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Connecting a World of Pharmaceutical Knowledge
Boston Area Chapter
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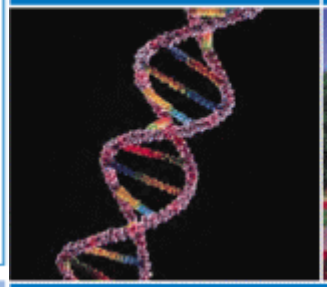

NEWSLETTER
May 2012, Volume XXII, No. 3

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President's Message: In Memoriam: Bob Urbanowski, Mark Walters, and Bill Stang

Dear ISPE Boston Area Chapter Members

This month's newsletter begins on a sad and tragic note, as the Boston Area Chapter of ISPE, friends, professional associates and family mourn the loss of three prominent ISPE members. Bob Urbanowski, Mark Walters, and Bill Stang were traveling together when they were killed in a car accident on April 16, 2012. Their lives have been inextricably linked for the past 20 years as they met professionally and worked together for many of those years. Though they ultimately pursued divergent professional paths, they remained the best of friends whose zeal for adventure and life was exceptional and admirable.

We honor their lives by remembering how these three met and grew together professionally and personally, all the while maintaining a loyalty that was a fierce as the winter wind at the top of the mountain peaks they so loved to ski. Mark Walters hired Bill Stang at Intellution back in the early days of the company. Bill assumed Mark's sales management role at the company when Mark left Intellution to start his own systems integration firm. Mark later co-founded Automatech, a software, hardware and services firm based in Plymouth, MA. Automatech soon became the exclusive distributor of Intellution, and Bill Stang was instrumental in making the deal that helped put Automatech on the map.

Bob Urbanowski joined Automatech as the company grew and was an account representative there for more than 10 years. Bob became a very active volunteer with ISPE, chairing the Chapter's Member Services Committee for the past several years. Under Bob's leadership, the Chapter won an International Award for Excellence in Member Services from ISPE. Bob served on the Chapter's Board of Directors for the past three years. These three fine gentlemen will be greatly missed by all who knew them.

Though we continue to mourn the loss of our friends and fellow Members, we are also moving forward with the many Chapter activities planned for the spring and summer months. We've just completed hosting a world-class collaborative educational program with ISPE International covering pharmaceutical grade water and steam and introducing the recently published ISPE Baseline Guide on the same topic. Our April educational program focused on the topic of engineering documentation associated with GMP facilities. Thanks to Chris Ames from Genzyme, Rob Beane from IPS, Mike Marino from Boston Scientific and Dave Mitchell from Cotter Brothers for a dynamic and informative panel discussion. (Both events are covered in detail elsewhere in this newsletter.)

There are more programs in store between now and the summer. Here are a few upcoming events of note:

- Thursday, May 10: Process Design: From Scientific Concept to Engineering Reality
- Thursday, June 21: Single Use, co-hosted with the New England Chapter
- Thursday, June 28: Summer Social & 20th Anniversary Celebration

Please note that the May 10th educational program is being held on the second Thursday in May due to a scheduling conflict.

With your input on content, the Chapter has scheduled a number of top-flight educational programs for the upcoming year, with the full slate of events available for viewing on our website at http://www.ISPEBoston.org/Events. Please help to shape our future programs by providing your input. Please look for - and participate in - our survey to identify educational programs of greatest interest to you. Remember, ISPE is your society and you can help shape the future here in Boston!

We're also in the middle of the Chapter's most well-attended CPIP™ session yet, with nearly 50 Boston Area Chapter Members working diligently toward their CPIP™ certification. at Genzyme in Framingham. We expect our Chapter to lead the way with more credentialed CPIPs than any other Chapter. This is a great opportunity to leverage ISPE resources for your own personal and career development. We're also pleased to announce the winners of five free CPIP™ applications awarded to the Boston Area Chapter Young Professionals at last year's ISPE Annual Meeting. Congratulations to:

Jakub Mocny, Superior Controls

Mani Mohapatra, Genzyme

Sweta Murarka, Genzyme

Aarash Navabi, Genzyme

Jillian Willard, Genzyme

Due to the popularity of the CPIP™ study group, keep a lookout on our Events Calendar for a possible fall session, targeted for the Cambridge area.

Enjoy spring while it lasts, and please don't hesitate to contact us directly if you have any ideas, suggestions, or other input.

Thank you,

Brian Hagopian
President, ISPE Boston Area Chapter

Chapter Bulletin Board - May 2012

Scholarship Program for Chapter Members & Families - Next Deadline June 15

Chapter Members (and their families) who are continuing their formal education in the life sciences or pursuing a degree in a life sciences field are eligible to apply for a scholarship - up to $2,000 per individual. Scholarship awards are funded by proceeds from Chapter activities and are designed to help defray tuition expenses. The Chapter hopes to be able to award up to 10 scholarships each year.

The application process has been streamlined to make it as efficient as possible. Application due dates are June 15 for fall courses and November 15 for spring courses.

Full information and an application can be found on the Chapter website at www.ISPEBoston.org/Scholarship. Questions should be directed to the Chapter by email at office@ISPEBoston.org or by telephone at 781-647-4773

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, containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your

name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Upcoming Chapter Events - Mark Your Calendar

Thursday, May 10, 2012
Process Design: From Scientific Concept to Engineering Reality

Genzyme Center, 500 Kendall Street, Cambridge, MA 02142
Reception: 5:30 pm; Program: 6:20 pm

The Process Design is one of the most challenging areas for Biopharm manufacturers. There are three unit operations that require consideration: Cell Culture, Clarification, and Downstream Purification. Each of these unit Operations informs the design of facilities and equipment. There are Regulatory, Quality, Science and Engineering considerations that are always part of successful Process Design, but also important is experience of what "works" in a Production environment and what doesn't. This session will examine all of this in the hope of explaining how processes end up getting designed and also provide hints on how to avoid common pitfalls. The Panelists represent leading figures who have designed many such processes and will share their wisdom and experience.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=184

Thursday, June 7, 2012
Product Show Training Camp:
How to Make October 3rd Easy, Fun and Profitable!

Gillette Stadium Clubhouse, Foxborough, MA
Registration and Reception: 1:30 pm; Program: 2:30 pm

Want to get the most out of your Product Show experience? Do you see other companies breezing in and out of Gillette and wonder how they do it? This informative session will take you from pre-Show marketing, to display best practices, materials load-in, trade show etiquette and a tour of Gillette Stadium that will show you the quickest way to get around. Hear from Product Show veterans, Gillette Stadium representatives and Capital Convention personnel.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=262

Sneak Preview of Upcoming Events

Thursday, June 21, 2012
Educational Program focusing on Single Use

Thursday, June 28, 2012
Annual Summer Social

Monday, July 30, 2012
Annual Summer Golf Tournament

Pharmaceutical Water & Steam Experts Capture Boston Audience

by Neda Zahid, Abbott Laboratories and Andrea Massa, Burkert Fluid Control Systems, photos by Brian Hagopian, Clear Water Consulting, Inc.

