Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

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NEWSLETTER

March 2013, Volume XXIII, No. 2

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President's Message: Neither Rain, Sleet, Snow nor Hail...

Dear Fellow Boston Area Chapter Members,

We all survived the blizzard Mother Nature hit us with in January. As I thought about this, I realized once again that the Boston Area Chapter has such a solid foundation and strong membership that if we were to experience a "storm" in our industry, the Chapter would be the backbone that helps hold us together!

I just returned home from our latest educational program, "Identifying and Mitigating Common Hazards in Business Properties," and FM Global facility tour and was very pleased on a number of fronts. First, this was a joint program put together by volunteers from the Boston Area and New England Chapters, which shows our commitment to work with our neighbor for the benefit of our membership. Second, those who went on the facility tour raved about the experience and the education they received, demonstrating the unique value the Chapter brings to its Members. Third, several new Members attended and were able to experience the benefits of ISPE membership first-hand. In other words, another success!

If you haven't taken the time to get involved and see first-hand what your membership offers, I encourage you to do so. With that said, I am going to reiterate the call for volunteers at any level. Work on a single event or join one of our great committees and help shape the future of the Chapter. Any contribution you make would be greatly appreciated by all.

In keeping with my promise to provide regular updates on the state of the Chapter:

- **Membership Growth**
  Our goal this year is to add 50 new regular Members and 15 Young Professional Members. This time of year has historically seen a slight drop in membership but I am happy to report that we are holding steady which is good news for the Chapter. I expect to see the numbers trending upward over the coming months. And our Member retention rate has risen to 81.5 percent, which is fantastic!
- **Student Chapter Growth and Development**
  Our goal for Student Chapters this year is 50 new Student Members. As stated in the last newsletter, we recently added seven new members. Currently, the number is down slightly, in line with historical trends for this time of year. This just means we are going to continue to push forward and work even harder to meet our student membership growth goals. All involved have been doing a fantastic job and I know that we are going to be skyrocketing in the coming months when the Student Leadership Forum, the Student Poster Competition, the next round of Joel Goldenberg Scholarship awards and an array of planned student activities kick in.
- **Educational Program Excellence**
  Just read the comments above - the FM Global tour was a great success and we look forward to many more equally successful events in the upcoming year. Check the Events Calendar on the Chapter website for a peek at what lies ahead.

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

Sincerely,

Jay Zaino
President ISPE Boston Area Chapter

Chapter Bulletin Board

Congratulations to Our Newest Certified Pharmaceutical Industry Professionals

The Chapter's Study Groups continue to add to the roster of Certified Pharmaceutical Industry ProfessionalsTM (CPIPs). The latest additions are:

- James Quinn, CPIP, M&W Group
- Andrew Faden, CPIP, Lantheus Medical Imaging

Congratulations to James and Andrew, both of whom participated in the CPIP Study Group held at Genzyme Framingham during the spring of 2012. They bring the total number of CPIPs from the Boston Area Chapter to 16. See below for information on the upcoming Study Group beginning in March 2013.

CPIP™ Study Group Starts March 19 at Sunovion in Marlborough, MA

Want to become a Certified Pharmaceutical Industry Professional? The ISPE Boston Area and New England Chapters want to help you get there! The Spring 2013 CPIP Study Group will be held at Sunovion Pharmaceuticals in Marlborough, MA and begins on March 19 with an informational session where you can learn more about the program. Members of both Chapters are eligible to participate.

The Spring Study Group will be the third led by John Spohn, CPIP and other area CPIPs who can share lessons learned on the way to earning their credentials. The course comprises nine, three-hour sessions on most Tuesday evenings, ending June 4. Dinner is included, as are all the necessary course materials. Look for upcoming emails or visit the Boston Area Chapter website calendar of events here for details and how to enroll.

The ISPE has declared that participating in a Study Group is the most effective path to achieving the CPIP global competency standard and the Boston Area Chapter has proven them right. Two study groups were held in 2012 and the results have been nothing short of spectacular: Participants in these two study groups have accounted for about 60 percent of the new CPIPs awarded worldwide!

In fact, Boston Area Chapter study groups have produced over 35 percent of the world's CPIPs, many of whom are practicing their craft locally. Those attaining the CPIP credential attest to its value, with many stating that they have gained a new perspective on the "interconnectedness" between the various stakeholders within an organization. This new and broader perspective makes every CPIP's contribution even more valuable to an organization. Check out the experts here.

For more information on CPIP™: http://www.ispe-pcc.org/index.cfm

Bio-Ball Special Olympics Fundraiser Needs Chapter Volunteers March 16

The Boston Area Chapter is once again a proud sponsor of Bio-Ball - a one-day basketball tournament and Special Olympics fundraiser which partners teams from participating biopharma companies with Special Olympics athletes. Chapter Members can join the excitement as volunteers to help pull the event together and support the teams. While the opportunity to participate in this high-profile event is a "slam dunk" for Chapter Members, the Chapter will again be recognized with its prominent sponsorship of the CEO Free Throw competition.

The Bio-Ball tournament will take place Saturday, March 16 at the Boston College Flynn Athletic Complex T the main campus in Chestnut Hill. For more information about Bio-Ball, please visit their website at

http://www.bioball.org. Contact the Chapter office at office@ispeboston.org if you would like to volunteer on the day of the event.

Board Member John Spohn, CPIP Co-Authors *Pharmaceutical Engineering* Article

Open your January/February 2013 issue of Pharmaceutical Engineering and you will find the article "Automating a Manual Cleaning Program in a Multi-Product Biopharmaceutical Manufacturing Operation" by Gordon Leichter, PhD, and John Spohn, CPIP. The peer-reviewed technical article describes how to implement automatic washing in facilities where manual washing is conducted. Congratulations, John!

Discounts Available for Unemployed Chapter Members

Between jobs? Changing careers? In partnership with international ISPE, the Boston Area Chapter makes it cost-effective for unemployed Chapter Members to maintain their membership and attend Chapter educational programs, both of which are more valuable than ever during career transitions.

