ISPE Connecting a World of Pharmaceutical Knowledge
Boston Area Chapter
www.ispeboston.org

NEWSLETTER
July 2012, Volume XXII, No. 4

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President's Message: "If You Build It, They Will Come..."

Dear ISPE Boston Area Chapter Members,

As we reach our summer break, I want to thank all of our Members for making this past year a GREAT year! We've accomplished so much, we've blazed some new trails, and we've shown the world that Boston is the best place to be in the biopharm industry!

The Boston Area Chapter can only be successful with the help of its volunteers and we are fortunate to have lots of highly-motivated people who chose to volunteer their time, effort and enthusiasm with us this year. The Chapter has seven committees and each has between four and 15 volunteers. Do the math - that's a lot of people! Our volunteers are the heart and soul of the Chapter - without their efforts, nothing gets done. This year, we've worked diligently to bring you:

- nine top-notch monthly educational programs,
- the Shire plant tour,
- six intro and advanced presentations at our Annual Product Show,
- the CPIP™ Study Group,
- dual track educational programs and
- the first-of-its-kind collaborative educational program with ISPE International.

So, please, if you see someone who volunteers for ISPE, thank them for their efforts. They mean a lot to the Chapter - and your thanks will mean a lot to them. If you'd like to step up and get more involved with ISPE, it's easy. Check out our Committee page at http://www.ispeboston.org/Boston_Area_Chapter_Committees.html and choose to volunteer some time, whether it's a half-hour a year or whatever you can. We can always use fresh ideas. And, you'd be surprised at the connections you will make while helping out the best ISPE Chapter in the country!

The Chapter just completed its educational program year with an extremely successful June event co-sponsored with the New England Chapter. The program was held at Shire's new manufacturing facility in Lexington and included an exclusive "members only" tour of Shire's unique single use facility (see related article).

Speaking of educational programs, you (that's right, I'm talking to you) helped us this past year by letting us know which programs are of the greatest interest to you. And the Chapter listened by giving you the most highly sought after programs, taught by local experts. There's a famous saying "If you build it.....they will come," and this rang true for the Chapter this year. With your input, our dedicated group of volunteers put together a slam dunk lineup of programs and the result was nothing short of stupendous! The success of our program year was punctuated by our final program, where over 150 people attended the tour and program at Shire. Look for more top-notch programs in the coming year.

If you think you've missed the chance to voice your opinion and help plan next year's educational program, it's not too late. Our Educational Programs Committee is meeting at Waltham Woods on July 25 to review the results of the recent Member survey and plan program content for the coming year. Contact our office at office@ispeboston.org if you'd like to participate. We'd appreciate having you share your ideas with us.

This spring, and for the third year running, the Boston Area Chapter was a major sponsor at the annual Bioball event, which pairs local biotech companies with Special Olympians for a day of basketball fun, competition and skill drills. There were over 800 people in attendance at this one-day event, held in Cambridge, which raised over $87,000 for the Special Olympics. The area teams at Bioball included:

- Agios
- Alnylam
- Ariad
- Aveo
- Biogen Idec
- Bluebird Bio
- Cubist
- Infinity
- Ironwood
- Momenta
- Novartis
- Sunovion
- Vertex
- Zalicus

Thanks for supporting a great cause!

Yours truly (in pink) surrounded by local CEOs who participated in the Free Throw competition sponsored by the Chapter.

The ballot was sent out on July 6, so be sure to vote for the Chapter's Officers and Board for the upcoming year. Our past presidents spent a great deal of time and effort putting forth this group of capable candidates for you to approve for the coming year.

On a personal note, I'll be joining the Chapter's "past presidents" club in August when the new Board and Officers are installed for the upcoming year. During my "emeritus year," I plan to continue the Chapter's efforts to grow and strengthen our Student Chapters, as well as actively participate in our Membership Committee. I am grateful and thankful for the opportunity to have served the Chapter this past year, and hope that I did justice to the trust placed in me. My heartfelt thanks to all!

Chapter Bulletin Board - July 2012

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 http://www.ispeboston.org/sponsorship.html, 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.

Chapter Receives record Number of Scholarship Applications

Joel Goldberg Memorial Scholarship applications received in advance of the June 15th deadline have soared to a total of 11. Entering freshman, undergrad Student Members and Members seeking continuing education credits are all represented in this latest round. Winners will be awarded up to $2000 each and will be announced in the September eNewsletter.

November 15th is the application deadline for the next round of scholarship awards. Visit the Chapter website at www.ispeboston.org/scholarship for more information.

Upcoming Chapter Events - Mark Your Calendar

Our fall calendar is already filled with an exciting array of Chapter activities designed to sharpen the mind and renew the spirit. So take a breather over the summer, then plan to join us in September...

Wednesday, July 25, 2012
Educational Programs 2012-2013 Season Planning Meeting

The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451
5:30-8:30

This summer, the Boston Area Chapter received valuable input on educational programs of interest to our Members. The Educational Program Committee has reviewed this information and we would like YOUR help to finalize the educational program content for the upcoming Chapter year.

Attendance and parking are free (we want your assistance) and food will be provided!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=264

Monday, July 30, 2012
10th Annual Golf Tournament

Indian Pond Country Club, 60 Country Club Way, Kingston, MA 02364
Registration and Continental Breakfast: 7:30-8:30 am
Shotgun Start - Scramble Format: 8:30 am
Reception/Cocktails/Buffet Lunch: 1:30-3:30 pm

Join colleagues and friends for the ISPE Boston Annual Golf Tournament. Space is limited so sign up today!

Sponsorships are still available, so call the office at (781) 647-4773 if you're interested in sponsoring the event.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=259

Thursday, August 16, 2012
Young Professionals Softball Showdown

Teddy Ebersol's Red Sox Field, Boston MA
6:45-9:00 pm

The Challenge: The 'Young Professionals' challenge the 'Seasoned Veterans' to a game of Softball.

The Stakes: The team that does NOT prevail will purchase the 1st round at Beacon Hill Pub, 149 Charles St, Boston, MA 02114, immediately following the game.

So grab your glove, do some stretching, and come support your comrades in an epic battle of newbie vs. old guard, young-at-work vs. young-at-heart, freshmen vs. seniors, rookie vs. done-that…you get the picture. The goal is to have a fun game (with some competitive rivalry) ,so both skilled and unskilled players are encouraged to play. Or if sports are not your thing, come be a fan and enjoy the views along the river.

Register Today: http://www.ispeboston.org/events/registration.htm?eventID=263

Sneak Preview of Upcoming Events

Thursday, September 20, 2012
Educational Program focusing on Retrofit Projects

Wednesday, October 3, 2012
21st Annual Product Show

"Process Design" Educational Program Attracts 80 to Genzyme

by Yuk Chun Chiu, Genzyme, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

The ISPE Boston Area Chapter educational program entitled "Process Design: From Scientific Concept to Engineering Reality" was held on Thursday, May 10 at Genzyme Center in Cambridge. This topic was the top request in the 2011 educational program survey and attracted over 80 attendees, both members and non-members.


A lively networking reception preceded the process design panel discussion.

Following the traditional networking reception, the evening began with opening remarks by Boston Area Chapter President Brian Hagopian and Program Manager John Spohn, CPIP. Doyle Johnson, New England Operations Leader for Hargrove Engineers + Constructors and previously Senior Director of Facilities Operations at Genzyme, was then introduced as our program moderator. Doyle gave an entertaining overview on process design requirements, challenges and issues the industry faces today, and the audience was fully engaged with the topic from the very beginning.