With the highly anticipated release of the ISPE Baseline Guide for Water and Steam Systems (Second Edition), The Pharmaceutical Water Conference was held at Biogen Idec in Cambridge on Thursday, March 15. The educational program is the result of a unique collaboration between the Boston Area Chapter, ISPE International and the ISPE Critical Utilities Community of Practice (COP).

After a vibrant afternoon networking session, Boston Area Chapter President Brian Hagopian delivered opening remarks which were followed by the event's first speaker. The comprehensive half-day seminar included both introductory and advanced tracks: an assortment of topics presented by authors of the guide itself. Going beyond the information presented in the guide, the distinguished group of speakers gave attendees a wealth of knowledge and an exclusive "behind the scenes" perspective.

Prominent subject matter experts attracted scores of attendees to both the introductory & advanced sessions.

Introduced as the "Smartest Microbiologist in the US," T.C. Soli started off the event with a riveting discussion of microbiology and its often misunderstood impact on pharmaceutical applications. T.C. was a smooth and engaging speaker as he imparted the reasons for adding a new chapter for microbiological considerations and provided exceptionally helpful CliffsNotes about common misconceptions, design considerations, and sanitization concepts.

Daryl L. Roll was the second speaker and gave an engaging discussion on rouge and techniques for monitoring, measuring, and remediation. After providing a topic overview, he explained various removal and control methods. Daryl illustrated how a science-based approach can be used when developing a derouging maintenance program. He outlined how technology for system monitoring and data collection can be used to set engineering action limits when developing such a program.

A buffet dinner provided an opportunity for networking between the afternoon & evening sessions.

Following these afternoon presentations, the audience had the pleasure of continuing conversations and follow up questions. A program "intermission" with dinner and networking paved the way for the evening's dual-track program.

In the advanced track, with more than 30 years of experience, Joe Manfredi led a dynamic discussion on the proper design and installation of sampling and instrumentation ports. He immediately captivated the audience by illustrating case studies of common obstacles and moreover, shared his expertise on design solutions and best practices. In short, Joe's presentation was highly enlightening as he emphasized the importance of considering sampling in design and project planning.

Next, Cameron Sipe presented a lively discussion on the new Baseline Guide's revised chapter on pharmaceutical steam. He outlined the purpose for revising this portion of the guide and was exceedingly informative as he described significant revisions. Cameron then explained system planning by illustrating types of steam and applications for use.

Last but not least in the advanced track, Phil Sumner gave a two-part presentation. He began by describing the new chapter on laboratory water, sharing the various perspectives necessary for designing a laboratory water system. Next, he shared glimpses into the soon to be released ISPE Good Practice Guide: Ozone, with over 30 specialists contributing to its creation. Phil gave a tremendously informative talk, providing the history of ozone sanitization and the tools for understanding a complete ozone sanitization system.

Andrew Collentro and Gary Zoccolante were natural teachers in the introductory track. Andrew Collentro, a dynamic and passionate presenter, explained the importance of water as the universal solvent and most widely used ingredient. He clearly and concisely described the types of pharmaceutical water, the governing regulations, and the various pre-treatment options; in parallel, he referenced the knowledge offered within the Baseline Guide and illustrated this with useful examples from his own experience.

To wrap up the evening in the introductory track, Gary Zaccolante delivered an "all-inclusive" presentation that took the audience into various final treatment processes and, additionally, described general considerations for both storage and distribution. He discussed theories behind these important concepts and used detailed illustrations and process diagrams to aid understanding. The audience had many excellent questions for Gary during his presentation, indicating their high level of engagement throughout.

In summary, this unique educational forum offered a top-notch cast of experts and tremendous presentations filled with complete and comprehensive information from beginning to end. In addition to the content presented, attendees had a unique opportunity to ply the presenters with dozens of questions, receiving additional information geared to their specific concerns. Following the formal program, a lively networking social was held at Mead where many of the discussions continued.

The Chapter would like to thank all of our speakers for their wonderful presentations and everyone who helped make this event a great success!

Chapter Membership Drive Hits the Road at Biogen Idec

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

The Boston Area Chapter took our membership drive on the road to Biogen Idec in Kendall Square on April 10. Dozens of interested professionals stopped by our booth, located in a high traffic area near the main cafeteria, to learn about ISPE and we welcomed over a dozen new members to ISPE as a result, with several more memberships pending. New members were attracted by the many benefits of ISPE membership, including:

- Learn: Educational Programs, Company Tours, Pharmaceutical Engineering Magazine, Guidance Documents
- Career Advancement: Job Search, CPIP certification, Online Learning
- Contribute Knowledge: Discussion Groups, Publish/Present Topics
- Network: Meet Industry Leaders & Key Suppliers, Build Relationships
- Have Fun: Golf, Ski, Boat Cruise, Volunteer,

Previous Issues

The cafeteria at Biogen Idec provided a perfect setting for launching the Chapter's ISPE membership drive.

With the overwhelming success of this drive, the Chapter wants to bring its membership drive to **your** company. We're looking for a few locations where we can spread the word about ISPE. If you think your company would be a good candidate, please get in touch with our office at (781) 647-4773 or contact me directly at brian@clear-water-consulting.com.

Special thanks to ISPE board member Tom Choyce for a superlative effort in coordinating the membership drive at Biogen Idec - your efforts are most appreciated! And welcome to all of our new members!

Annual Student Poster Contest Winners to Compete at ISPE Annual Meeting in San Francisco

by Jim Grunwald, Boston Area Chapter Past President

On Saturday April 14th, the ISPE Boston Area Chapter conducted its Annual Student Poster Contest. This year the Worcester Polytechnic Institute (WPI) Student Chapter - the newest of the Boston Area Chapter's seven Student Chapters - hosted the event. WPI's Campus Center proved to be an excellent venue to allow all the contestants an opportunity to present their research, and network over a shared breakfast, then lunch after completion of the presentations. Special thanks to WPI Student Chapter leaders, Hashim Ismail, Jennifer Kamara and Alex Misch, for organizing a great event that everyone thoroughly enjoyed.

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Students from several local colleges and universities displayed their research at the Annual Poster Contest held at WPI.

Presentations by graduate and undergraduate students from WPI, Northeastern and UMass Amherst kept the judges busy and made the final decision a difficult one. All entrants presented amazing content and did so very professionally. After careful consideration, the judges named the following Boston Area Chapter Student Poster Contest winners:

- Graduate Category - Noreen Rizvi of Northeastern University presenting "Transcriptional Regulation of Alkaloid Biosynthesis in *Catharanthus roseus* Cultures"
- Undergraduate Category - Daniel Shea of Northeastern University presenting "Increased Alkaloid Production from Cell Cultures of the California Poppy through Elicitation and In Situ Extraction with XAD-7"

These winners have earned the privilege of presenting at the international level Student Poster Contest at the ISPE Annual Meeting in San Francisco this November where they will compete with Student Members representing ISPE Chapters from universities globally. Their travel expenses will be sponsored by the Boston Area Chapter.