The ISPE Hardship Program enables Members in good standing to retain their membership at a significantly reduced rate for one year. Instead of print, Hardship Members get an electronic copy of Pharmaceutical Engineering magazine, along with all other Member benefits. Contact the international ISPE office at ask@ispe.org for more information or to discuss your membership status.

At the local level, the Chapter allows unemployed members to attend most Chapter-sponsored educational programs at the student rate ($5 or $10 per event) - simply call or email the Chapter office (781.647.4773 or office@ispeboston.org) when registering to attend.

Lastly, joining one of the Chapter's volunteer committees is another great way to maintain and expand your professional network during career transitions, while simultaneously supporting the Chapter's activities. Visit the Chapter website at http://www.ispeboston.org/Boston_Area_Chapter_Committees.html to learn more about the many volunteer opportunities available.

Advertise on www.ispeboston.org

Did you know the Boston Area Chapter Website attracts over 8000 visits monthly from the region's life sciences professionals? Now you can reach the same audience by advertising on www.ispeboston.org. A limited number of advertising spots are now available - including some with animation - so don't delay. Ads are sold on a first-come, first-served basis. To learn more about this unique opportunity and reserve your space, contact Amy Poole, Chapter Manager, at 781-647-4773 or office@ispeboston.org.

Want to Become a Chapter Sponsor? It's Easy!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at 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.

Upcoming Chapter Events - Mark Your Calendar

Saturday, March 16, 2013
Bio-Ball

Boston College Flynn Athletic Complex

Bio-Ball is a unique and exciting opportunity for biotechnology companies of Massachusetts to reap the rewards of volunteerism and invest in the community by sponsoring and staffing a special kind of March Madness. The marriage of the Massachusetts biotechnology industry and Special Olympics Massachusetts centers on a shared goal: the promise of a better tomorrow. While biotechnology companies strive to discover and create the innovations that will make for a healthier future, Special Olympics Massachusetts is

dedicated to empowering individuals with intellectual disabilities and other closely related disabilities by giving them opportunities to develop physical fitness, demonstrate courage and participate in a brighter tomorrow. In addition to the synergies between the two organizations, volunteers at Bio-Ball have the unique opportunity to interact with the very beneficiaries of the event itself. The Massachusetts biotechnology industry is making the promise of a better tomorrow a reality by pursuing cures for many of the illnesses and disabilities that affect these athletes. In turn, the resilience of these athletes reminds us all in the biotechnology community why we strive so hard as an industry to persevere and fight to realize our goals of curing disease.

For more information on Special Olympics Massachusetts or to volunteer to help at Bio-Ball, visit their website here.

Tuesday, March 19, 2013
CPIP Spring Study Group Introductory Session

Sunovion Pharmaceuticals, 84 Waterford Drive, Marlborough, MA 01752

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

Come to an informational meeting to learn more about the CPIP program and the spring study group. Each class will run from 5:30pm-9pm and the cost includes all 9 sessions.

If after the informational session you choose *not* to continue the course, we will refund your registration fee.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=351

Thursday, March 21, 2013
The Science and Risk Based Approach to C&Q: The Road to ASTM E2500

Goulston & Storrs, 400 Atlantic Avenue, Boston, MA 02110

The introduction of ASTM E2500 and ICH Q9 (Quality Risk Management) have provided the Pharmaceutical Industry with a methodology to optimize commissioning and qualification activities resulting in improved compliance and a defined focus on product quality and patient safety. Efficient implementation of these practices provides the additional opportunity to reduce capital project timelines, and reduce life cycle costs.

Although the ASTM and ICH documents indicated the “What” in defining a science and risk based approach to system verification, the “How’s” of practical and efficient implementation of the supporting work processes had not been fully described and associated best practices had not been developed.

In order to help fill this need, the C&Q CoP sponsored the development of the *ISPE Guide: Science and Risk Based-Approach for the Delivery Facilities, Systems, and Equipment* that presents a structured life cycle approach to the delivery and verification of GxP regulated facilities, systems, and equipment. It supports the ASTM industry and ICH regulatory initiatives, including science based risk management approaches, a focus on product and process understanding, and the application of Quality by Design concept. In addition the C&Q COP formed a Task Team to develop a *Good Practice Guide - Applied Risk Management for C&Q* that maps the transition and provides implementation strategies for moving from the traditional, or “Baseline Guide 5 approach” based on Impact Assessment to ICH Q9/ASTM quality risk management implementation.

This presentation will provide an overview these recent ISPE guidance documents and provide an overview of the implementation principles and elements contained therein.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=293

Thursday, March 28, 2013
Young Professionals Networking Social

Previous Issues

The Medieval Manor, 246 East Berkeley Street, Boston, MA

Come join the ISPE Boston Area Chapter Young Professionals at the Medieval Manor for a bawdy but lighthearted interactive romp through the dark ages! Enjoy one-of-a-kind entertainment as you feast on six courses without a fork, knife, or spoon **(vegetarian meals are available).** Beer and Red/White wine will also be provided with the dinner. If you need a vegetarian meal, please contact the office at 781-647-4773 or office@ispeboston.org.

Get there early as there will be a "meet and greet" social at 6:30!

Space is limited, so get your tickets now before it's too late!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=348

Sneak Preview of Upcoming Events

Thursday, April 18, 2013
Dual-Track Program focusing on 11 FDA Process Validation Guidance and Intro to Biotech

Thursday, May 16, 2013
Educational Program focusing on Process Control Automation

Thursday, June 20, 2013
Educational Program focusing on Validation

Members Celebrate "Chapter of the Year" Win with Ice Skating and More

by Fasha Onorato, RW Sullivan

The Boston Area Chapter kicked off the New Year on January 10 in the beautiful glass atrium at 650 East Kendall Street in Cambridge to celebrate the Chapter's fourth "Platinum Grand Award for Excellence and Innovation" in a row. The atrium was transformed into a winter wonderland filled with everything but falling snow. With over 80 people in attendance, Kendall Square was buzzing with great people, great conversation and even ice skating!