Dr. Anton Edmund followed Doyle's introduction. As an expert in cell culture and with over 15 years of experience at Genzyme and in the consulting field, he shared his experience and knowledge in the first area of process design. Anton presented the fundamental concepts of upstream process design, from areas such as cell density optimization, to media delivery, to harvest transfer. He also presented real industry examples highlighting areas that could easily be overlooked during the design phase, namely training of operating personnel and integration and coordination with other manufacturing functions, such as buffer delivery and CIP.


Moderator and Chapter Past President Doyle Johnson (r) with panelist Rajesh Beri, Ph.D. of Lonza Biologics.

Dr. Rajesh Beri, Director of Manufacturing Science and Technology at Lonza Biologics, spoke next about the second area in process design - clarification. Throughout his engaging presentation, Raj discussed the options and parameters for different clarification processes, such as TFF, NFF and centrifugation; and manufacturing considerations including design, equipment, quality, regulatory and supply chain. He then presented a case study describing the impact on an actual manufacturing process when a vendor modified its raw materials and manufacturing procedures. He used this example to emphasize that vendor management should be one of the key considerations during the design phase.

Next, Christian Lim, Process Engineer and Project Manager from CRB, presented a lively discussion on the downstream process design. The presentation focused on the challenges encountered in chromatography and filtration operations, especially in the areas of supporting equipment, safety concerns and scale-up issues. In addition, Christian discussed single-use technology implementation in downstream processing. In short, while the process itself should be the main focus, Christian emphasized that other supporting equipment and functions (e.g., CIP, SIP, maintenance and safety) should not be overlooked.

Last but not least, Judy Bodette, Deputy Director of EIT at Sanofi Pasteur, presented some of the considerations regarding facility design, including HVAC room classifications, gowning and locker room areas, containment, material transfers and

Previous Issues

waste handling. Judy further discussed the need for attention to other supporting aspects of a facility, such as staging areas, access for maintenance, QC sampling, safety measures, and room and equipment layout.

Chapter CPIPs Joyce Chiu, Allan MacDonald and John Spohn (l to r) were among the evening's attendees.

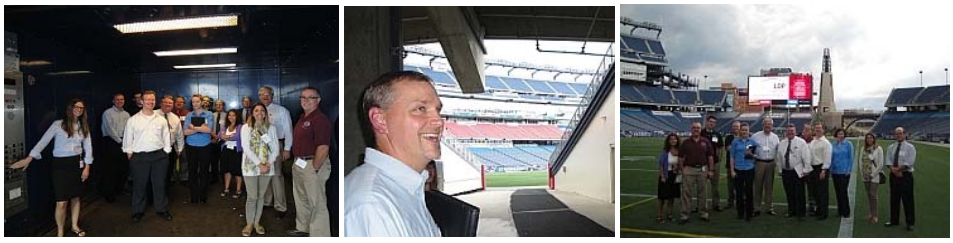
In summary, a great deal of information was shared during the evening by three highly- knowledgeable presenters. A series of lively questions and comments from the audience on their own experiences followed, with topics ranging from incorporating QbD into process design, to raw material validation, to hiring and training of personnel. The evening's program, as a whole, was a resounding success, delivering quality information on a topic of great interest and relevance to Chapter members.

The Boston Area Chapter and Program Managers John Spohn, CPIP, Michael Levesque and Yuk Chun Chiu would like to thank the panelists, moderator and audience members for their valuable contributions to this program, and to Genzyme for providing the venue for the event.

Exhibitors Prepare for Product Show at Vendor Training Camp

by Louis Baccari, GMP Piping, with photos by Amy Poole, CAMI

The second annual Vendor Training Camp held at Gillette Stadium on June 7 was very informative, and was perfect for any first-time exhibitors with questions about how to better prepare for the October 3 Product Show. To start off, attendees were treated to lunch in one of Gillette's executive suites overlooking the field, with time provided afterwards for networking.



Vendors enjoyed an up-close look at Gillette's freight elevator, visiting team entrance and (finally!) the field itself.

Following lunch and networking, attendees were given a tutorial on trade show etiquette as well as some tips on how to better present their booth, including ideas for incentives to encourage visitors to drop by to see their products - all in all, great input for anyone new to the trade show experience.

With Gillette Stadium personnel on hand, vendors were then brought around the stadium to tour the trade show area and were able to ask questions regarding logistics for moving in exhibit materials and how to best coordinate these needs with the facility. To cap off the day, the group was ushered out onto the playing field (where they were allowed to take photos) and were given a nice tour of the general facility. Overall, the event was a successful learning opportunity, especially for those unfamiliar with general trade show protocol or the specifics of exhibiting at Gillette.

Members Get a Behind-the-Scenes Look at Shire's New Biologics Manufacturing Facility

by Peter Fox, Rovisys, and Mert Aktar, Shire Human Genetic Therapies, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

On June 21, the Boston Area and New England Chapters joined together to present an educational program and facility tour at Shire Human Genetic Therapies in Lexington, MA. The program, entitled "Single Use Systems for Biopharmaceutical Manufacturing: The End User's Perspective," was combined with a Members-only tour of Shire's new Biologics Manufacturing Facility at 400 Shire Way. The program was co-chaired by Boston Area Chapter Director Mert Aktar from Shire and New England Chapter Director Peter Fox from Rovisys who pooled the resources of the neighboring Chapters to present an exciting and informative educational session.

The program began with a sold-out, Members-only tour of the Biologics Manufacturing Facility at Shire. Approximately 70 attendees were able to get a first-hand look at a bioprocessing facility significantly leveraging single-use technology. Friendly and professional Shire tour guides escorted groups of 10 from the sharp-looking lobby of 400 Shire Way into the manufacturing area, where four stations had been set up by Shire manufacturing personnel in the inoculum, cell culture, media/harvest hold and purification areas.

First up was Alex Tschumakow, Director of Manufacturing, who provided a detailed overview of the purification area. This was followed by a stop at the inoculum preparation area where Shawn Fitzpatrick, Senior Project Manager, described the inoculum operations. The tour then ventured into the cell culture area with an in-depth explanation of the cell culture operations by Chuck Hart, Director of Manufacturing. The single-use components were

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)

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exhibited on a table top where Chuck discussed their use in various equipment such as disposable bioreactors and disposable centrifuges. The tour concluded in the media/harvest hold area with Dan Neville, Associate Director of Manufacturing, who reviewed the operation of media/harvest hold stations utilizing 3000L single-use bags.

Shire's gorgeous Lexington campus welcomed the Boston Area and New England Chapters.

(l to r) Charles Rabie and Sam Liggero, both of program sponsor Tufts Gordon Institute, with Meeting Manager (and Tufts grad) Mert Aktar.

The tour was followed by a very well-attended networking session, complete with delicious hors d'oeuvres, which preceded the formal presentations. Following opening remarks from Brian Hagopian and Kevin Chronley, Presidents of the Boston Area and New England Chapters, respectively, Meeting Manager and Boston Area Director Mert Aktar introduced the first speaker, Christopher Adams from Shire. Chris gave an outstanding presentation on the practical aspects of simultaneously developing both a process and single-use products in biologics manufacturing. He shared some of the challenges inherent in developing cutting edge technologies and described how Shire overcame those single-use (S/U) challenges. Chris stressed the importance of choosing the right suppliers and then qualifying each prior to becoming "married" to them.

The sold-out facility tour and educational program attracted over 150 Members and guests.