In addition to the winners, the Chapter would like to acknowledge all of the entrants for their excellent work:

- Jing Xu of Northeastern - "Multimodal Therapeutic Approach for Pancreatic Cancer: Delivery of Combination wt-p53 Gene and Gemcitabine in Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles"
- Alexander Misch of WPI -"Employing Template-Directed Assembly to Create a Novel Coagulation Assay"
- Arsava Kemal Sarp of WPI - "Smart Structures Under Fires Following High Impact Loads"
- Jennifer Kamara & Hashim Ismail of WPI - "Synergistic Activity of Essential Oils and Ketoconazole Against Drug-Resistant *C. Albicans*"
- David Gamliel of UMass Amherst - "Fabricating Chemically Robust Chitosan Films for Water Purification"

The Chapter would also like to acknowledge the effort and guidance offered by the volunteers who provide support to our Student Chapters and who traveled to WPI to participate as judges for this event: Andrea Massa, Josh Strauss, Dan Ramsey and Jim Grunwald.

The Student Chapter Committee welcomes all Members who would like to volunteer and give back to ISPE or perhaps the institution that you attended. The Boston Area Chapter currently supports Student Chapters at Northeastern, UMass Amherst, WPI, UNH, UMass Lowell and Tufts. In addition, a new Student Chapter is under formation at Boston University. Please contact us at office@ISPEBoston.org if you have questions about our Student Chapters or would like to consider getting involved.

Panelists and Audience Members Share Information on Documentation

by Dave Gallagher, GxP Automation, with photos by Brian Hagopian, Clear Water Consulting, Inc.

On the evening of Thursday April 19, the ISPE Boston Area Chapter held an educational event entitled "Documentation Surrounding GMP Facilities and Processes: The Real (and Sometimes Not-So-Real) Expectations." The program took place at the Royal Sonesta in Cambridge and was hosted by Chapter Members Jay Zaino and Dave Gallagher, both of GxP Automation. It had a large turnout, not just from Boston Area Chapter members but also from non-members and members from other ISPE Chapters, highlighting the importance of this topic in our industry.

The program took a unique approach by having a panelist of four speakers representing over 70 years of experience (combined) on the topic under discussion provide insight into various aspects of documentation. These included general guidelines, change control and equipment verification. The panelists consisted of:

- Rob Beane - Regional Manager, Compliance, IPS (Integrated Project Services)
- Jack Campion - Manager of Project Controls, Genzyme
- Mike Marino - Senior Quality Engineer, Corporate Quality Systems, Boston Scientific
- Dave Mitchell - Senior QA/QC Lead, Cotter Brothers

An overflow crowd turned out to hear a panel of experts discuss documentation in GMP facilities.

The event began with Jay Zaino asking the panelists a series of questions on different topics related to documentation. With this topic being so diverse, the panel discussion provided a broad spectrum of insights and opinions from the panelists as well as the audience. Each panelist is involved in a different aspect of the industry (consultants, vendors, end users) and thus was able to address the topic from a different set of experiences and viewpoints. The event benefited further from active and engaged audience members who did not hesitate to share their point of view on the subject.

The questions for the panelists started with general documentation guideline methodologies (traditional IQ,OQ,PQ methodologies, Baseline Guide 5 approach, ASTM E2500), specifically which standards and approaches are acceptable within their respective organizations. The audience learned that each organization has a different viewpoint and approach to documentation guidelines, especially with respect to

how ASTM E2500 should be implemented.

The discussion then led to questions about change control documentation focused on the differences between engineering change control and validation change control. In addition, the panelists addressed change control ownership during the course of a project with the general consensus that each project should have a subject matter expert (SME) controlling the documentation requirements.

Next the panelists were asked about the documentation responsibilities of vendors and what is expected from them. The questions started with what is expected from vendors during engineering, construction and commissioning of indirect systems with respect to the ISPE Baseline Guide 5 and ASTM E2500. This was followed by a discussion of the gaps typically seen in vendors' documentation and where they were most prevalent. The issue of equipment documentation verification was also touched upon, with emphasis on field/factory calibration reports and attempts to limit duplication.

Panelists (l to r) Mike Marino (Boston Scientific), Rob Beane (IPS), Dave Mitchell (Cotter Brothers) and Jack Campion (Genzyme) shared expertise gained over many years in the industry.

The program ended with a series of lively questions and comments from the audience on their own experiences, whether it involved building on the points brought up by the panelists or simply seeking advice from them. The program as a whole was a success as it did not focus on just one aspect of the topic or one individual's viewpoint but rather on the abundance of knowledge and experience of the four panelists and many extremely well-informed and engaged attendees.

The Boston Area Chapter would like to thank the panelists, moderators and audience members for contributing to a unique and effective educational program on this important topic.

Boston Area Chapter Sponsors Its Biggest CPIP™ Study Group

by John Spohn, CPIP, Castle Hill Technologies and Brian Hagopian, Clear Water Consulting, Inc.

Did you know that ISPE offers an array of professional development information and tools to its members? The Boston Area Chapter takes pride in the many ways it helps its members connect to that content. The Chapter is currently in the middle of its third CPIP™ Study Group to mentor members in pursuit of this valuable credential.

Developed at the behest of the FDA, the CPIP™ (Certified Pharmaceutical Industry Professional™) credential is the:

first professional certification program for the pharmaceutical industry covering development though manufacturing, based on an international, knowledge and skills competency standard...and an industry and government-wide initiative to drive innovation and improve drug product quality.

according to the ISPE website. However, the program, which was introduced about three years ago, had unusually rigorous eligibility criteria, which dissuaded many from pursuing the credential. But times have

changed!

Utilizing feedback from ISPE members and several CPIP's, ISPE's Professional Certification Commission (ISPE-PCC) streamlined and simplified the eligibility requirements while maintaining the technical content of the CPIP credential. To qualify to obtain the CPIP credential, applicants must have the following:

- Bachelor's degree
- Three years of pharma industry experience or five years of industry experience

Now that the eligibility has been streamlined, the Boston Area Chapter has started its third Study Group, which will produce qualified candidates by the end of May. This spring, the Study Group has been able to focus exclusively on group review and discussion of the 18 study modules to prepare for the examination. Ordinarily, modules cost $150 each for Members (that's right, $2,700 total if you do the math), but ISPE International and the Boston Area Chapter have teamed up to incentivize Study Group participants by providing access to all the study modules at no charge! That shows just how committed Boston and ISPE International are to the CPIP™ credential.

With these changes and incentives, the spring 2012 Study Group, again hosted by Genzyme in Framingham, is our largest ever with nearly 50 registered participants. Dozens of participants have already received notification of their eligibility, so hopes are high for a bumper crop of CPIP's from Boston this year! Way to go!

If you missed the spring Study Group and would like to participate in a future CPIP™ study group, don't worry - you will get your chance. Look for announcements later this year for the next Study Group. Tentative plans are to have the next session in the metro Boston-Cambridge area.

For more information on CPIP™, please visit the ISPE website at: http://www.ispe-pcc.org/index.cfm

Young Professionals Corner: Chapter Events Cater to Young Professionals

by Jillian Willard, Genzyme Corporation

It's been a busy few months for the Young Professionals and for collaborations with other Chapter Committees to create a series of events, both educational and social. First, the YPs teamed up with the Student Affairs Committee to host a tour of the new Genzyme manufacturing facility in Framingham for area students. Over 40 students attended, including a strong contingent from WPI - our newest Student Chapter - who chartered a bus to bring everyone from Worcester to Framingham.