Paul Sullivan and fellow Members prove the Chapter
that sings together stays together!

Many members and their guests braved the cold and made it out onto the ice for a few laps knowing that there was plenty of warm comfort food and libations provided by Broadway Gourmet awaiting them inside. To top it off, we were lucky enough to have the Biogen Blues Band play an energizing set and many of our members even joined in on the chorus for a couple of songs. It was a wonderful way to ring in the New Year and acknowledge everyone's hard work and commitment to our favorite ISPE Chapter.

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(l to r) Social Committee Chair and Board Member Chris Opolski, Member Sherwood Butler and Past President Jim Grunwald help celebrate the Chapter's success

A special thanks to Social Committee members Fasha Onorato (R.W. Sullivan Engineering), Paul Sullivan (R.W. Sullivan Engineering), Chris Opolski (Alexion Pharmaceuticals), Tom Forster (Rockwell Automation), and Christina Herron (ahp Architects) for their tireless efforts at putting together a festive event for the Chapter. For additional fun photos, please visit the Chapter website at www.ispeboston.org.

Building Information Modeling: From Concept to Substantial Completion (and Beyond)

A wintry scene greeted Chapter Members at the brand new Albert Sherman Center (foreground) at UMass Medical in Worcester.

by John Sheridan, PMA Consultants, Ronda Paradis and Brian Sykes, AIA, HDR, Inc.

Not your typical venue for an ISPE event but one that stood out for a number of reasons, the new Albert Sherman Center at the UMass Medical School campus was lit up like the showcase structure it is. Sixty-five professionals attending the January 17 educational program were treated to coveted, guided tours through one of the premier research facilities in the country - in advance of its official opening. After the tours, attendees feasted on appetizers in the facility conference room while enjoying two exciting presentations on a quickly evolving technology that is changing how projects are getting built: Building Information Modeling or BIM.

HDR's Brian Sykes, AIA began the program with a presentation that described the shift between the individual, digital way of designing, fabricating and assembling buildings, and the 21st century, social database strategy of building conceptualization and realization. BIM represents the A/E/C industry's visual answer to the database.

BIM is currently following the same path as other disruptive technologies. One analogy Sykes highlighted is the music industry, particularly the way personal music databases replaced compact discs. BIM is currently disrupting traditional A/E/C services and unlocking new value for architects, contractors and, in particular, owners. The importance of BIM is the "I", or information. The ability to harness this information in a context which is "human comprehensible and machine computable" is vital to the success of the team and the users.

The behind-the-scenes tour of the ASC was a special benefit available to Members only.

BIM is not limited to new construction. Existing facilities are realizing the value of BIM for managing their facilities on multiple levels. Owners also do not have to jump into the deep end of the commitment pool with a new BIM project for their facility; they can easily work into leveraging a model for facilities management.

For each building, the business case is unique and each BIM project should reflect the business case of the client.

Sample showcase BIM applications overviewed by Sykes included the renowned Howard Hughes Medical Institute's Janelia Farms Research Campus in which a space planning BIM was used throughout the 540,000 ft^2 facility. This allowed accounting, human resources, and facilities to baseline their information off common data that is transparent to the viewer. Facility data replication and confusion are kept to a minimum thanks to the BIM model and the information's graphic representation.

The second presentation, which focused on the Albert Sherman Center (ASC), had four speakers:

- Erik Servies, AIA, Associate, PMA Consultants, Owner's Project Manager
- John Baker, Associate Vice Chancellor of Facilities, UMass Medical School
- Mark Dolny, AIA, LEED AP, Associate Principal, Architectural Resource Cambridge (ARC)
- Tom Watson, Regional BIM/VDC Manager, Suffolk Construction

The 515,000 ft^2 Albert Sherman Center is a biosafety level 2 (BSL-2) laboratory which achieved substantial completion in December 2012. The UMMS "BIM vision," established at project inception, was to improve the user acceptance process through visualization, improve construction productivity, increase MEP coordination and clash detection, and utilize the model for facility planning, operations and maintenance.

Speakers Brian Sykes (l) of HDR Architecture and Tom Watson (r) of Suffolk Construction described the role played by BIM during construction and beyond.

The project was on an aggressive time frame required to meet the goal set by Chancellor Michael Collins to provide a home for research that was going to change medicine and save lives. To achieve this goal, a fast track design model delivery process was implemented using BIM. This included a total of 11 design models (Architecture, MEP/IT Core Shell, Structural, Lab and Kitchen, and Site/Civil).

It was determined early on that parallel modeling was the best way to manage the model development between ARC and Suffolk. Some of the benefits of parallel modeling include high levels of quality control, less planning than single phase modeling, flexible relationship and fewer legal hurdles. Some additional considerations include a higher cost for two models and increased need for coordination between the architect and CM. However one of the additional benefits was the result of the model being shared with subs as part of the bidding process. Although the models could be used for schedule (4D) and cost/estimating (5D), the big advantage to UMMS was the facilities planning (6D) considerations:

- Full spatial as-built
- Design and actual capacity of systems - auto updates for design changes
- Asset tagging
- Ability to isolate a system for review
- Database of building information linked to a model
- Building Management System link

In other words, there is a tremendous amount of information incorporated into the model that will continue to be an invaluable resource long after the last punchlist item gets completed. The model becomes a tool that goes far beyond its effective use during design and construction. As just one example, benefits to the HVAC system include:

- Balanced air flow data
- Balanced water flow data
- System identification
- Capacity testing ("what if" scenarios)
- Barcode data for equipment

Training is another area where BIM can be invaluable, including initial training to learn about the new

building, new employee training, refresher training, contractor training, etc. The 3D models are always available and provide an electronic, searchable data base of all construction and maintenance documents and enable the tracing of all piping, ductwork, electrical, etc.