Chris also described challenges in process characterization, process scale-up and how product development was closely linked to process engineering and product engineering. He discussed the human factors associated with single-use technologies and how these can be minimized with careful planning and the use of "skilled artisans" in the development process. Chris talked about disposal of disposables and the impact S/U technologies can have on the organization, especially when it is being rolled out for the first time. Seemingly mundane changes by suppliers can have a significant impact on manufacturing and eventual disposal of these consumables.

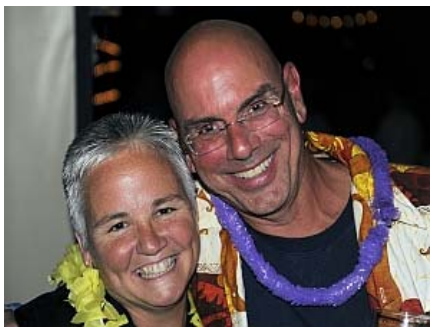
Mert next introduced Mark McElligott from Process Design Solutions whose presentation was entitled "Deployment of Single Use Systems for Large Scale Commercial Manufacturing." Mark gave a terrific presentation on his practical experiences at Shire as they developed and began commercial manufacturing. Mark spoke to some of the challenges inherent in building the first-of-its-kind facility and how they met those process challenges successfully. Specifically, he discussed material transfer and the criticality of tubing sizes, as well as routing of temporary tubing runs. Mark brought up other issues involved in S/U technologies, like heat transfer, mixing and scale up, and how they differ from traditional technologies in biologics manufacturing. He stressed the necessary transition of the process engineer from traditional stainless steel to the knowledge required for successful S/U implementation.

Mark went on to offer some insights on risk mitigation strategies and described the "sandbox" Shire used to model and test new technologies and processes. He reviewed some of the operational differences in S/U technologies versus traditional manufacturing techniques and why S/U is not always the clear cut winner. He also shared some of the operational and integrity challenges they faced daily with the daunting task of tubing runs, and the accountability necessary to produce 100 percent quality on tubing welds. Mark reiterated previous comments about supply chain criticality and being married to your suppliers, making the point that "you cannot outsource quality."

The Boston Area and New England Chapters would like to thank Meeting Managers Mert Aktar and Peter Fox, and the presenters and tour guides for their valuable contributions to this program; and Shire Human Genetic Therapies for graciously hosting the event and inviting ISPE members behind the scenes at their new Biologics Manufacturing Facility.

Summer Social Celebrates Chapter's 20th Birthday in Style

by Joyce Chiu, CPIP, Honeywell Safety Products, with photos by the author and Chris Opolski, Alexion Pharmaceuticals

On a warm summer evening, the Boston Area Chapter celebrated its 20th birthday under the stars with a Hawaiian-style luau outdoors at the Kendall Square institution, Tommy Doyle's. Young and old, male and female, Members and non-members all dressed in their best Hawaiian attire, some with grass skirts, leis or a flower in their hair. Everyone enjoyed a sumptuous meal of BBQ pork (complete with actual pig heads) and Hawaiian chicken, salmon and beef with all the trimmings. The Biogen Blues Band played some terrific tunes that inspired "Dancing with the Stars" hopefuls to brave the uneven brick floor and "American Idol" wannabes to take to the microphone and belt their hearts out.

The event also raised over $1,100 for BTBC Community Fit-Reach created by Beantown Bootcamp. The nonprofit is running public "boot camp" fitness classes this summer as part of Mayor Menino's "Boston Moves for Health" campaign challenging Boston residents to lose one million pounds and move (walk, run, hop, swim or skip) 10 million miles. For more information, visit http://www.bostonmovesforhealth.org/.

In the spirit of fundraising, the 50-50 raffle winner, Gene Dennen of UltraFiltronics, graciously donated his winnings back to the charity. Thank you Gene! After the group sang Happy Birthday and devoured the Chapter's birthday cake, a few diehard (aspiring) singers continued their all-out effort to serenade passers-by in Kendall Square late into the delightful evening while the band rocking away. Fun was had by all!

Big thanks to Social Committee members Fasha Onorato and Paul Sullivan, both of R.W. Sullivan Engineering, for their tireless efforts at putting on another great event for the Chapter. In addition, thanks to event sponsors R.W. Sullivan Engineering, Perkins + Will, Furniture Consultants, The Richmond Group and NELSON. This event would not have been possible without their generous support. For additional fun photos, please visit the Chapter website at www.ispeboston.org.

YPs Celebrate Summer at Fenway Park

by Dave Gallagher, GxP Automation, with photos by Aarash Navabi, Genzyme

With the start of summer, the Young Professionals hosted their last social event of the year at Fenway Park to watch the Red Sox take on the Orioles on June 7. The night started off with a pre-game social at Remy's bar where everyone met and picked up their tickets. The event had a great turnout - including some familiar faces but also many new ones. Special thanks to Chiderah Okoye of Rockwell Automation for organizing the event.


Great seats, beautiful weather and a win for the Sox - who could ask for more?!


Clay Buchholtz's four-hit shutout against the Orioles provided a treat for the Chapter's YPs on June 7th.

Our next event will be the YP softball game vs. the seasoned veterans on August 16. This has been a great event the past few years (although last year's event was cancelled due to the weather), allowing the Young Professionals a chance to meet and network with the Chapter's "seasoned veterans," and hopefully take home the bragging rights for the rest of the year! The

losing team has also been known to purchase the first round of drinks at the nearby Beacon Hill Pub after the game. Spread the word and make sure to bring your friends!

The Chapter also recently won the YP membership recruitment competition sponsored by ISPE International, and as a result was awarded five free CPIP™ applications. The recipients were Jakub Mocny, Mani Mohapatra, Sweta Murarka, Aarash Navabi, and Jillian Willard. Congratulations and good luck to all of the recipients!

When September rolls around, the Young Professionals will be back in full swing planning the upcoming year's socials and educational events. Also, don't forget to tell non-members about the new discounted ISPE membership rate for Young Professionals!

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.

Merrimack Pharmaceuticals Shares Fall after IPO

Merrimack Pharmaceuticals went public at the end of March, debuting at $7 per share but falling by 14 percent on the first day. The Cambridge-based company had announced it would delay its IPO in February and said it would lower its sights on how much it planned to raise in the IPO, to $100 million from $166 million. The company raised $77 million in a seventh round of venture funding in April 2011, bringing its total venture investment to about $175 million. Merrimack's IPO is the second this year for a Massachusetts biotechnology company.

The company, founded in 2000, is initially focused on cancer therapeutics and diagnostics, and has five potential therapies in its pipeline. The company has a partnership with French drug maker Sanofi. Its lead product is a potential treatment for pancreatic cancer which the company licensed from a Taiwanese firm this past May. (Source: Boston Business Journal, 29 March 2012)

Inspiration Biopharmaceuticals FDA Filing Triggers $35M Milestone Payment

Inspiration Biopharmaceuticals of Cambridge has filed a biologics license application (BLA) with the FDA for its hemophilia B therapy, which in turn triggered a $35 million milestone payment from Ipsen SA, a French biopharmaceutical company with which Inspiration has an agreement.