The tour was well worth the trip as the students got an overview of the manufacturing process and a tour of the brand new cell culture and utilities suites at the facility. Afterward, they had an opportunity to talk to some of the young professionals working in engineering roles at the facility. Overall, it was an excellent event that brought the next generation of young professionals into contact with young professionals currently working in the biotech industry. Hopefully it was only the first of many YP/Student Affairs Committee collaborations.

Next, the YPs teamed up with the Educational Program Committee and ISPE International to help create an introductory track for the Water & Steam Systems program at Biogen Idec in March. We had strong

attendance for the track, capping off the evening with a social at Mead Hall for attendees. The large selection of beer on tap and the comfortable space provided by Mead Hall was perfect for winding down after a day of hard work and learning about water and steam systems. Special thanks to Andrea Massa of Bürkert Contromatic Corp. for planning the social and working with the EPC to get this program rolling.

Close on the heels of the Water & Steam program, the YPs hosted a social at Harpoon Brewery, where various members of the Harpoon staff talked about the systems they use to brew their beers and the brewing process. Nine beers were on tap for tasting, including some limited releases and small batch beers only available at the brewery. It was a fun social event for all in attendance. Special thanks to Dave Gallagher of GxP Automation for organizing the event.

Our final YP social event for the year will be a Red Sox game on June 7th, but keep your eyes open for more events starting up in September, including our annual boat cruise and softball game. Be sure to attend and bring your friends. And don't forget to tell non-members about the 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.

Alexion Completes Acquisition of Enobia Pharma

Alexion Pharmaceuticals and Enobia Pharma have announced that the companies have signed a definitive agreement under which Alexion will acquire 100% of the capital stock of Enobia. Enobia is a private biopharmaceutical company based in Montreal, Canada and Cambridge, Massachusetts, which is focused on the development of therapies to treat patients with ultra-rare and life-threatening genetic metabolic disorders.

Enobia's lead product candidate ENB-0040 (asfotase alfa), is a human recombinant targeted alkaline phosphatase enzyme-replacement therapy for patients suffering with hypophosphatasia (HPP), an ultra-rare, life-threatening, genetic metabolic disease for which there are no approved treatment options. Alexion will acquire full worldwide development and commercial rights to asfotase alfa. Asfotase alfa was awarded orphan drug designation in the US and EU in 2008 and Fast Track status in the US in 2009, and is currently in Phase II clinical development.

Alexion will acquire Enobia in an all-cash transaction. Under the terms of the agreement, Alexion has agreed to pay $610 million in cash upon consummation of the transaction, and up to $470 million in cash to be paid upon achievement of various regulatory and sales milestones. Alexion is not issuing equity in connection with the acquisition. The transaction is subject to customary conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. The Boards of both companies have approved the transaction and the companies currently anticipate that the transaction

will be completed in the first quarter of 2012. (Source: www.alexionpharma.com, 12 February 2012)

Genzyme Begins Shipping Fabrazyme from Framingham Plant

Genzyme, a Sanofi company, has announced that it has begun shipping Fabrazyme® (agalsidase beta) produced at its newly approved plant in Framingham, Massachusetts. As previously communicated, patients in the U.S. are now able to return to full dosing in March. In addition, all new patients in the US are eligible to begin Fabrazyme treatment, at full dosing levels.

In Europe, the process of moving the most severely affected patients to full dose of Fabrazyme will begin in March 2012. Globally, the complete return to normal supply levels of Fabrazyme will begin in the second quarter and continue throughout the year as planned, as Genzyme works to obtain all global regulatory approvals throughout the year and to build inventory.

The FDA and the European Medicines Agency (EMA) approved the manufacturing plant in Framingham for the production of Fabrazyme in January 2012. (Source: Genzyme Website, 01 March, 2012)

Biopharma Advocacy Group Formed in MA

A group of business, academic and labor organizations have announced the formation of a coalition that will advocate for the biopharmaceutical industry in Massachusetts. The group will be called the We Work For Massachusetts Coalition. It will be part of a national group, We Work For Health, which is active in 11 other states. Three Central Massachusetts organizations have joined the Massachusetts group: the Blackstone Valley Chamber of Commerce, the Worcester Regional Chamber of Commerce and Worcester-based Massachusetts Biomedical Initiatives.

Kevin O'Sullivan, president and CEO of Massachusetts Biomedical, said the formation of the coalition "is an important effort that will showcase the vital work the bioscience and technology sector does here. We are home to a thriving bioscience industry, first-class research institutions and a strong workforce." (Source: Rick Saia, Worcester Business Journal, 06 March, 2012)

GE Healthcare to Acquire Xcellerex

GE Healthcare, a unit of GE, has announced that it has reached an agreement to acquire Xcellerex, Inc. a supplier of innovative manufacturing technologies for the fast-growing biopharmaceutical industry. The acquisition of Xcellerex will allow GE Healthcare to expand its offering of products and services for the manufacture of biopharmaceuticals such as recombinant proteins, antibodies and vaccines. The strong strategic fit between the two companies, combined with expanded capabilities in product development and marketing, will offer significant customer benefits. Financial terms were not disclosed.

Xcellerex develops and produces turn-key biomanufacturing systems and production-scale bioreactors based around single-use components. The proprietary products offer significant advantages such as faster installation, lower capital investment, reduced risk of cross-contamination, and significantly increased flexibility compared with traditional manufacturing technologies.

Xcellerex's production-scale single-use bioreactor systems are complementary to GE Healthcare's products and range of media for cell culture. Xcellerex's FlexFactory® is a complete custom-designed modular production platform based around single-use technologies that helps customers deploy manufacturing capacity more quickly. Combining the expertise and capabilities of the two companies will enable GE Healthcare to offer a substantially wider range of added-value, integrated products and services to the biopharmaceutical industry. The acquisition, which is subject to customary closing conditions, is expected to close in Q2 2012. (Source: GE Healthcare Website, 07 March, 2012)

ZOLL Medical to be Acquired by Japan's Asahi Kasei

Asahi Kasei Corporation, and ZOLL Medical Corporation have jointly announced that Asahi Kasei, Japan's leading diversified chemical manufacturer with businesses in the health care, chemicals & fibers, homes & construction materials, and electronics sectors, has entered into a definitive merger agreement with ZOLL, a manufacturer of resuscitation and critical care devices and related software solutions, pursuant to which Asahi Kasei will acquire ZOLL for approximately $2.21 billion. ZOLL develops and manufactures its products in multiple locations in the US, including those in Massachusetts and Rhode Island. The transaction has been approved by the Boards of Directors of both companies.

Moving forward, Asahi Kasei plans strategic investments to accelerate the realization of ZOLL's mission of leading the world in resuscitation technologies, and to build on the ZOLL platform to achieve Asahi Kasei's long term strategic objective of creating a globally competitive health care business with a clear and unique focus on the field of critical care. Asahi Kasei has identified health care as a key strategic sector that will power a new phase of growth for the group, and believes that the acquisition represents a significant milestone in fulfilling its core vision for the health care sector: improving patient quality of life through the creation of innovative technologies and devices for critical care.