Another area where the model can be useful is the accreditation visit when it can be used to:

- Show a sense of confidence in building operations and code compliance
- Visualize the extent and location of special spaces
- Link to critical air balancing reports
- Link to real time data from the BAS and central fire alarm controls
- Link to the computerized maintenance management system
- Show the sequence of operations
- Show the HVAC fault diagnostic system
- "Trust but verify"

However the work on the model is still not 100 percent complete and there are areas that need to be updated and maintained. Some of the questions that remain are how will the models be managed by the owner? Will the maintenance staff be able to move beyond the traditional facilities mindset? How to effectively use models in a renovation environment in the future? What is the approach to utilizing models for future design improvements? How to link to BAS Systems in the future?

The audience left this session with many compliments for the building itself, the tutorial on BIM and options for modest to robust application, as well as ideas to ponder for expanded use of building information modeling in the future. The Chapter would like to extend its thanks to our host, UMass Medical, and to all of the presenters who brought clarity to this important topic. For more detailed information, including the many graphic illustrations included in the presentations, please visit the Chapter website at www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=291.

FM Global SimZone Dazzles Educational Program Attendees

by Mike Severino, Festo Corporation & Russ Parry, CM Services East LLC

As a yearly tradition, the New England and Boston Area Chapters joined forces to present the February educational program entitled "FM Global SimZone Tour and Program: Identifying and Mitigating Common Hazards in Business Properties." This unique event incorporated a visit to the FM Global learning center facility for a "hands-on" classroom experience which dovetailed perfectly with the follow-on presentations and made for a sold-out program.

For the tour, the first part of this two-part program, attendees were broken up into small groups to allow them to get a true appreciation of the SimZone, a state-of-the-art training facility that is part of FM Global's Center for Property Risk Solutions in Norwood, MA. The 12,000 ft^2 SimZone facility contains a variety of learning areas that simulate property hazards. This unique learning environment provides students with the knowledge and critical thinking skills to identify and manage risk by experiencing real-world scenarios - common hazards such as fires, equipment malfunctions and electrical breakdowns can be simulated in a hazard-free environment. Each attendee had the opportunity to experience all 10 different zones:

- **Construction Assemblies** Incorporates an array of different roofing and wall construction samples challenging you to identify appropriate construction components, and those components that potentially increase combustibility and how they would perform in a windstorm or when exposed to fire.
- **Steam & Industrial Heating Lab** Simulates the potential hazards associated with industrial heating equipment. Within the lab are an oil-fueled boiler, two-zone drying oven, autoclave/sterilizer, industrial plating tank and small-scale, multi-burner furnace.
- **Electrical Lab** Provides exposure to various hazards associated with electrical equipment, including indoor transformers and switchgear. De-energized switchgear and a dry transformer, various circuit breakers and a cutaway of an oil-filled transformer present a unique view.
- **Ignitable Liquid Use Lab** A simulated liquid process (recovery still) offers nine positions where four to seven different devices are interchangeable to create millions of possible hazardous combinations. Another illustration is dispensing of ignitable liquids from a 55-gallon drum.
- **Ignitable Liquid Storage Lab** This properly arranged and equipped room demonstrates the protective features and rationale for ignitable liquid protection. There are steel drums and intermediate bulk containers constructed of plastic and stainless steel. Ceiling-only sprinklers, in-rack sprinklers and compressed air foam nozzles illustrate fire protection options.
- **Storage Racks** Warehouse storage conditions create the highest concentration of combustible material. With 96 different storage combinations of commodities, shelving, pallets, etc. there are more than 2,000 possible storage protection problems that can be simulated.
- **Fire Pump Room** There are two fire pumps, an electric pump (500 gpm @ 100 psi) and a diesel pump (750 gpm @ 100 psi), that suction water from a 21,500 gallon outdoor storage tank to feed the wet lab. This environment illustrates all aspects of electric/diesel fire pump operation, arrangement, testing, maintenance and performance measurement.
- **Wet Lab** This "wet-friendly" environment demonstrates various sprinkler discharge characteristics and facilitates all facets of water-flow testing: hydrant, fire pump performance, loops, hydraulic gradients, flushing investigations and dry-pipe/valve-trip testing.

- **Riser Lab** Risers are vertical pipes that deliver water to the fire protection system in a building. Operable riser configurations in this lab offer a wide selection of wet, dry, deluge and pre-action systems involving different manufacturer's equipment and operating concepts.
- **Nondestructive Examination (NDE)** NDE is a major predictive maintenance tool used as a part of a conditioning program for any piece of equipment or process and aids in identifying imperfections and cracks in welds, rotating equipment shafts and gears, and power presses used in industry. Test equipment in this lab illustrates ultrasonic, eddy current, visual, dye penetrant and other techniques.

Following the stimulating SimZone tour, attendees gathered at the adjacent Four Points Sheraton for a spontaneous, 20-question verbal exercise and networking reception. At approximately 6:40pm the lights dimmed signaling the start of the presentation portion of the evening. An energized Boston Area Chapter President Jay Zaino provided opening remarks, followed by introductions by Program Managers Russ Parry and Mike Severino of the New England and Boston Area Chapters, respectively.

The SimZone tours gave Chapter Members a chance to visit training labs where common safety hazards are simulated

Chemical Processing

Steam & Industrial Heating

Electrical Safety

Sprinkler Systems

The evening's opening presentation was given by Dennis M. Anderson, P.E., Vice President, Engineering Application Manager, FM Global. Dennis utilized his 35+ years with FM Global to provide an inspirational presentation on the dos and don'ts of sound property preparedness for the "unexpected" which can come in many forms including fire, wind, earthquake, flood and/or snow. Dennis's mantra "Built to Last or Built to Code" was driven home by several very impressive videos illustrating how building to code does not always equate with sound and/or common sense property protection design principals. Based at FM Global's Research Campus in West Glocester, RI and responsible for addressing client, media and business partner groups to illustrate the science and engineering capabilities, Dennis introduced attendees to the research campus and presented several sprinkler test scenarios that took place in a large burn lab environment.