In January 2010, Inspiration entered into a strategic agreement with Ipsen to develop a broad portfolio of hemophilia products. In late August 2011, Ipsen and Inspiration extended their agreement to create a hemophilia business unit structure that will act as the exclusive sales organization for all hemophilia products commercialized under the Inspiration brand in Europe. (Source: Boston Business Journal, 17 April 2012)

Vertex, J&J May Widen Cooperation on Hepatitis C Drug Research

Johnson & Johnson's Janssen unit said it may explore widening cooperation on hepatitis C with Vertex Pharmaceuticals that may develop in tandem with a separate partnership with Medivir AB on the disease. Cambridge-based Vertex has said it "will start enrolling patients in a midstage study combining three medicines, excluding interferon, a core component of the current standard of care." Bloomberg News explained, "Vertex and competitors, including Gilead Sciences Inc., Bristol-Myers Squibb Co., and Abbott Laboratories are racing to develop next-generation treatments for hepatitis C that exclude interferon because of flu-like side effects." (Source: BostonGlobe.com via Bloomberg News, 21 April 2012)

Sanofi Aims to Expand MS Business

Sanofi, which bought Cambridge-based Genzyme Corp. last year, is seeking new treatments to expand its multiple sclerosis business. The Paris-based drug maker said its experimental medicine, Lemtrada, which it gained from Genzyme, improved disability scores in patients suffering from multiple sclerosis, compared with an older treatment, in a late-stage trial. The company has another experimental MS therapy, Aubagio, which was under development before the Genzyme purchase. Beyond Lemtrada and Aubagio, Sanofi has other experimental MS compounds in its pipeline, according to Michael Panzara, Therapeutic Area Head, Multiple Sclerosis, Immune Diseases and Neurology at Genzyme.

Sanofi's chief executive, Chris Viehbacher, spent $20.1 billion to acquire Genzyme, the largest maker of medicines for rare genetic diseases. After the purchase, he folded Aubagio into Genzyme to build up a multiple sclerosis business. Aubagio is an oral therapy; Lemtrada is a monoclonal antibody administered to patients through infusions for five consecutive days when they begin the treatment and for another three days 12 months later. The two drugs "we view as a beginning," Panzara said. (Source: Boston.com, 25 April 2012)

Watson Pharmaceuticals to Buy Swiss Drug Firm

Watson Pharmaceuticals has announced it is buying Swiss rival Actavis, in a $5.92 billion deal that will advance the US-based group up the global rankings of generic drug makers, people familiar with the matter said. Watson, of Parsippany, NJ, will pay $5.59 billion upfront and another $330 million provided Actavis reaches specific milestones. The deal will allow US-focused Watson to expand its international footprint and become the world's third-largest maker of generic drugs behind Israel-based Teva Pharmaceutical Industries and Swiss drug giant Novartis AG's unit, Sandoz. Currently third largest is US-based competitor Mylan. (Source: Wall Street Journal, 25 April 2012)

RXi Completes Spin-Off, Names New CEO

RXi Pharmaceuticals of Worcester has begun trading on the OTC Bulletin Board, marking the final step in its spin-off from Galena Biopharma Inc. The company, which is developing therapies based on RNA interference technology, also appointed Geert Cauwenbergh as its president and CEO. Cauwenbergh previously headed Barrier Therapeutics, a publicly traded biopharmaceutical company. Before that, he held senior management positions at Johnson & Johnson.

The original RXi company was cofounded by Craig Mello, an RNA researcher from the University of Massachusetts Medical School who won a 2006 Nobel Prize. Last September, the company changed its name to Galena Biopharma and moved its headquarters to Oregon. At the same time, it spun off the new RXi Pharmaceuticals, which has remained in Worcester. Galena now focuses on cancer therapies, while RXi continues to work with RNA research. (Source: Livia Gershon, Worcester Business Journal, 10 May 2012)

FDA Approves Bristol-Myers Squibb Devens Biologics Manufacturing Facility

The FDA has approved the BMS Devens biologics manufacturing facility for production of Orencia (abatacept). The facility is a state-of-the-art bulk biologics manufacturing plant employing roughly 300 scientists, engineers, bioprocess operators, quality specialists and other skilled workers.

Abatacept is used to treat rheumatoid arthritis (a condition in which the body attacks its own joints causing pain, swelling, and loss of function) in patients who have not been helped by other medications. Abatacept is in a class of medications called selective costimulation modulators (immunomodulators). It works by blocking the activity of T-cells, a type of immune cell in the body that causes swelling and joint damage in people who have arthritis.

Bristol-Myers Squibb currently manufactures its biologic medicines in a company-owned facility in Syracuse, NY and through third party suppliers, and finishes and packages them in Manati, Puerto Rico. The Syracuse site will remain a key component of the company's biologics strategy and will serve as a center of excellence in process development and early product launch for the company's biologic medicines.

"Bristol-Myers Squibb is committed to building a strong manufacturing capability to support our growing biologics portfolio, and Devens is a key component of this strategy," said Peter Moesta, Senior Vice President, Biologics Manufacturing and Process Development.

In 2010, the company announced the Devens facility received Leadership in Energy and Environmental Design (LEED) Silver certification while the laboratory and office building at the same facility received LEED Gold certification in December 2009. LEED certification, established by US Green Building Council and verified by the Green Building Certification Institute, is the nation's preeminent program for the design, construction and operation of high performance green buildings. (Source: Bristol-Myers Squibb Company, 15 May 2012)

New Bid to Prevent Alzheimer's Early

An Alzheimer's drug to be tested mostly on an extended family predisposed to the disease will mark the first large-scale trial of an experimental treatment on people who don't yet exhibit symptoms. The $100 million trial by a group of government and academic researchers and the drug maker Genentech will test the injectable drug crenezumab to see if it can prevent cognitive decline in 300 people who have a genetic mutation that makes it likely they will experience Alzheimer's symptoms by age 45. Crenezumab targets a sticky protein in the brain called amyloid that is thought to contribute to Alzheimer's when it clumps together. (Source: Wall Street Journal, 16 May 2012)

Vertex's Cystic Fibrosis Treatment Wins EU Regulator's Backing

Local drug maker Vertex Pharmaceuticals' Kalydeco, the first medicine to attack the underlying cause of cystic fibrosis, has won the backing of the European Union's drug regulator. Kalydeco should be approved by the European Commission for use against a rare form of cystic fibrosis in patients ages 6 and older who have a specific gene mutation, the London-based European Medicines Agency has said in a statement. The FDA approved Kalydeco in January 2012. (Source: Boston.com, 05/25/12)

Rhythm Pharmaceuticals Raises $25M

Boston-based Rhythm Pharmaceuticals has announced it raised $25 million in a Series B financing round, bringing its total capital raised to $65 million, according to information from the company. Rhythm said it will use the proceeds to advance its small-peptide therapeutics for metabolic diseases through Phase 2 clinical trials. The company recently started a Phase 2 clinical trial of its RM-131 ghrelin agonist for treating diabetic gastroparesis. And RM-493, an agonist of the melanocortin 4 receptor (MC4R), is in Phase 1 clinical trials for the treatment of obesity and diabetes. (Source: Lori Valigra, Boston Business Journal 13 June 2012)

Organogenesis Kicks Off Major, Multi-Year Expansion in Canton
Organogenesis, developer of a skin treatment called Apligraf that is based on living human cells, is in the midst of a major, multi-year expansion of its global headquarters, R&D and manufacturing facilities in Canton. The company estimates its total investment in the two-phased expansion will be approximately $63 million.

Organogenesis has selected Cambridge-based SMMA/Symmes Maini & McKee Associates as the architect and CRB Consulting Engineers, Inc. as the engineer for the state-of-the-art regenerative medicine manufacturing plant. The company will use advanced robotic and modular manufacturing technologies within this planned facility, which will allow the company to leverage its leadership in the regenerative medicine field to attract substantial resources and jobs to Massachusetts over the next ten years.