The acquisition extends the development of Asahi Kasei's "Health Care for Tomorrow" project, under which the company seeks to advance the development of new businesses through organic growth, targeted acquisitions, and strategic alliances. A key focus area of this effort is the resuscitation sector, an area where ZOLL is already a market leader in the US and has a strong international market presence.

This transaction builds on the alliance between the two companies that was announced in July 2011, under which Asahi Kasei has exclusive rights to market and distribute ZOLL's AED PLUS™ automated external defibrillator (AED) in Japan-the first AED in Japan with a function supporting cardiopulmonary resuscitation (CPR) that incorporates voice guidance and message displays. (Source: ZOLL Website, 12 March, 2012)

Shire Withdraws FDA Biologics License Application for Drug to Treat Fabry Disease

Shire has announced that it has withdrawn its Biologics License Application (BLA) for REPLAGAL® (agalsidase alfa) with the FDA. Shire has been in ongoing dialogue with the FDA since the supply shortage of the only US approved treatment for Fabry disease.

In 2009 and again in 2011, the FDA encouraged Shire to submit an application for the approval of REPLAGAL. The information in the application included relevant updates such as manufacturing and open long-term clinical trial data. These discussions led the Company to file a BLA last November in anticipation of a quick review process and eventual approval, allowing Shire to supply more US patients with a therapy

they desperately needed at the time.

Recent interactions with the FDA have led Shire to believe that the agency will require additional controlled trials for approval. No concerns over the product's safety profile were raised by the FDA. Shire has concluded that the likely additional studies would cause a significant delay, and an approval of REPLAGAL for US patients would only be possible in the distant future. Shire has therefore decided to withdraw its BLA.

REPLAGAL has been approved in the European Union for over 10 years and is marketed in 46 countries around the world, treating over 70 percent of the Fabry patient population worldwide. Over 1000 patients have switched to REPLAGAL since the beginning of the supply shortage in mid-2009. Shire has been providing REPLAGAL free of charge to around 140 US patients - about 20 percent of the treated US patients - through treatment access programs. Today's decision by Shire does not have any impact on the treatment of REPLAGAL patients outside the US. (Source: Shire Website, 14 March, 2012)

Biogen Idec Takes Option to MAKScientific MS Program

Massachusetts-based MAKScientific, LLC, a privately held company focused on the discovery of novel therapeutics modulating cannabinoid pathways, today announced that it has entered into an exclusive, worldwide option and collaboration agreement with Biogen Idec to develop and commercialize drug candidates for the treatment of multiple sclerosis (MS) and other neurodegenerative diseases.

Under the agreement, Biogen Idec will receive an option for an exclusive license to select discovery-stage MAKScientific drug candidates for all indications worldwide. Upon Biogen Idec's exercise of the option, MAKScientific will be eligible to receive an exercise fee of up to $3 million and up to an additional $31 million in milestone payments associated with the clinical development of the drug candidates. In addition, MAKScientific will be eligible to receive royalties on net sales worldwide. (Source: MAKScientific Website, 14 March, 2012)

Sanofi to Acquire Woburn's Pluromed

Sanofi and Woburn-based Pluromed, a medical device company, have announced that they have entered into a definitive agreement under which Sanofi is to acquire Pluromed. Massachusetts. The acquisition is subject to customary closing conditions.

Pluromed has developed a proprietary polymer technology, called Rapid Transition Polymers, pioneering the use of injectable plugs to improve the safety, efficacy and economics of medical interventions. Sanofi will commercialize Pluromed's LeGoo®, a highly innovative FDA approved and CE marked gel for temporary endovascular occlusion of blood vessels during surgical procedures.

"LeGoo represents a major advancement in surgical technology because of its ability to control bleeding without clamps or snares that can injure delicate blood vessels" said Dr. William E. Cohn, Director, Minimally Invasive Surgical Technology at the Texas Heart Institute in Houston and a member of Pluromed's Board of Directors. "This breakthrough gives surgeons a way to temporarily stop blood flow into the surgical field which is imperative for clear visualization and accurate placement of sutures. I believe this technology will be widely adopted in cardiovascular surgery and perhaps in other fields in the future."

(Source: Sanofi Website, 16 March, 2012)

Biogen Idec Donates $500K to UMass Fund

Biogen Idec has donated $500,000 to a University of Massachusetts Medical School fund that finances research of Lou Gehrig's disease, also known as ALS. The fund was created with the help of former Gov. Paul Cellucci, who announced early last year that he had been diagnosed with ALS. He is receiving treatment at UMass, where Dr. Robert H. Brown leads the institution's research efforts on ALS and other neuromuscular diseases.

The fund has raised $1.3 million to date. Biogen's donation, the largest yet, comes in advance of a Boston fundraiser chaired by all living former Massachusetts governors, as well as Gov. Deval Patrick and Lt. Gov. Tim Murray. (Source: Matt Pilon, Worcester Business Journal, 16 March, 2012)

Sanofi Loses Appeal in Suit over Rituxan & Avastin

Sanofi lost an appeals court ruling on its patent-infringement claims against Roche Holding AG's Genentech and Biogen Idec for the cancer drugs Rituxan and Avastin. The US Court of Appeals for the Federal Circuit upheld a lower court ruling that the drugs don't infringe two Sanofi patents. The opinion was posted on the court's website.

Sanofi sued Genentech and Biogen Idec in 2008 after Genentech said it was canceling a licensing agreement that had dated back to 1991. Paris-based Sanofi said the cancer drugs were made using inventions it owned to enhance the expression of a gene and make production more efficient.

US District Judge Susan Illston in San Francisco ruled that Genentech and Biogen Idec didn't use the same steps as those covered by the Sanofi patents. Sanofi said Illston had misconstrued certain terms of the patents. The Federal Circuit rejected the arguments. Sanofi, which said it was disappointed in the decision, can ask the court to reconsider the opinion. (Source: Sanofi Website, 22 March, 2012)

Long-Stalled Lab Building Underway in Longwood Medical Area

The construction of a long-stalled laboratory building in Boston's Longwood Medical Area has resumed. The $300 million project is part of several development activities in the region's health care sector. The complex, to be called Longwood Center, will be a multi-tiered glass building containing street level shops and laboratory space at what is now a large vacant lot at Brookline and Longwood Avenues.

Construction was previously halted in 2008 due to the economic downturn and limited potential tenants and difficulty with securing financing. The economy appears to be rebounding and medical and health care companies are investing and expanding again with several area hospitals or universities interested in occupying the complex or building their own new complexes in the area. Much of the development is being driven by pharmaceutical companies expanding in Boston and Cambridge as well.

Several area pharma companies are building in Boston or Cambridge, including Novartis AG, Biogen Idec, and Vertex. Several others are looking to move into larger spaces in the area. These include Ironwood

Pharmaceuticals, Momenta, Ariad and Merrimack. (Source: Casey Ross, Boston Globe, 23 March, 2012)

AstraZeneca FDA Lawsuit Dismissed

AstraZeneca announced that on March 23, 2012 the US District Court for the District of Columbia issued an opinion and order in AstraZeneca's lawsuit against the FDA regarding final marketing approval of generic quetiapine. The Court denied the Company's request for a preliminary injunction and dismissed the lawsuit without prejudice. Notwithstanding the Court's decision, the Company continues to believe strongly in the merits of its position and is evaluating its options. Quetiapine is marketed by AstraZeneca under the tradename Seroquel. (Source: AstraZeneca Website, 26 March, 2012)

Amgen and AstraZeneca Announce Collaboration

Amgen and AstraZeneca have announced an agreement to jointly develop and commercialize five monoclonal antibodies from Amgen's clinical inflammation portfolio (AMG 139, AMG 157, AMG 181, AMG 557 and brodalumab (AMG 827)).

