant to or progressed after an oxaliplatin-containing chemotherapy regimen. Zaltrap is manufactured by sanofi-aventis based in Bridgewater, New Jersey.

Zaltrap is being approved with a Boxed Warning alerting patients and health care professionals that the drug can cause severe and sometimes fatal bleeding, including gastrointestinal bleeding, and the development of holes in the gastrointestinal tract. Zaltrap can also make it more difficult for wounds to heal. (Source: FDA Website, 03 August, 2012)

FDA Approves First Generic Versions of Singulair to Treat Asthma & Allergies

The FDA has approved the first generic versions of Singulair (montelukast sodium) for use in adults and children to control asthma symptoms and to help relieve symptoms of indoor and outdoor allergies. Montelukast is in a class of medications called leukotriene receptor antagonists. It works by blocking the action of leukotrienes, substances in the body that cause the symptoms of asthma and hayfever (allergic rhinitis).

Apotex, Aurobindo Pharma, Endo Pharmaceuticals, Glenmark Generics, Kudco Ireland, Mylan, Roxane Laboratories, Sandoz, Teva Pharmaceuticals and Torrent Pharmaceuticals have gained FDA approval for generic montelukast tablets. Apotex, Aurobindo, Endo, Kudco, Mylan, Roxane, Sandoz, Teva, and Torrent have received approval for chewable tablets. Teva has received approval for the oral granule form. (Source: FDA Website, 03 August, 2012)

FDA Approves Marqibo to Treat Rare Type of Leukemia

The FDA has approved Marqibo (vincristine sulfate liposome injection) to treat adults with a rare type of leukemia called Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL). ALL is a rapidly progressing form of blood and bone marrow cancer that is more commonly diagnosed in children than adults. According to the National Cancer Institute, an estimated 6,050 men and women will be diagnosed with ALL and 1,440 will die from the disease this year.

Marqibo is approved for patients whose leukemia has returned (relapsed) two or more times, or whose leukemia has progressed following two or more regimens of anti-leukemia therapy. Marqibo contains vincristine, a commonly used anti-cancer drug, encased within a liposome, a drug delivery vehicle composed of material similar to that of cell membranes. It is an injection administered once a week by a health care professional. Marqibo is marketed by Talon Therapeutics based in South San Francisco, California. (Source: FDA Website, 09 August, 2012)

FDA Approves Lucentis to Treat Diabetic Macular Edema

The FDA has approved Lucentis (ranibizumab injection) for the treatment of diabetic macular edema (DME), a sight-threatening eye disease that occurs in people with diabetes. DME is a condition in which fluid leaks into the macula, the center part of the retina where sharp, straight-forward vision occurs. The fluid makes the macula swell, causing vision to blur. An injection administered once a month by a health care professional, Lucentis is intended to be used along with good diabetic blood sugar control. Lucentis is marketed by Genentech.

According to the CDC, diabetes (type 1 and type 2) affects about 26 million people in the United States and is the leading cause of new blindness among people ages 20 to 74 years. In 2010, 3.9 million adults diagnosed with diabetes reported trouble with their vision.

The FDA previously had approved Lucentis to treat wet (neovascular) age-related macular degeneration (AMD), a condition in which abnormal blood vessels grow and leak fluid into the macula. Lucentis also is approved to treat macular edema following retinal vein occlusion, a blockage of the small veins that carry blood away from the retina that can cause fluid to leak into the macula. (Source: FDA Website,10 August, 2012)

European Agency Backs Approval of a Gene Therapy

The European Medicines Agency has recommended approval of a gene therapy to treat a rare genetic disease, according to the agency's website. If the European Commission follows the advice, as it usually does, this would be the first regulatory approval of a gene therapy drug in the Western world. That could give a boost to the field, which at times has struggled for credibility and financing.

An approval "is really potentially going to change the way the field is looked at," said Jeffrey Ostrove, chief executive of Ceregene, a gene therapy company in San Diego. Some pharmaceutical companies have been reluctant to invest in the field, he said, because "there are no approved products in the major markets they sell in."

Gene therapy involves providing the body with genes it needs, like correct copies of defective genes that cause genetic disorders. Its use in the West so far has been confined to clinical trials. The therapy recommended for approval in Europe, called Glybera, was developed by uniQure, a Dutch company. It treats lipoprotein lipase deficiency, a disease that affects only several hundred people in the European Union and a similar number in North America. Glybera provides correct copies of the lipoprotein lipase gene, which allows patients to make some of the needed enzyme. A single treatment, consisting of injections into multiple spots on the leg muscles on the same day, is expected to last for several years, if not longer, said Jorn Aldag, chief executive of uniQure." (Source: Andrew Pollack, New York Times, 21 July, 2012)

New Members

Carlene Barous, *Senior Associate, Regulatory Affairs CMC*, Genzyme, a Sanofi Company

Mr. Robert J. Bognar, *Associate, Quality Systems*, Cubist Pharmaceuticals

Ms. Dorota Brousmiche, *QA Compliance Specialist*, ImmunoGen, Inc.

Mr. Sean Burgess, *PM/ Estimator*, Integrated Builders, Inc.

Mrs. Ellen Cabral, *Marketing Director*, IBC Life Sciences

Shawn E. Cassidy, *Validation Engineer*, Commissioning Agents, Inc.