The second presenter, Howard Sneider, Senior Process Engineer at Clark Richardson Biskup (CRB) Engineers and Constructors, presented "How to Hunt Down and Handle Hazards." Howard's opening question "What is a Hazard?" set the stage for an insightful look at guidelines for hazard evaluation procedures. In a simplistic analogy, Howard used a four-way intersection to illustrate how a relatively safe event can cause an undesirable event when a barrier that is normally in place to control the hazard fails. He then went on to describe and explain tried and true techniques for identifying hazards including Checklist, What If, HAZOP, LOPA, FMEA and Fault Tree Analysis.

Once a hazard is identified, options for eliminating/reducing and controlling the hazard need to be evaluated.

If the situation allows, employ an ISD (Inherently Safer Design): "The most effective approach to process risk management is the elimination of hazards where feasible, rather than relying on safety systems and procedures to manage risk."

The final presenter utilized the two opening acts as a foundation-builder for his discussion of building codes. Eric A Peterson, AIA., Senior Associate/Project Architect, Symmes Maini & McKee Associates (SMMA), presented "Building Code Requirements for Storage and Handling of Flammable & Combustible Liquids." Eric's opening remark: "The cost of fire and fire prevention is 2.3 percent of GDP or $331 billion in the US" definitely got the attendees' attention. He then went on to review the Commonwealth of Massachusetts' governing standards/codes for the identification, classes, allowable maximum quantities and storage requirements for flammable and combustible liquids. The presentation then merged into building requirements in accordance with IBC (International Building Codes) and NFPA (National Fire Protection Association) standards for the design, layout, construction and fire prevention and fire risk control for this classification of liquids. He concluded his remarks with a real world example utilizing "NFPA 45 - Fire Protection for Laboratories Using Chemicals" and how different lab designs can accommodate the various flammable and/or combustible liquids based on each product's classification.

The melting pot of New England and Boston Area Chapter Members thoroughly enjoyed the evening's events and were exceedingly impressed by the program as a whole. Overall, the design of the event allowed attendees to build on each program that he or she attended. For those lucky enough to participate in the sold-out SimZone tour, the tour dovetailed perfectly with the presentations that followed. But the presentations were equally valuable by themselves. Albeit somewhat out of the norm for an ISPE educational program, the sold-out program proved to be of great interest to many Members from both Chapters who left with a simple and compelling question: "How safe is my facility and/or work environment and am I practicing commonsense procedures to meet safety requirements?"

On behalf of the entire Boston Area and New England Chapters, the program managers would like to thank FM Global for opening their doors and allowing our Members to experience the SimZone. We would also like to thank the FM Global volunteers who made each of the tours a fun and memorable event; and all three presenters who provided a thoroughly interesting and educational introduction to the topic of common hazards in business properties.

Student Chapter Activities Ramping Up

by Brian Hagopian, CPIP, Clear Water Consulting, Inc.

You may not know it, but the Boston Area Chapter has five Student Chapters at local institutions of higher learning. Student Chapters connect ISPE with colleges, giving students a connection with the local life sciences industry and providing ISPE with a continuous stream of new members and young professionals. The Boston Area Chapter currently has five Student Chapters:

- Northeastern University (NU)
- Tufts University
- UMass Amherst
- University of New Hampshire (UNH)
- Worcester Polytechnic Institute (WPI)

and we may be expanding in the future by adding Student Chapters at Boston University and Wentworth Institute.

Right now, we have about 60 Student Members, but expect that number to begin increasing steadily toward our long term goal of 200 active Student Members. The Chapter board of directors has increased emphasis on students as ISPE's "pipeline to the future" and the Chapter has "stepped up" its emphasis on students, with more volunteers focused on student-related activities than ever before. If you are a graduate of any of our Student Chapters and would like to help ISPE and your alma mater, consider participating in some of our programs. It won't take much time and it's for a great cause. This newsletter will provide regular updates on our Student Chapter activities, so check us out and please choose to get involved!

The Chapter's "Careers in Life Sciences" panel discussion drew a good turnout at Tufts in February

Student Chapter activities are really beginning to ramp up, with a variety of events already planned for the

spring and much more to follow. The Chapter recently held meetings at Tufts, Northeastern, and UNH, with similar events being organized at WPI and UMass Amherst to spread the word about the incredible opportunities offered to students by the Boston Area Chapter. At these meetings students showed a keen interest in learning more about the local biotech industry including participating in plant tours, internship programs, and learning about career paths available to them.

On February 25, the Chapter had a panel discussion focused on "Careers in Life Sciences" for the Tufts Student Chapter. Each panelist was both an ISPE Member and a Tufts alum working in the local life sciences industry. The event generated a lot of interest with lively discussion and helped students understand how they can translate their degree into a career in the life sciences industry. The Chapter also attended a career fair at UNH on March 5, spreading the word about the great career building and networking opportunities afforded by ISPE.

On March 30, the Chapter is holding a career forum for Student Members at Northeastern. Boston Area Chapter experts will gather to help students with resume building, job seeking, and interviewing skills as they transition from college to the local workforce or seek internships as they progress through college.

The Chapter's annual Student Poster Competition will be held on April 13 at Northeastern with NU students competing against those from other Student Chapters. The two winners will receive an expense paid trip to represent the Boston Area Chapter at the ISPE Annual Meeting this November where they will compete against students from other Chapters and Affiliates. Boston Area Chapter entrants have always performed exceedingly well at the national level, taking home three awards in the last five years.

The Chapter is also organizing a plant tour of a local biotech company this spring. Plans have not yet been fully solidified, so be sure to check the Chapter website Events Calendar for details. And while you're there, look for the color-coded student events for an overview of student activities planned for the upcoming months.