The companies believe all the molecules have novel profiles and offer the potential to deliver important treatments across multiple indications in inflammatory diseases. The collaboration will provide Amgen with additional resources to optimally progress its portfolio, and Amgen will benefit from the strong respiratory, inflammation and asthma development expertise of MedImmune, AstraZeneca's biologics arm. The collaboration will also capitalize on AstraZeneca's global commercial reach in respiratory and gastrointestinal diseases. The agreement does not include certain territories previously partnered by Amgen for brodalumab with Kyowa Hakko Kirin and AMG 557 with Takeda.

Under the terms of the agreement, AstraZeneca will make a one-time $50 million upfront payment and the companies will share both costs and profits. Based on current plans, approximately 65 percent of costs for the 2012-2014 period will be funded by AstraZeneca. Thereafter, the companies will split costs equally. Amgen will book sales globally and will retain a low single-digit royalty for brodalumab and a mid single-digit royalty for the rest of the portfolio, after which the companies will share profits equally. (Source: Amgen Website, 02 April, 2012)

Synageva BioPharma Expands Collaboration with Japanese Pharma

Massachusetts-based Synageva Biopharm, a clinical stage biopharmaceutical company developing therapeutic products for rare disorders, announced today an expansion of its previous collaboration with Mitsubishi Tanabe Pharma Corporation of Osaka, Japan to develop a second protein therapeutic for an undisclosed orphan disease using Synageva's product development capabilities and proprietary protein expression platform.

Under the terms of the agreement, Mitsubishi Tanabe Pharma will make an upfront payment of $9 million. Synageva will receive reimbursement for development costs, potential future development and commercial milestone payments, as well as royalties from potential product revenue. Today's announced agreement does not impact Synageva's previously stated net operating loss guidance of between $40 and $45 million for 2012. (Source: Synageva BioPharma Website, 02 April, 2012)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

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

FDA Seeks $4.5 Billion for FY 2013, 17 Percent Increase from FY 2012

The FDA is requesting a budget of $4.5 billion to protect and promote the public health as part of the President's fiscal year (FY) 2013 budget - a 17 percent increase over the FDA enacted budget for FY 2012. Industry user fees would fund 98 percent of the proposed budget increase. The FY 2013 request covers the period from Oct. 1, 2012 through Sept 30, 2013. In addition to recommending new user fees to support the review of generic drugs and biosimilars, the FDA budget also contains increased funding for priorities such as import safety, medical countermeasures and research facilities to protect patients and consumers. Highlights of the budget pertaining to the pharmaceutical industry include:

- **Protecting Patients Initiative** (+$364 million) recommends new user fees to support FDA generic drug activities and to support development and review of biosimilar biological products. FDA's budget request for these user fees is consistent with the agreement reached with industry.
- **Food and Drug Inspections in China**: The Transforming Food Safety and Protecting Patients Initiatives include $10 million in new resources for FDA to enhance collaboration with our Chinese counterparts and increase the agency's presence in and expertise on China. This investment will strengthen the safety of the food and drugs produced in China for export to the United States. (Source: FDA Website, 13 February, 2012)

FDA Approves Merck's Zioptan to Treat *Glaucoma*

The FDA has approved Zioptan (tafluprost ophthalmic solution) to help reduce elevated eye pressure in people with open-angle glaucoma. The drug is also approved for use in patients with higher-than-normal eye pressure (ocular hypertension), an important risk factor for glaucoma, the second leading cause of blindness in the United States. Patients with ocular hypertension frequently are considered to have a greater chance of developing glaucoma. (Source: FDA Website, 14 February, 2012)

FDA Approves Korlym for Patients with Endogenous Cushing's Syndrome

Korlym (mifepristone) was approved by the FDA to control high blood sugar levels (hyperglycemia) in adults with endogenous Cushing's syndrome. This drug was approved for use in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and are not candidates for surgery or who have not responded to prior surgery. Korlym should never be used by pregnant women.

Endogenous Cushing's syndrome is a serious, debilitating and rare multisystem disorder. It is caused by the overproduction of cortisol (a steroid hormone that increases blood sugar levels) by the adrenal glands. This syndrome most commonly affects adults between the ages of 25 and 40. About 5,000 patients will be eligible for Korlym treatment, which received an orphan drug designation by the FDA in 2007. Prior to FDA's approval of Korlym, there were no approved medical therapies for the treatment of endogenous Cushing's syndrome.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is not necessary for Korlym to ensure that the benefits outweigh the risks for patients with endogenous Cushing's syndrome. Korlym is manufactured by Corcept Therapeutics of Menlo Park, CA. (Source: FDA Website, 17 February, 2012)

FDA Acts to Bolster Supply of Critically Needed Cancer Drugs

The FDA has announced a series of steps to increase the supply of critically needed cancer drugs and build on President Obama's Executive Order to help prevent future drug shortages. In addition, in response to President Obama's Executive Order on prescription drug shortages, FDA today issued draft guidance to industry on detailed requirements for both mandatory and voluntary notifications to the agency of issues that could result in a drug shortage or supply disruption.

Increased awareness of the importance of early notification due to President Obama's October 31, 2011 Executive Order and FDA's letter to manufacturers on the same day has resulted in a six-fold increase in voluntary notifications by industry of potential shortages. In 2011, there were a total of 195 drug shortages prevented. Since the Executive Order, FDA has prevented 114 drug shortages. (Source: FDA Website, 21 February, 2012)

FDA Approves First Quadrivalent Vaccine to Prevent Seasonal Influenza

FluMist Quadrivalent, a vaccine to prevent seasonal influenza in people ages 2 years through 49 years, has been approved by the FDA. FluMist Quadrivalent is the first influenza vaccine to contain four strains of the influenza virus, two influenza A strains and two influenza B strains. Like the already approved FluMist (trivalent), the quadrivalent vaccine contains weakened forms of the virus strains and is administered as a spray into the nose.

There are two types of influenza viruses that cause illness and death in people: influenza A and B. Each year, the FDA-approved seasonal influenza vaccine includes three strains of influenza virus, two strains of influenza A and one of influenza B. During a typical influenza season, there may be two different influenza B strains circulating, or the B strain selected for inclusion in the trivalent influenza vaccine may not be the influenza B strain that eventually circulates causing illness. The inclusion of a second B strain in FluMist Quadrivalent increases the likelihood of adequate protection against circulating influenza B strains. FluMist Quadrivalent is manufactured by MedImmune LLC of Gaithersburg, Md. (Source: FDA Website, 29 February, 2012)

Organogenesis Announces FDA Approval of Gintuit for Gum Tissue Regeneration

Organogenesis has announced that the FDA has approved GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen), a cell-based product that has been shown to predictably generate new and aesthetically appealing oral soft tissue (gum tissue). The GINTUIT approval marks two important firsts: the first-ever approval of an allogeneic cell product via the Center for Biologics Evaluation and Research (CBER) arm of the FDA, and the first cell-based technology that is FDA-approved for use in the dental market.