The company also announced the purchase of 65 Dan Road in Canton. Approximately 30 percent of the 78,000 square foot building will be utilized for warehousing/storage with additional space to accommodate the company's rapid growth. The acquisition of 65 Dan Road brings the company's total headquarters size to four buildings, comprising 330,000 square feet of space.

The Massachusetts Life Sciences Center, charged with implementing the State's ten-year, $1 billion Life Sciences Initiative, awarded a $7.4 million grant to Organogenesis help facilitate the expansion. The Center provided $3.7 million in FY 2009 and $3.7 million during FY 2010.

The Massachusetts Office of Business Development worked closely with Organogenesis to create a $12.9 million incentive package, including the Life Sciences Center grant, as well as tax credits for research-and-development expansion. In addition, the State facilitated $5 million in low-interest loans for growth initiatives. The Life Sciences Initiative also addressed tax inequalities when compared with competing states.

As part of the agreement, Organogenesis committed to creating 280 new in-state jobs by 2013, and specifically to creating 17 new in-state jobs in 2011. In the first quarter of 2011, the company surpassed its target expectations for 2011 Massachusetts job creation by adding 19 in-state jobs, with an additional 35 open positions. (Source: Organogenesis Website, 13 April 2012)

European Life Sciences Companies Flocking To Massachusetts

In a front-page story, the Boston Globe's Robert Weisman reported, "Massachusetts, often considered a difficult place to do business, is becoming a popular choice for a key global sector: European life sciences companies." Some of these companies "see the Massachusetts biomedical cluster as a gateway to a US market that increasingly looks like a safe haven from Europe's debt crisis." No less than "15 companies from Europe have set up shop or expanded operations in the Bay State over the past four years, representing more than half of all life sciences firms that have done so, according to the Massachusetts Life Sciences Center." (Source: Boston.com, 17 June 2012)

Infinity Halts Trials of Saridegib

Infinity Pharmaceuticals has announced that it would halt trials of saridegib (IPI-926), a potential treatment for advanced, inoperable chondrosarcoma. The reason given was that in a Phase 2 clinical trial the drug failed to outperform a placebo and

failed to meet its main goal of progression-free survival. Infinity also announced that it will not continue its Phase 2 exploratory trial of saridegib in patients with myelofibrosis. This decision was made based on data from the initial cohort of 12 evaluable patients. The level of clinical activity observed in this cohort did not satisfy the company's pre-specified criteria for expansion. (Source: Infinity Pharmaceuticals Website, 18 June 2012)

Alexion Wins Connecticut Aid for 300 Jobs

Connecticut Gov. Dannel P. Malloy has announced that Alexion Pharmaceuticals is expected to create up to 300 jobs after moving its headquarters to New Haven with up to $51 million in state aid. Alexion, which posted profits of $175.3 million in 2011, was founded in 1992 as a biopharmaceutical startup in New Haven's Science Park. It moved to Cheshire, CT in 2000.

State aid includes a 10-year loan of $20 million at a 1 percent rate with principal and interest deferred for five years, loan forgiveness of up to $20 million based on the creation of 200 to 300 full-time jobs and a $6 million grant to build laboratories and equipment. (Source whdh.com, 19 June 2012)

BIO Sparks Pharma-University Deal Making

Seven drug companies have joined together in a collaboration with Massachusetts academic institutions to develop new approaches to move forward development of drugs for neurodegenerative diseases. The amount of money pledged is $250,000 each and the list of new pharma partners for Massachusetts universities includes Pfizer, Merck, Biogen Idec, EMD Serono, Sunovian, Abbott Laboratories and Janssen Research and Development, a division of Johnson & Johnson.

If this trend continues - the biggest names in pharma joined with universities - there is probably no better place to be than Massachusetts. It's hard to imagine many other cities with enough schools with enough researchers in neurodegenerative diseases to make a really robust consortium possible. In addition, three of the companies involved - Biogen, Sunovion and EMD Serono - are headquartered in Massachusetts, making it easy to meet in person when necessary; and Abbott, Pfizer and Merck all have significant local facilities too. (Source: Julie M. Donnelly, Boston Business Journal, 20 June 2012)

AstraZeneca Completes $1.26B Ardea Purchase

AstraZeneca has completed its $1.26 billion acquisition of gout drug developer Ardea Biosciences. AstraZeneca agreed to buy Ardea in April for $32 per share, a 54 percent premium to the stock's closing price the trading day before the deal was announced. Ardea is studying two potential treatments for gout and an experimental treatment for cancer.

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease.

San Diego-based Ardea is a biotech company focused on the development of small-molecule therapeutics for the treatment of serious diseases. Ardea's most advanced clinical-stage product candidates include lesinurad, formerly known as RDEA594, a selective, oral URAT1 transporter inhibitor for the chronic management of hyperuricemia in patients with gout, and BAY 86-9766, formerly known as RDEA119, a specific inhibitor of mitogen-activated ERK kinase (MEK) for the treatment of cancer, which is being developed under a global license agreement with Bayer HealthCare AG. (Sources: The Associated Press & Ardea Website, 20 June 2012)

Pfizer Gets a No from EMA on Drug for Gaucher Disease

The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has recommended against issuing marketing authorization for taliglucerase aAlfa, an enzyme replacement treatment for Gaucher disease. The CHMP did however give a positive risk-benefit assessment for taliglucerase alfa saying that the benefits of the medicine outweighed its risks in the treatment of Type 1 Gaucher disease.

The Committee said it could not give Marketing Authorization at this time because another company, Shire, has a drug called velaglucerase alfa, a similar treatment, and already received prior Marketing Authorization with orphan drug designation for the same condition. Pfizer made a request for derogation from Shire's orphan market exclusivity based on a number of factors, however the EMA denied their application.

Pfizer and Protalix said they are dedicated to the treatment of Gaucher disease worldwide and will continue to move forward with other global regulatory filings for taliglucerase alfa. Taliglucerase alfa, known under the brand name Elelyso, was approved by the FDA on May 1, 2012 for the long term enzyme replacement therapy (ERT) of adults with a confirmed diagnosis of Type 1 Gaucher disease.

Pfizer and Protalix BioTherapeutics have been working together since 2009 to develop and commercialize taliglucerase alfa. Under the agreement, Pfizer received exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix retained the exclusive commercialization rights in Israel. (Source: Medical News Today, 22 June 2012)

Perkin Elmer Changes Underway in Hopkinton for Former Caliper Life Sciences

Waltham-based PerkinElmer, the global manufacturer of health and safety products that purchased Hopkinton-based Caliper Life Sciences last year for $600 million, is making some changes to its new property, where it plans to add employees. The company received local approval in May to construct a 60,000-square-foot, three-story addition at the Hopkinton site, which will house a facility the company is calling Personalized Health Innovation Center of Excellence.

The addition, which will also include reconfiguration of some existing space, will bring the Hopkinton facilities to a total of approximately 200,000 square feet, according to a statement from Bruce Bal, the company's vice president of operations, life sciences and technology. The company also expects to grow its workforce from 180 to 350 after the center is built. PerkinElmer also received approval to build 25,000 square feet of warehouse space at a nearby building.

Perkin Elmer's products include laboratory equipment, clinical diagnostic and neonatal screening systems, testing services, and software, among others. The acquisition of Caliper added further imaging and detection products for life sciences researchers to PerkinElmer's portfolio.

Specifically, researchers in the center will focus on products for researchers of genomics, imaging, biomarkers, biotherapeutics, targeted small-molecule development and cell-based assay solutions, PerkinElmer said.