The next round of Joel Goldenberg Memorial Scholarship applications are due June 15. This year, the Chapter's board of directors increased the Chapter's commitment by doubling the scholarship budget, raising the scholarship fund from $10,000 to $20,000 per year. The scholarships are available to Boston Area Chapter ISPE Student Members and incoming freshmen who are the children of Chapter Members. To see if you qualify, check out the "Scholarship Program" tab on the Chapter's website for information and details.

Lastly, the Chapter is also developing an internship program to link our Student Members with local biotech and life sciences companies. This program allows students to work in industry over the summer or as part of a co-op program while providing companies with a steady stream of qualified and motivated candidates. The Chapter is actively seeking companies offering internships. If you work at a local life sciences company and have or are considering an internship program, please get in touch to be sure you are included in this program.

With the Chapter's renewed commitment to increasing our student membership and the many activities and benefits available to students who become Chapter Members, reaching our long term goal of 200 Student Members is well within our reach. But it will take lots of work and dedication on the part of Chapter volunteers to get there. Please contact Student Development Committee Chair Brian Hagopian at brian@clear-water-consulting.com to get involved.

YP Social Events, Networking & Educational Programs – There's Something for Everyone…

by Dave Gallagher, GxP Automation

Hello fellow YPs! For those of you who didn't attend, our last event on January 23 was the YP's BioTech Trivia Social ("Geeks who Drink Trivia") at Tommy Doyle's in Kendall Square. The YPs had a strong showing at the event, and there was a 50/50 raffle on hand to benefit MGH's Home Base Program. Thank you to everybody who participated and to John Ward and Sophie Bambrick for organizing the event!

YPs headed to Tommy Doyle's in January to compete at the Chapter's first Biotech Trivia Social

As far as upcoming events go, the YPs will be hosting another social event on the 28 of March at the Medieval Manor in Boston. For those who have not been to the Manor before, prepare yourself for a bawdy but lighthearted, interactive romp through the dark ages! Enjoy one-of-a-kind entertainment as you feast on six courses without a fork, knife, or spoon. Beer and wine will be provided with dinner and vegetarian meals will also be available. Get there early as there will be a networking social before the "formal" festivities begin at 6:30pm.

In a more serious vein, there is a dual-track educational program scheduled for April 18 at WPI in Worcester. Dual-track programs have been very successful in previous years due to their wide range of appeal. There will be two sessions, one - BioTech 101 - an introductory level presentation geared toward those new to the industry and the other - Process Validation - a more advanced session designed to polish the skills of seasoned industry professionals. Whether you're a new YP member or a seasoned veteran, there is something

for you at this event!

We have started sending out our own emails to let YPs know about all of our activities, so make sure to keep an eye out for them. Look forward to seeing all of you at our upcoming events!

Industry News in Brief

by Lauren Melton, Alnylam

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.

Arrowhead and Shire Partner to Develop Peptide-Targeted Therapeutics

Arrowhead Research Corporation, a targeted therapeutics company, announced that it has signed a research collaboration and license agreement with Shire AG to develop and commercialize targeted peptide-drug conjugates (PDCs) by utilizing Arrowhead's human-derived Homing Peptide platform and Shire's therapeutic payloads. Arrowhead will receive research funding and could be eligible for development, regulatory, and commercialization milestone payments of up to $32.8 million for each development candidate, plus additional milestone payments for a second indication, and royalties on worldwide sales. Additional financial terms of the agreement were not disclosed.

"Shire's expertise in developing innovative medicines for rare diseases makes them an ideal partner for Arrowhead as we advance our platform of human-derived Homing Peptides," said Dr. Chris Anzalone, President and Chief Executive Officer of Arrowhead. "Our library of over 42,000 unique targeting peptide sequences can potentially be used to deliver therapeutics to more than 30 tissue types while avoiding non-specific uptake. We view this collaboration as a significant validation of our technology and discovery capabilities. Moreover, this agreement underscores our strategy of building value by developing an internal pipeline of PDCs and RNAi therapeutics and by working with partners to improve their proprietary medicines with our peptide targeting."

"With this novel platform technology, Shire has the potential to move into a wider range of orphan diseases," said Dr. Phil Vickers, Head of R&D at Shire HGT. "Our goal is to develop treatments that profoundly change the lives of patients with a variety of rare life-altering and life-threatening conditions. This collaboration with Arrowhead is evidence of Shire's commitment to patients with rare diseases and our intent to work with the best partners to achieve this."

Under the agreement, Arrowhead will identify peptides that selectively bind and internalize in an undisclosed tissue type and that are capable of delivering a therapeutic payload to that tissue. The company will receive funding for its internal and external research program-related costs and Shire will have an option to obtain an exclusive license to develop and commercialize a therapeutic agent targeted by the designated peptides and be responsible for clinical development and commercialization of products arising. (Source: Arrowhead Research Website, 18 December, 2012)

Amgen Takes Third License for Rights to Use ImmunoGen's TAP Technology

ImmunoGen, a biotechnology company that develops anticancer therapeutics using its Targeted Antibody Payload (TAP) technology and antibody expertise, announced that Amgen has licensed the exclusive right to use the Company's maytansinoid TAP technology to develop anticancer therapeutics to a third target, which is undisclosed. Amgen licensed rights for two other targets in 2009 and has two compounds in clinical testing under those licenses.

"We're pleased with the interest major healthcare companies are showing in developing multiple product candidates with our TAP technology," commented Daniel Junius, President and CEO. "In recent years, there has been a marked increase in the quantity of targets considered to be potentially appropriate for TAP compounds, which has expanded the opportunity for us and our partners."