"This FDA approval is a significant milestone for our company, for the FDA, and for the regenerative medicine and dental surgery fields," said Organogenesis President & CEO Geoff MacKay. "As a pioneer in regenerative medicine, Organogenesis continues to lead the way by ushering in a completely new therapeutic class in dentistry. Our second breakthrough cell-based product, GINTUIT will help dental surgeons generate new gum tissue for their patients without turning to palate graft surgery."

GINTUIT is a cellular sheet that contains human fibroblasts, keratinocytes, human extracellular matrix proteins and bovine collagen. These cells produce a wide array of cytokines and growth factors, signals that allow cells to communicate with each other. These proteins are important factors for the healing and regeneration of tissue.

Organogenesis expects that GINTUIT will be commercially available via a controlled market release beginning in the summer of 2012 and available to the broader US market in 2013.

The latest FDA approval comes at a time of rapid growth and development for Organogenesis. The company is currently in the midst of a major, multi-year expansion of its global headquarters, research and development, and manufacturing facilities in Massachusetts. (Organogenesis Website, 12 March, 2012)

FDA Approves First Generic Lexapro to Treat Depression and Anxiety Disorder

Teva Pharmaceutical Industries/IVAX Pharmaceuticals has gained FDA approval to market generic escitalopram - the first generic Lexapro - to treat both depression and generalized anxiety disorder in adults.

Depression is characterized by symptoms that interfere with a person's ability to work, sleep, study, eat, and enjoy once-pleasurable activities. Episodes of depression often recur throughout a person's lifetime.

People with generalized anxiety disorder (GAD) are filled with exaggerated worry and tension, even though there is little or nothing to provoke it. They anticipate disaster and are overly concerned about health issues, money, family problems, or difficulties at work. GAD is diagnosed when a person worries excessively about a variety of everyday problems for at least six months. People with GAD can't relax, startle easily, and have difficulty concentrating.

Escitalopram and all other antidepressant drugs have a boxed warning and a patient medication guide describing the increased risk of suicidal thinking and behavior in children, adolescents, and young adults ages 18 to 24 during initial treatment. The warning also says data did not show this increased risk in those older than 24 years and that patients ages 65 and older who take antidepressants have a decreased risk of suicidal thinking and behavior. The warning says depression and other serious psychiatric disorders themselves are the most important causes of suicide and that close monitoring of patients starting these

medications is necessary.

Teva has been granted a 180-day period of generic drug exclusivity, which means that FDA cannot approve another generic version of escitalopram tablets before the end of that period. Generic drugs approved by FDA have the same high quality and strength as brand-name drugs. The generic manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs. (Source: FDA Website, 14 March, 2012)

FDA Proposes Lower Risk Classification for Certain Tuberculosis Tests

The FDA issued a proposed rule today that would encourage the development of a type of test used to detect cases of tuberculosis (TB). This rule would lower the current risk classification for nucleic acid-based tests allowing manufacturers to utilize the faster, more streamlined clearance pathway for medical devices. The FDA is seeking public input on the draft guidance for 90 days.

Nucleic acid-based tuberculosis tests can detect the presence of copies of tuberculosis bacterium genetic materials (RNA or DNA) in a mucus (sputum) sample obtained from the patient. This allows timely identification of TB disease.

Currently, these tests are Class III (high-risk) devices that require the more rigorous pre-market approval application. In proposing to downclassify to Class II (moderate-risk), the FDA also issued a draft guidance for manufacturers that identifies the risks associated with false positive and false negative test results, the risks to health care workers handling specimens, and makes recommendations on how to mitigate those risks. (Source: FDA Website, 16 March, 2012)

FDA Approves First Boniva Generics to Treat or Prevent Osteoporosis

The FDA has approved the first generic versions of Boniva (ibandronate) tablets, a once-monthly product to treat or prevent osteoporosis in women after menopause. Apotex, Orchid Healthcare, and Mylan Pharmaceuticals are the manufacturers that have gained FDA approval to make generic 150 milligram ibandronate tablets.

The most common type of bone disease, osteoporosis, is characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures of the hip, spine, and wrist. Ibandronate is in a class of medications called bisphosphonates that help increase bone mass and reduce the chance of having a spinal fracture. According to the National Institutes of Health, in the United States more than 40 million people either already have osteoporosis or are at high risk due to low bone mass.

An FDA-required Medication Guide, given to patients and caregivers when ibandronate is dispensed, describes the risks and adverse reactions people should be mindful of when using the drug. Ibandronate can cause serious side effects including: esophagus problems; low calcium levels in the blood; bone, joint, or muscle pain; severe jaw bone problems; and unusual thigh bone fractures. (Source: FDA Website, 19 March, 2012)

FDA Approves Omontys to Treat Anemia in Adult Patients on Dialysis

The FDA approved Omontys (peginesatide) to treat anemia, a condition in which the body does not have enough healthy red blood cells, in adult dialysis patients who have chronic kidney disease (CKD). Omontys is marketed by Affymax of Palo Alto, CA.

Omontys is a new erythropoiesis-stimulating agent (ESA) that aids in the formation of red blood cells. It works by stimulating the bone marrow to produce more red blood cells, usually measured as hemoglobin levels, to reduce the need for transfusions in patients with CKD. Omontys is administered as a once-a-month injection.

The FDA approved Omontys with a Risk Evaluation and Mitigation Strategy (REMS), which added safety measures consisting of educational elements for health care professionals and a requirement to assess drug use data. (Source: FDA Website, 27 March, 2012)

FDA Approves Additional Blood Test for Viruses Linked to Certain Diseases

Avioq HTLV-I/II Microelisa System, a test designed to detect antibodies to viruses in donors of human blood and blood components that are associated with several diseases, including some forms of leukemia and neurologic diseases, has been approved by the FDA. It is the only test now available that can be used to both screen the blood supply for antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and Human T-Lymphotropic Virus Type II (HTLV-II), and help diagnose infection with these viruses.

The Avioq HTLV-I/II Microelisa System is intended for screening living individual human donors, including volunteer donors of whole blood and blood components for the presence of HTLV antibodies. It is also approved for testing serum and plasma specimens to screen potential organ donors when specimens are obtained while the donor's heart is still beating. It is not intended to be used to screen cord blood specimens. The Avioq HTLV-I/II Microelisa System is manufactured by Avioq Inc. of Research Triangle Park, NC. (Source: FDA Website, 27 March, 2012)

FDA Approves Eli Lilly Imaging Drug Amyvid for Use in Alzheimer's Diagnosis

The FDA has approved Amyvid (Florbetapir F 18 Injection), a drug for Positron Emission Tomography (PET) imaging of the brain in adults who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline. Cognitive decline refers to a condition where the ability to think and form clear, rational thoughts and decisions has decreased. It can cause an individual to lose touch with reality, oneself, other people, and external events and surroundings.