PerkinElmer is already familiar with the Center of Excellence model, which tends to describe a collaborative, R&D effort to discover new products or achieve efficiencies. "PerkinElmer has a number of Centers of Excellence around the world to foster collaboration and knowledge sharing between PerkinElmer experts and customers," according to Bal. (Source: Matt Pilon, MetroWest495 Biz, 12 June 2012)

Sanofi and Joslin Diabetes Center Collaborate on New Drugs for Diabetes

Drug maker Sanofi and Joslin Diabetes Center, a teaching and research affiliate of Harvard Medical School and the world's leading diabetes research and clinical care organization, have announced a new collaboration to promote the development of

new medicines for the treatment of diabetes and related disorders. The collaboration was unveiled on June 19 at the 2012 Bio International Convention in Boston.

Building on Joslin's experience in diabetes research and care, the collaboration will focus on four key areas within diabetes and related metabolic disorders to identify potential new biologics or small drug candidates for the treatment of late complications of diabetes and new insulin analogs with more targeted efficacy. Additionally, research will address the challenges of insulin resistance and personalized medicine, with the overall aim of improving the lives of people living with diabetes. Under the terms of the agreement, Sanofi has options to commercialize the results of the research. Both parties will have access to intellectual property for internal research use. (Source: Sanofi Website, 19 June 2012)

Life Technologies and Children's Hospital Launch Collaboration

Life Technologies Corporation and Boston Children's Hospital, home of the world's largest pediatric research enterprise, have announced a research and development collaboration to develop an end-to-end genetic sequencing lab workflow based on Life Technologies' Ion Proton Sequencer. The parties plan to collaborate and develop an optimized laboratory infrastructure and lab protocols for an advanced sequencing facility to be built at Children's in compliance with CLIA and CAP certification standards.

The collaboration expects to benefit from Life Technologies' leading expertise in DNA sequencing technology and bioinformatics, and Boston Children's clinical research, genomics and informatics expertise. Dr. David Margulies, director of The Gene Partnership Program at Boston Children's Hospital said: "This collaboration is an important first step toward providing informed, personalized care for patients whose conditions are difficult to treat. The development of an optimized laboratory infrastructure will support our mission of providing the highest quality, innovative and cost effective care to our patients." (Source: Children's Hospital Website, 20 June 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.

GSK Receives FDA Approval for New Vaccine

GlaxoSmithKline has announced that the FDA has approved the vaccine MenHibrix to prevent invasive disease caused by Neisseria meningitidis serogroups C and Y and Haemophilus influenzae type b. MenHibrix is approved for use in children aged six weeks through 18 months.

The vaccination schedule for MenHibrix is a four-dose series given at two, four, six, and 12 through 15 months of age. The first dose can be given as early as six weeks of age and the last as late as 18 months of age. MenHibrix was developed to align with the Centers for Disease Control and Prevention's recommended infant immunization schedule for Hib vaccination and to allow for vaccination against meningococcal groups C & Y without adding additional shots. GSK will provide additional details on when MenHibrix will be available in the near future.

"All of us at GSK Vaccines look at today's approval as a good day for infants, toddlers and healthcare providers," said Leonard Friedland, M.D., Vice President, Head, Clinical and Medical Affairs, North America Vaccine Development, GSK Vaccines. "MenHibrix gives healthcare providers the option of combining Hib immunization with meningococcal C and Y immunization without increasing the number of shots for infants and toddlers." (Source: GSK Website, 14 June 2012)

FDA Issues Draft Guidance on Nanotechnology

Two draft guidance documents that address the use of nanotechnology by the food and cosmetics industries have recently been issued by the FDA. Nanotechnology is an evolving technology that allows scientists to create, explore, and manipulate materials on a scale measured in nanometers - particles so small that they cannot be seen with a regular microscope. The technology has a broad range of potential applications, such as the packaging of food or altering the look and feel of cosmetics.

The two draft guidance documents are: "Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives" and "Guidance for Industry: Safety of Nanomaterials in Cosmetic Products."

Both guidances encourage manufacturers to consult with the agency before taking their products to market. Such consultation can help FDA experts address questions related to the safety or other attributes of nanotechnology products, or answer questions about their regulatory status.

Strong science is critical to FDA's ongoing review of the products it regulates. FDA is investing in an FDA-wide nanotechnology regulatory science program to further enhance FDA's scientific capabilities, including developing necessary data and tools to identify properties of nanomaterials and assess the impact they may have on products. (Source: FDA Website, 20 April 2012)

Report: FDA Strengthens Monitoring of Post-Approval Drug Safety

A strengthened and modernized postmarket drug safety program has resulted in a substantial improvement in the FDA's oversight of drugs once they reach the American public, according to a new report by the agency's Center for Drug Evaluation and Research (CDER). The report, "Advances in FDA's Safety Program for Marketed Drugs," describes new scientific tools and enhanced capabilities that give the same priority to postmarket drug safety monitoring as to premarket drug review.

The report says CDER is also delivering earlier, more effective drug safety information to the public to protect patients from harm. In 2011, CDER issued 68 drug safety communications - up from 39 in 2010. The communications provide early information to patients and health care professionals about drug safety issues as they emerge.

New programs such as Safety First, Sentinel and Safe Use all demonstrate CDER's work to strengthen the critical sciences that underpin drug safety monitoring. These new capabilities advance the FDA's ability to track drug safety concerns, identify potential safety signals early, analyze data for its clinical significance, and determine whether a regulatory change or other solution is needed to further protect patients from drug risks. (Source: FDA Website, 21 April 2012)

FDA Strengthens International Collaboration to Ensure Quality & Safety of Imported Products

FDA Commissioner Margaret A. Hamburg, MD has released the agency's "Global Engagement Report," detailing the many activities and strategies FDA is using to transform from a domestic to a global public health agency. The report describes the

steps the agency is taking to ensure that imported food, drugs, medical devices, and other regulated products meet the same rigorous standards for safety and quality as those manufactured domestically.

Global production of FDA-regulated goods and materials has exploded over the last decade and continues to grow. Each year from 2005-2011, imports of pharmaceutical products have increased nearly 13 percent and device imports have grown more than 10 percent. More than 80 percent of the active pharmaceutical ingredients used to make medicines are imported.

The report outlines a variety of engagement strategies the FDA is using in partnership with other agencies, organizations and coalitions around the world to strengthen global regulatory capacity-building efforts; develop and harmonize science-based regulatory standards; increase awareness about the importance of regulatory systems; and share information and data globally. (Source: FDA Website, 23 April 2012)

FDA Approves Novartis Drug to Treat Kidney Tumors Caused by Rare Genetic Disease

The FDA has approved Novartis' Afinitor (everolimus), the first drug approved specifically to treat non-cancerous kidney tumors (renal angiomyolipomas) not requiring immediate surgery in patients with tuberous sclerosis complex (TSC), a rare genetic disease that causes the growth of various non-cancerous tumors in the brain, kidney and other vital organs. TSC affects as many as 40,000 patients in the United States, with an estimated 70 to 80 percent developing kidney problems. TSC generally causes multiple tumors in both kidneys that compress normal kidney tissues as they increase in size, leading to kidney failure and bleeding.

A pill taken once daily, Afinitor blocks the uncontrolled activity of a certain protein, the mTOR kinase, which plays a critical role in the development and growth of the various non-cancerous tumors occurring in patients with TSC. The FDA granted Afinitor orphan drug designations to treat renal angiomyolipomas and a certain type of brain tumor called subependymal giant cell astrocytoma (SEGA) in patients with TSC in 2009.