The licenses were taken under a 2000 agreement. For each license, ImmunoGen receives a $1 million upfront payment and is entitled to receive milestone payments potentially totaling $34 million plus royalties on the sales of any resulting products. Amgen is responsible for the development, manufacturing and marketing of any products resulting from the license. (Source: Immunogen Website, 19 December, 2012)

FDA Approves Aegerion's Juxtapid for Homozygous Familial Hypercholesterolemia (HoFH)

Cambridge-based Aegerion Pharmaceuticals, a biopharmaceutical company dedicated to the development and commercialization of novel, life-altering therapies for patients with debilitating, often fatal, rare diseases, announced that the FDA has approved Juxtapid (lomitapide) capsules as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein

cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B) and non- high-density-lipoprotein cholesterol (non-HDL) in patients with homozygous familial hypercholesterolemia (HoFH).

"We are excited that Juxtapid will become a new treatment option for patients with HoFH," said Marc Beer, Chief Executive Officer at Aegerion. "The approval of our first product also marks an important corporate milestone for Aegerion and reflects our commitment to help patients in need."

HoFH is a serious, rare genetic disease that impairs the function of the receptor responsible for removing LDL-C ("bad" cholesterol) from the body. A loss of LDL receptor function results in extreme elevation of blood cholesterol levels. HoFH patients often develop premature and progressive atherosclerosis, a narrowing or blocking of the arteries.

Juxtapid contains a Boxed Warning citing the risk of hepatic toxicity. The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH. The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined. The safety and effectiveness of Juxtapid have not been established in pediatric patients.

The FDA based its approval of Juxtapid on Aegerion's pivotal Phase III study, which evaluated the safety and effectiveness of the medicine to reduce LDL-C levels in 29 adult patients with HoFH. The study was a multinational, single-arm, open-label, 78-week trial that was recently published in the November 2, 2012 online version of the *Lancet*. (Source: Aegerion Website, 24 December, 2012)

FDA Approves Genzyme's Kynamro for HoFH

The FDA has approved Kynamro (mipomersen sodium) injection as an addition to lipid-lowering medications and diet to treat patients with a rare type of high cholesterol called homozygous familial hypercholesterolemia (HoFH). The addition of Kynamro helps to reduce low-density lipoprotein-cholesterol (LDL-C), apolipoprotein B, total cholesterol, and non-high density lipoprotein-cholesterol (non HDL-C).

HoFH, an inherited condition that affects about one out of every one million people in the United States, occurs when the body is unable to remove LDL-C, often called "bad" cholesterol, from the blood causing abnormally high levels of circulating LDL-C. For those with HoFH, heart attacks and death often occur before age 30. Kynamro is an orphan drug approval, meaning it was developed to treat a disorder affecting fewer than 200,000 people.

"Kynamro, an injection given once a week, works with other lipid-lowering medications and diet to impair the creation of the lipid particles that ultimately give rise to LDL-C," said Eric Colman, M.D., deputy director of the Division of Metabolism and Endocrinology Products at the FDA's Center for Drug Evaluation and Research.

The safety and effectiveness of Kynamro were evaluated in a clinical trial of 51 patients with HoFH. On average, levels of LDL-C fell by about 25 percent during the first 26 weeks in those receiving the drug. Kynamro carries a Boxed Warning on the serious risk of liver toxicity because it is associated with liver enzyme abnormalities and accumulation of fat in the liver, which could lead to progressive liver disease with chronic use.

The FDA approved Kynamro with a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use, including prescriber and pharmacy certification, and documentation of safe-use conditions, which requires a prescription authorization form for each new prescription. The most common adverse reactions in the clinical trial included injection site reactions, flu-like symptoms, nausea, headache and elevations in liver enzymes (serum transaminases).

The FDA is requiring four postmarketing studies for Kynamro: the development of a sensitive assay that binds double-stranded (ds) DNA; a study to assess for the presence of antibodies to ds-DNA in patients treated with Kynamro; a long-term registry of patients with HoFH to determine the long-term safety of Kynamro; and an enhanced pharmacovigilance program to monitor reports of malignancy, immune-mediated reactions, and hepatic abnormalities in patients treated with Kynamro. (Source: FDA Website, 29 January, 2013)

GTC Biotherapeutics Changes Name to rEVO Biologics

GTC Biotherapeutics announced that it has changed its name to rEVO Biologics. The name change reflects the recent commercial growth of the company and better aligns with the company's business strategy of evolving recombinant medicine for the treatment of rare diseases.

"Our company is taking a revolutionary approach to the development of recombinant therapies, as evidenced by our lead product ATryn Antithrombin (Recombinant) and its remarkable growth over the past year," stated rEVO Biologics President Yann Echelard, Ph.D. "With this change, our name now reflects that core strength. Our rPRO Technology enables us to maintain all of the advantages that recombinant science offers, but through an entirely different approach. The result is better efficiency, better scalability, better cost control and ultimately better patient access to these innovative therapies."

ATryn Antithrombin (Recombinant) is the first and only recombinant antithrombin concentrate, and is

currently the fastest-growing antithrombin product with market share that has tripled in the last 12 months.

The original GTC Biotherapeutics name dates back to when the company was Genzyme Transgenics Corporation, and a spinoff of Genzyme Corporation. Today, the company is a subsidiary of LFB Biotechnologies S.A., a leading European-based biopharmaceutical group. rEVO Biologics corporate offices are in Framingham, MA, with protein production facilities in Charlton, MA. (Source: GTC Biotherapeutics Website, 04 January, 2013)

Biogen Halts ALS Drug Development

Biogen Idec reported top-line results of a Phase 3 trial investigating dexpramipexole in people with amyotrophic lateral sclerosis (ALS). The trial did not meet its primary endpoint, a joint rank analysis of function and survival, and no efficacy was seen in the individual components of function or survival. The trial also failed to show efficacy in its key secondary endpoints. Additional analyses of multiple subpopulations failed to demonstrate any efficacy among these groups. Based on these results, Biogen Idec will discontinue development of dexpramipexole in ALS.