Amyvid is used to produce PET scans that estimate the brain ß-amyloid neuritic plaque density in patients with cognitive impairment. ß-amyloid protein is a type of protein that forms in patients with AD and some other cognitive disorders. Neuritic plaques, also called amyloid plaques, are abnormal clumps of brain cells mixed with ß-amyloid protein. A negative Amyvid scan indicates few to no neuritic plaques and reduces the likelihood that any cognitive impairment is due to AD. A positive scan indicates moderate to frequent plaques. This amount of ß-amyloid plaque can be found in patients with AD, in patients with other types of

cognitive impairment, and in older people with normal cognition.

"Many Americans undergo evaluations to try to determine the cause for a decline in cognitive functioning," says Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "Until now, the brain content of ß-amyloid neuritic plaques could only be determined with a brain biopsy or examination of the brain at autopsy. This imaging agent is one tool to help physicians in the assessment of their patients by serving as an adjunct to other diagnostic evaluations."

Following intravenous injection, Amyvid (a radioactive drug) binds to brain ß-amyloid. A radioactive signal is detected with a PET scanner to produce images of the plaque in the brain. A positive Amyvid scan indicates moderate to frequent plaques. However, a positive Amyvid scan does not establish a diagnosis of AD because, although patients with AD always have an increased brain content of plaque, the test also may be positive in patients with other types of neurologic conditions, as well as in older people with normal cognition.

Amyvid is not a test for predicting the development of AD-associated dementia and is not for monitoring patient responses to AD therapy. Amyvid does not replace other diagnostic tests used in the evaluation of cognitive impairment. This is a new type of nuclear medicine test and images should be interpreted only by healthcare professionals who successfully complete a special training program developed by the manufacturer. The Amyvid label includes information on interpretation of Amyvid PET images.
Amyvid is manufactured for Avid Radiopharmaceuticals, Philadelphia, PA. Avid Radiopharmaceuticals is a wholly-owned subsidiary of Eli Lilly & Company. (Source: FDA Website, 6 April, 2012)

New Members

Mr. Alexander C. Allam, *Manager Engineering Documentation,* Genzyme

Mr. Kemal Sarp Arsava, PhD, Student, *Worcester Polytechnic Institute*

Sofia M. Bambrick, *Sr Project Engineer,* Biogen Idec

Ms. Courtney C. Burrell, Abbott Bioresearch Center

Mr. Antonio A. Cardoso, *Process Engineer,* Biogen Idec

Mr. John A. Chickosky, *President & CEO,* Natrix Separations, Inc.

Ms. Ceciley M. Chisholm, *Eng'g Documentation Specialist Associate,* Genzyme Corp

Mr. Peter W. Cramer, *Vice President Life Science Facility Design,* M+W Group

Heather Croxford, PharmaLogics Recruiting

Nicole Y. DeCruz, *Sr Process Engineer,* Biogen Idec

Mr. Shane Ells, *Calibration Tech,* Ipsen

Ms. Maria Escolono, , Abbott Bioresearch Center

Mr. Zachary P. Finegan, *Archiectural Designer,* DPS Biometics

Mr. Renaldo Francois, *Validation Consultant,* Apex Validation and Consulting

Mr. David Pierce Gamliel, *Student,* University of Massachusetts Amherst

Michael Ganey, Pfizer

Mr. Joshua Gravlin, Genzyme Corp

Mr. Eric Gray, *Vice President,* FH Chase Inc

Paul J. Hanbury, DPS Biometics

Mr. Attila Herczeg, Watersep Technology Corp.

Victor J. Hernandez, *Project Engineer III,* EMD Millipore

Rich Inman, *Sr Engineer II,* Biogen Idec

Mr. Michael P. Kalvaitis, *Engineer III,* Biogen Idec

Mr. Paul Koloseus, *Senior Plant Engineer,* SHIRE HGT

Mr. Sean S. Lamont, *Sr Manager Automation,* Biogen Idec

Mrs. Maria T. Leal, *Eng'g Documentation Specialist,* Genzyme Corp

Mr. Lex Lim, *Engineer,* Genzyme

Kimberly Luke, *Quality Engineer,* Pall Corporation

Ms. Anna Maziarz, *Validation Engineer,* Commissioning Agents Inc

Mr. Sean J. McManus, *Student,* Villanova University

Mr. Ailton C. Mulin, *Facilities Engineer,* Olympus Biotech Corporation

Mr. Brian M. Murphy, *Validation Specialist,* Commisioning Agents Inc.

Amy K. Nehring, *Process Engineer,* Genzyme Corporation

Ms. Prasanna Neti, *Sr. System Engineer,* New England Controls

Ms. Leah M. Newton, *Senior Manufacturing Manager,* Genzyme Corporation

Mr. Michael Paquette, *Director of Manufacturing,* Intelligent MDx, Inc.

Mr. Dick Parry, *Global Head Security, Archives and Records Management and Quality Assurance,* Novartis

Ms. Tammy J. Paul, *Microbiologist,* GTC Biotherapeutics

Marcia Peisach, *Marketing Manager,* Block Engineering

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

Mr. Bengt G. Persson, *Vice President,* Watersep Bioseparations

Mr. Allan R. Piekos, , High Purity New England

Mr. John Raymond, *Engineering Manager,* Siemens Medical Solutions Diagnostics

Ms. Meghan Rock, *Sales Engineer,* Dakota Systems

Daniel Rodkey, *Process Engineer,* Genzyme

Mihir H. Sanghvi, *Process Engineer,* Panorama Consulting & Engineering

Ms. Karin R. Schlicht, *Manufacturing Associate III,* Lonza Biologics

Mr. Henry R. Selvitella, *Process Engineer,* Biogen Idec

Mr. Daniel J. Shea, *Student,* Northeastern University

Ms. Marianne Sleiman, University of Massachusetts Amherst

Mr. Michael Sullivan, SBB Inc

Kristina Thomas

Mr. Jeffrey Wagner, Fort Point Project Management

Yushi Wang, *Student,* Tufts University

Mr. David W. Winters, *Instrumentation & Control Eng,* Biogen Idec

Ms. Jing Xu, *PhD Candidate,* Northeastern University

Cherie Young, Cognition

Kristina D. Zink, *Automation Engineer,* Biogen Idec

Member Anniversaries

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp

Mr. John P. Alleruzzo

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

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. Joseph P. Dupre, Abbott Bioreasearch Center

Dr. Stephen W. Fitzpatrick, PhD, DPS BioMetics Inc

Mr. Peter J. Mann, Shire HGT

Mr. Richard A. Pierro, Superior Controls Inc

10 Year Anniversary

Ms. Marie E. Chung, Genzyme Corp.

Mr. Peter W. Plucinski, New England Controls Inc

Mr. Gilbert A. Sirois, Rhodes Technologies

Mr. Jeffrey M. Smith, Nypro Healthcare

5 Year Anniversary

Mr. William P. Burg, Decco

Dr. Brian E. Burke, Purdue Pharma

Ms. Hang Thi Chu

Jennalyn E. Coulp-Yu, Lonza Biologics

Mr. Anthony D. Haskell, Shire HGT

Ms. Agnes M. Ortega, AstraZeneca

Mr. Thomas C. Page, OPK Biotech

Dr. Timothy J.N. Watson, Pfizer Inc

Mr. Michael T. Wilson, Lonza Biologics Inc

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