The FDA has previously approved Afinitor to treat patients with advanced renal cell carcinoma that has progressed after treatment with other cancer therapies; SEGA associated with TSC in patients who require treatment but are not candidates for surgical removal of the tumor; and progressive neuroendocrine tumors located in the pancreas that cannot be removed by surgery or that have spread to other parts of the body. (Source: FDA Website, 26 April 2012)

FDA Approves GSK Drug to Treat Advanced Soft Tissue Sarcoma

The FDA has approved GSK's Votrient (pazopanib) to treat patients with advanced soft tissue sarcoma who have previously received chemotherapy. Soft tissue sarcoma is a cancer that begins in the muscle, fat, fibrous tissue, and other tissues. Votrient is a pill that works by interfering with angiogenesis, the growth of new blood vessels needed for solid tumors to grow and survive.

Votrient carries a boxed warning alerting patients and health care professionals to the potential risk of liver damage (hepatotoxicity), which can be fatal. Patients should be monitored for liver function and treatment should be discontinued if liver function declines.

Votrient was granted an orphan drug status designation for this indication. An orphan designation is given to a drug intended to treat a disease affecting fewer than 200,000 patients in the United States. Votrient was first approved in October 2009 for the treatment of advanced kidney cancer. (Source: FDA Website, 26 April 2012)

FDA Approves New Antibacterial Treatment for Plague

The FDA has approved Levaquin (levofloxacin) to treat patients with plague, a rare and potentially deadly bacterial infection. The agency also approved the drug to reduce the risk of getting plague after exposure to Yersinia pestis, the bacterium that causes the disease. Levaquin is manufactured by Raritan, N.J.-based Janssen Pharmaceuticals, a part of Johnson & Johnson.

The FDA approved Levaquin for plague under the agency's Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to be used in cases where it is not feasible or ethical to conduct trials in humans. Because plague is such a rare disease, it would not be possible to conduct adequate efficacy trials in humans.

The application for Levaquin was granted a priority review by the FDA. It joins streptomycin, doxycycline, tetracycline, and other antibacterial drugs in the tetracycline group as FDA-approved treatments for plague. (Source: FDA Website, 27 April 2012)

FDA Approves New Orphan Drug to Treat a Form of Gaucher Disease

The FDA has approved Elelyso (taliglucerase alfa) for long-term enzyme replacement therapy to treat a form of Gaucher disease, a rare genetic disorder. Elelyso is manufactured and distributed by New York City-based Pfizer, under license from Protalix BioTherapeutics. Elelyso will compete with Sanofi's Cerezyme, approved in 1994, and Shire's Vpriv, approved in 2010.

Gaucher disease occurs in people who do not produce enough of an enzyme called glucocerebrosidase. The enzyme deficiency causes fatty materials (lipids) to collect in the spleen, liver, kidneys, and other organs. The major signs of Gaucher disease include liver or spleen damage, low red blood cell counts (anemia), low blood platelet counts and bone problems. (Source: FDA Website & Bloomberg News, 01 May 2012)

FDA Issues Final Rule on Sterility Testing of Biological Products

The FDA recently issued its final rule on sterility testing, amending the requirements for most licensed biological products and providing greater flexibility for development of sterility test methods. The action follows a retrospective review of agency regulations to promote improvement and innovation and is in response to Executive Order 13563 that is designed to improve regulation and regulatory review.

The FDA recognizes the role innovation plays in bringing safe and effective products to market in a timely and cost-efficient manner. This action reflects the agency's efforts to review and, as necessary, update biologics regulations, to keep pace with technological developments and to boost regulatory science. The amendments to the sterility testing rule will provide manufacturers of biological products the flexibility, as appropriate, to keep pace with technological and scientific advances. (Source: FDA Website, 03 May 2012)

FDA Approves Generic Versions of Blood Thinner Plavix

The FDA has approved generic versions of the blood thinning drug Plavix (clopidogrel bisulfate), which helps reduce the risk of heart attack and stroke by making it less likely that platelets in the blood will clump and form clots in the arteries. Plavix is marketed by Bristol-Myers Squibb and Sanofi. Clopidogrel is FDA-approved to treat patients who have had a recent heart attack or a recent stroke, or have partial or total blockage of an artery (peripheral artery disease).

Clopidogrel has a boxed warning to alert health care professionals and patients that the drug may not work well for those with certain genetic factors that affect how the body metabolizes the drug. Patients can be tested for these genetic factors to ensure that clopidogrel is the right choice for them. Also, certain medicines, such as proton pump inhibitors Prilosec (omeprazole) and Nexium (esomeprazole), reduce the effect of clopidogrel, leaving a person at greater risk for heart attack and stroke.

Dr. Reddy's Laboratories, Gate Pharmaceuticals, Mylan Pharmaceuticals, and Teva Pharmaceuticals have gained FDA approval for 300 milligram (mg) clopidogrel. Apotex Corporation, Aurobindo Pharma, Mylan Pharmaceuticals, Roxane Laboratories, Sun Pharma, Teva Pharmaceuticals, and Torrent Pharmaceuticals have received approval for 75 mg clopidogrel. (Source: FDA Website, 17 May 2012)

FDA-Led Team Discovers Autoimmune Mechanism for Drug-Induced Adverse Reactions

A team of researchers led by the FDA has discovered a new mechanism for identifying and understanding drug-related autoimmune reactions. In an article available online in the journal "AIDS," the team found that in certain at-risk patients, the anti-HIV drug Ziagen (abacavir) causes the immune system to "see" a patient's own healthy tissues and proteins as a foreign invader. The effect is similar to what happens when the immune system recognizes a viral or bacterial protein during an infection. Abacavir is known to cause allergic reactions in certain, at-risk patients. These reactions can range from mild skin reactions to severe allergic shock and even death.

The research team's work will provide the FDA with new tools to analyze the safety of drugs that have the potential to cause severe allergic reactions. This latest discovery will advance the FDA's ability to approve therapies that are personalized for safety. (Source: FDA Website, 22 May 2012)

FDA Approves Genentech's Perjeta for Type of Late-Stage Breast Cancer

The FDA has approved Perjeta (pertuzumab), a new anti-HER2 therapy, to treat patients with HER2-positive late-stage (metastatic) breast cancer. Intended for patients who have not received prior treatment for metastatic breast cancer with an anti-HER2 therapy or chemotherapy, Perjeta is combined with trastuzumab, another anti-HER2 therapy, and docetaxel, a type of chemotherapy.

HER2 is a protein involved in normal cell growth. It is found in increased amounts on some types of cancer cells (HER2-positive), including some breast cancers. In these HER2-positive breast cancers, the increased amount of the HER2 protein contributes to cancer cell growth and survival. Perjeta is a humanized monoclonal antibody, manufactured through biotechnology methods. It is administered intravenously and is believed to work by targeting a different part of the HER-protein than trastuzumab, resulting in further reduction in growth and survival of HER2-positive breast cancer cells.

Perjeta is being approved with a Boxed Warning alerting patients and health care professionals to the potential risk of death or severe effects to a fetus. Pregnancy status must be verified prior to the start of Perjeta treatment. Perjeta is marketed by South San Francisco-based Genentech, a member of the Roche Group. (Source: FDA Website, 08 June 2012)

FDA Approves Generic Version of Shire's ADHD Drug Adderall XR

Shire has announced that the FDA has responded to Shire's Adderall XR citizen petition. The FDA's response requires that all abbreviated new drug applications (ANDAs) have to establish bioequivalence using partial area under the curve measurements at 5 hours and beyond 5 hours, for both d- and l- amphetamine. The FDA response is consistent with its recent decisions on other long acting ADHD products.