- Jennifer S. Chasse, *Validation Scientist*, Commissioning Agents, Inc.
- Mr. Neil Dankievitch, *Manager-MTS*, Shire
- Mr. Cesar B. Del Castillo Herrera, *Validation Analyst*, Teva Peru S.A.
- Ms. Sara M. Eldridge, *Process Engineer*, Barry-Wehmiller Design Group
- Michael P. Fitzpatrick, *Process Engineer*, Biogen Idec
- Mr. Kevin M. Foley, *IT - Director*, IPSEN
- Mr. Jim Giancalone, *AD Facilities*, Genzyme
- Mr. Patrick A. Haradem, *Systems Engineer*, NNE Pharmaplan
- Martin J. Holloran, *Chief Executive Officer*, AHA Consulting Engineers Inc.
- Brenda Hugh, *Manufacturing Manager*, ImmunoGen, Inc.
- Mr. Jason F. Kallio, *Sales Executive*, Terracon
- Mrs. Imane Karaouani, Jr. Eng, *Sales Project Development Engineer*, Larry Enterprises
- Ryan Keith
- Michael Kelly, *Engineer III, Project*, Biogen
- Ms. Laura Kischitz, *Director, Managed Solutions*, Software Quality Associates
- Mr. Daniel A. Kocur, *Senior Mechanical Engineer*, DPS Biometrics
- Mr. Kwadwo Owusu Koranteng, *Clinical Engineer*, Diamond Diagnostics Inc.
- Mr. Roberta A. Leon, Jr., *Region Manager*, General Environmental Services, Inc.
- Mr. Jonathan S. Lowe, *Manufacturing Manager*, Genzyme
- Mrs. Corrine Maleski, *Director of Interior Design*, ahp Architects
- Miles Martin, *Sales Engineer*, Freudenberg Process Seals
- Mr. Alex McKinnon, *Senior Account Executive*, RCM Technologies
- Ms. Jenny S. Meneses, *Northeastern University*
- Mr. Sam A. Miller, *Business Development Manager*, Suffolk Construction Company
- Mr. Samuel A. Minno, *Process Engineer*, Bio-Concept Laboratories
- Mrs. Meagan T. Monat, *Marketing*, Integra Companies
- Bahaa S. Nashed, *Process Engineer, Organogenesis Inc.*
- Mr. Akihiko Ono, *Senior Scientist I*, Millenium
- Mr. Christopher S. Poitras, *Systems Engineer*, RoviSys
- Mr. Alan Popkin, *Principal*, ahp Architects Inc.
- Matthew Puchowicz, *Validation Engineer*, Genzyme (a Sanofi Company)
- Joseph Ramoutar
- Mr. Scott Riggi, *VP of Sales*, Block Engineering
- Mr. John Skeritt, *Sales*, Tri Dim Filter Corp.
- Dr. Neil Soice, *Scientist*, EMD Millipore
- John Strobel, *MRO Specialist*, Victaulic Company
- David Tse, *Engineer*, Stahlman Group
- Dr. Satyam Upadrashta, PhD, RAC, *Sr. Dir., Global Reg Affairs/CMC*, Millennium: The Takeda Oncology Company

Member Anniversaries

20+ Years of Membership

- Mr. Saboo Aghababayan, Genzyme Corp
- Mr. John P. Alleruzzo
- Mr. Richard F. Caires, Jr., Shire Human Genetic Therapies
- Dr. Charles L. Cooney, Massachusetts Institute of Technology
- Mr. Cesar B. Daou, PE, Daou Engineers Inc
- Ms. Greta W. Davis, Lantheus Medical Imaging
- Mr. George C. Enos, Aztec Technologies Inc
- Mr. John H. Evers, Lantheus Medical Imaging
- Mr. Brian M. Hagopian, CPD, CPIP, Clear Water Consulting, Inc.
- Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz
- Mr. David C. Hardy
- Mr. Edwin L. Harmon, III, Genzyme Corp
- Mr. David G. Harney, Microfluidics
- Ms. Shelly Henderson, NNE Pharmaplan
- Mr. Stephen R. Higham, PE, Genzyme Corp
- Mr. David L. Hyde, Lantheus Medical Imaging, Inc.
- Ms. Sandra Illich, Pfizer
- Mr. Thomas R. Jerome
- Mr. Robert W. Juffras, MS, Olympus Biotech
- Mr. Jerome E. Justin, Shire HGT
- Dr. Richard V. Levy, PDA
- Mr. Peter F. Levy, PL Consulting, LLC
- Mr. Dwight C. Long, Integra Companies Inc
- Mr. Frank J. Manning, VNE Corp
- Dr. Robert C. Menson, PhD, Menson & Associates Inc
- Mr. Hank Moes
- Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc
- Mr. Thomas W. Moss, Applied Process Solutions, Inc
- Mr. Armen J. Nahabedian, Pfizer
- Mr. Christopher R. Perley, Biotech Ops Consultants
- Mr. Stephen R. Potter, Baxter
- Mr. Richard D. Priestester, Strategic Facility Planning LLC
- Mr. Thomas A. Ramundo, New England Controls Inc
- Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc

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

Mr. Gregory M. Ruklic, Independent

Mr. Pasquale M. Sacco, Shire HGT

Mr. Hooman F. Sajedian, Pfizer Inc

Mr. Robert J. Sheehan

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

Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

Mr. Robert P. Vecchione, Christ Aqua Pharma & Biotech NA

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

15 Year Anniversary

Mr. Richard J. Malone, HH Technology Corp.

10 Year Anniversary

Mr. Jack E. Greene, Allena Pharmaceuticals

Mr. Chad E. Michael, Commissioning Agents Inc

Dr. Gokaraju K. Raju, PhD, MIT

Mr. Michael B. Zlatin, Siemens Water Technologies Corp

5 Year Anniversary

Mr. Christopher J. Blackburn, Shire HGT

Ms. Susan Ferrin, Siemens Healthcare Diagnostics

Mr. Gennady Mindlin, Shire HGT

Mr. Charles E. Pappalardo, Berry

Ms. Katherine Shannon, Biogen Idec

Mr. Kevin R. Unger, Atlas Watersystems Inc