The FDA also informed Shire that it has approved the ANDA for generic Adderall XR filed by Actavis. The FDA has not approved any other Adderall XR ANDAs.

Shire believes that it will remain competitive in the Adderall XR marketplace through the distribution of branded Adderall XR and through its two authorized generic partners, Teva and Impax. While recognizing that there will be multiple dynamics affecting the overall market following the approval of the Actavis generic, Shire continues to believe that it will deliver good, full year 2012 earnings growth. (Source: Shire Website, 23 June 2012)

BMS and Pfizer Receive Complete Response Letter from FDA for Eliquis

The FDA has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for Eliquis (apixaban) for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. The CRL requests additional information on data management and verification from the Aristotle trial.

Bristol-Myers Squibb and Pfizer will work closely with the FDA on the appropriate next steps for the Eliquis application. The FDA has not requested that the companies complete any new studies. FDA and the companies are committed to working expeditiously to address the outstanding questions and move the application forward. The companies continue to progress the Eliquis application for stroke prevention in atrial fibrillation in markets outside of the US, including the European Union and Japan, based on the Aristotle and Averroes studies.

In 2007, Pfizer and Bristol-Myers Squibb entered into a worldwide collaboration to develop and commercialize ELIQUIS, an investigational oral anticoagulant discovered by Bristol-Myers Squibb. This global alliance combines Bristol-Myers Squibb's long-standing strengths in cardiovascular drug development and commercialization with Pfizer's global scale and expertise in this field. (Source: Bristol-Myers Squibb Website, 25 June 2012)

New Members

The Boston Area Chapter continues to grow at a record rate. Welcome to all our new Members...

Mr. Louis Baccari, *Project Manager,* GMP Piping, Inc.

Dr. Dolores Baksh, *Director, R&D,* Organogenesis, Inc.

Mr. George E. Barringer, III, *Student,* Johns Hopkins University

Mrs. Deborah Bartol, *Business Development Associate,* Spraying Systems Co/Fluid Air

Stephanie Beatrice, OPK Biotech

Ms. Shannon L. Benn, *Customer Service,* High Purity New England

Mr. Tillus H. Beverly, *Mfg Tech (Chem E)*

Mr. Stephen Britton, *Business Intelligence Engineer,* New England Controls

Mrs. Julie Brown, *Director of Client Services,* Tocci Building Company

Mr. Michael J. Callahan, *Supervisor,* Shire HGT

Mr. Christopher A. Carlin, New England Controls, Inc.

Deirdre J. Casale, *Associate Director, Supply Operations,* Infinity Pharmaceuticals Inc.

Ms. Breeana Cebula, *Search Consultant,* HireMinds, LLC

Dr. John Chun, *Associate Director,* Millennium Pharmaceuticals Inc.

Ryan C. Coughlan, *Systems Engineer,* New England Controls

Ms. Erin Coughlin, *Executive Assistant,* E+E Elektronik Corporation

Ms. Theresa A. DeVincentis, *Marketing,* Plastic Concepts, Inc.

Gina Di Sanzo, *Project Manager,* Genzyme

Mr. James R. Dion, Jr., *Systems Engineer,* RoviSys

Ryan Dower, *Technical Sales Representative,* Sentinel Process Systems

Ms. Jeanne A. Fiore, *V.P., RA & Quality,* Pharmalucence, Inc.

Mr. Miguel A. Fuentes, *Facilities Operations Manager,* Genzyme Corp

Dr. Gloria Gadea-Lopez, *Associate Director Manufacturing Systems,* Shire HGT

Mr. Michael A. Gardener, PE, *Facilities Manager NE Region,* Merck

Mr. Samir Gondalia, *Scientist,* Pfizer

Mr. Jeffrey S. Hanson, Jr., *Student,* University of Rhode Island

Mr. Jeff Hartnett, *Marketing Specialist,* Millipore Corporation

Dr. Eric J. Hayduk, *Senior Bioengineer II,* Shire

Mr. Joshua Hays, *Field Marketing,* EMD Millipore

Mr. James N. Ingraham, *Vice President of Sales,* PSI Controls

Dr. Slawomir Z. Janicki, *Chemical Engineer,* Synta Pharmaceuticals Inc.

Mr. Dougals Jones, *Project Mgr, Distribution QA,* Boston Scientific

Mr. Justin Kamin, *Maintenance Planning/Materials Supervisor, Lonza Biologics Inc.*

Ms. Ramona E. Krogman, *Marketing Manager,* OnCode, a div. of Gem Gravure

Ms. Hoda Mansour, *Senior Associate,* Genzyme

Mr. Mark R. Maselli, *Process Engineer,* Shire HGT

Mr. Jesse McLaughlin, *Account Manager,* STERIS Corp

Ms. Tejal A. Mehta, *Quality Assurance Manager,* Harrison Specialty Co., Inc.

Mr. Anthony D. Moffa, Northeastern University

Mr. James M. Molloy, *Electrical Engineer,* Pall Corp.

Mr. James M. Oleary, *Manager,* Shire HGT

Mr. Donal OMahony, *Operations Manager,* PM Group

Mr. Wayne W. Palmer, *Maintenance Facilitator*

David Patten

Mr. Joseph M. Pelkowski, *Engineering CAD Designer,* Genzyme/Sanofi

Mr. Thomas E. Perry, *Director Engineering Services,* Shawmut Design & Construction

Ms. Emily J. Peterson, *Development Engineer,* EMD Millipore

Mr. Christopher S. Poitras, *Systems Engineer,* RoviSys

Mr. Kyle Powers, *Systems Engineer,* RoviSys

Jose L. Ramirez Rocha, *Process Engineer,* Jacobs Engineering

Noreen Rizvi, *Student,* Northeastern University

Tyler Robillard, *Engineer,* Feldmeier Equipment, Inc.

Mr. William F. Ryan, *Owner/Partner,* Ryan Specialty Valve Products

Ms. Sarah Spangenberg, Park Square Executive Search

Mr. Geoff Sylvester, *Director of Quality Assurance,* Infinity Pharmaceuticals

Mr. Thomas M. Williams, *Principal Reliability Engineer,* Genzyme Corp

Mr. Jacob M. Yany, *Business Intelligence Officer,* New England Controls

Member Anniversaries

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

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp

Mr. John P. Alleruzzo

Mr. Richard Caires, Jr., Shire Human Genetic Therapies

Dr. Charles L. Cooney, Massachusetts Institute of Technology

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

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, 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

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. Richard D. Priester, 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. 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. Jack N. Wentz, Lantheus

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

15 Year Anniversary

Mr. Keith A. Farnsworht, Mascoma Corp.

Ms. jeanine M. Gigante, Genzyme Corporation

Mr. Ed Goudreau, Biogen Idec Inc

Mr. Timothy J. Horgan, Bristol-Myers Squibb

10 Year Anniversary

Mr. Stephen Campbell, CRC Consulting LLC

Mr. James J. LaBonty, Sr., Pfizer

Mr. Bartholomew Madruga, Parsons

Mr. Christopher Sandusky, Integrated Process Technologies

Ms. Kathleen Zirpola, Steris

5 Year Anniversary

Ms. Ann Augeri, Shire

Mr. Michael S. Beckwith, Biogen Idec

Mr. Peter J. Esselstyn, Biogen Idec

Mrs. Nancy J. Poirier, CRC Consulting

Mr. Frederick Ratta, ImmunoGen Inc

Mr. Paul Stanovich, Process Design Solutions, LLC

Mr. Thomas J. Vaughan, Jr., P.E., GSC Engineering

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