"We share the disappointment of members of the ALS community, who had hoped that dexpramipexole would offer a meaningful new treatment option," said Douglas E. Williams, Ph.D., Executive Vice President of Research and Development at Biogen Idec. "Nevertheless, the...trial represents a significant contribution to ALS research, and Biogen Idec is committed to advancing ALS science. We continue to work with researchers around the world to understand the causes of ALS and find potential treatments for people with ALS." (Source: Biogen Idec Website, 03 January, 2013)

AVEO Announces Closing of Public Offering

Cambridge-based AVEO Pharmaceuticals has reported that it has closed its recently announced public offering of common stock. The total number of shares sold was 7,667,050, comprised of 6,667,000 shares of common stock initially offered and an additional 1,000,050 shares of common stock sold pursuant to the underwriters' exercise of their over-allotment option, at the public offering price of $7.50 per share. Aggregate net proceeds to the company were approximately $53.8 million, after deducting underwriting discounts and commissions and estimated offering expenses. (Source: Aveo Website, 24 January, 2013)

Biogen MS Drug Shows Signs of Promise in Phase 3 Clinical Trial

Biogen Idec released the primary efficacy analysis and safety data from its Phase 3 pivotal clinical trial, ADVANCE. Results support peginterferon beta-1a as a potential treatment dosed every two weeks or every four weeks for relapsing-remitting multiple sclerosis (RRMS). Peginterferon beta-1a is a new molecular entity in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body, enabling study of a less frequent dosing schedule.

The primary endpoint of ADVANCE, annualized relapse rate (ARR) at one year, was met for both the two-week and four-week dose regimens. Results showed that peginterferon beta-1a also met the secondary endpoints of risk of 12-week confirmed disability progression, proportion of patients who relapsed and magnetic resonance imaging (MRI) assessments for both dose regimens. Adverse events (AEs), serious adverse events (SAEs) and discontinuations due to AEs were similar across both dose groups. Overall with both dose regimens studied, the risk-benefit profile of peginterferon beta-1a appears to be favorable. (Source: Biogen Idec Website, 24 January, 2013)

Idenix & Janssen to Work Together on Hepatitis C Treatments

Cambridge-based Idenix Pharmaceuticals, a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases, announced a non-exclusive collaboration with Janssen Pharmaceuticals of Titusville, NJ for the clinical development of all-oral direct-acting antiviral (DAA) HCV combination therapies. The collaboration will evaluate combinations including IDX719, Idenix's once-daily pan-genotypic NS5A inhibitor; simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir AB; and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

Clinical development plans include an initial drug-drug interaction study to begin in the first quarter of 2013, followed by phase II studies as agreed between the companies, and pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir plus ribavirin for 12 weeks in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir and TMC647055/r, with and without ribavirin. The clinical trials will be conducted by Idenix. Both companies retain all rights to their respective compounds under this agreement.

"We are very pleased to be working with Janssen and look forward to initiating a phase II study in the first quarter of this year," said Ron Renaud, Idenix's President and Chief Executive Officer. "This will allow us to

achieve a key goal of ours for 2013, which is to advance the development of IDX719 as part of all-oral HCV combinations in two- and three-drug regimens." (Source: Idenix Website, 28 January, 2013)

AstraZeneca & Bristol-Myers Squibb Deepen Diabetes Alliance

AstraZeneca and Bristol-Myers Squibb have deepened their diabetes-drug partnership by merging their diabetes marketing teams and moving them to a new U.S. headquarters separate from either company, AstraZeneca's new chief executive, Pascal Soriot, said in an interview.

The two companies jointly appointed executives from their ranks to run the new team, which is based outside of Philadelphia, between their respective U.S. headquarters in Wilmington, Del., and New York, Dr. Soriot said Thursday. "That is on purpose," he said of the separate location, "because we want them to think diabetes. We want them to have their own company, in a way - Diabetes Inc.," he said. (A Bristol-Myers spokesman emphasized that the venture isn't a separate legal entity but otherwise had no comment.)

The new diabetes marketing group was formed in October with several hundred employees, Dr. Soriot said. In November, the European Union approved for sale the companies' new diabetes drug, Forxiga, which is designed to remove excess glucose from the body. AstraZeneca said Thursday the companies will resubmit Forxiga to the FDA for approval in mid-2013. Last year the FDA requested more clinical data on the drug.

Asked whether AstraZeneca would consider expanding the Bristol-Myers partnership to include other therapy areas, Dr. Soriot said he sees no reason to view Bristol-Myers as an exclusive partner, noting that AstraZeneca has a similar deal with Amgen to jointly develop five experimental drugs for inflammatory disease. (Source: Jeanne Whalen and Jessica Hodgson, The Wall Street Journal Online, 31 January, 2013)

Leica Biosystems Increases Presence in Boston with Opening of U.S. R&D Lab

Leica Biosystems, a German cancer diagnostic firm, has announced the establishment of its R&D facility in Massachusetts, in operation since August 2012. Citing the state's global leadership in the life sciences and a growing customer base in the United States, Leica's presence in Massachusetts will focus on research and development of companion diagnostics. The company's temporary offices and R&D lab space are in Danvers, MA but the Leica Biosystems team has plans to expand by the end of 2013.

The main focus of the Leica Biosystems presence in Massachusetts is to support the pharmaceutical industry through development of targeted companion diagnostic tests. The company is headquartered in Nussloch, Germany, with operations also in the U.K., Australia, China, Singapore and Illinois.

"We are delighted to announce the opening of the Leica Biosystems R&D facility in Boston," said Matthias Weber, M.D., President of Leica Biosystems. "Being in Massachusetts gives us the ability to collaborate closely with the pharmaceutical industry on a domestic level, and this was a major influence in choosing Boston as our U.S. R&D location. We are already seeing the benefit of our decision, and look forward to our second round of recruitment in 2013."

"Thanks to our growth strategy of investing in education, innovation and infrastructure, Massachusetts continues to lead the world in life sciences," said Governor Deval Patrick. "We welcome Leica Biosystems to the Commonwealth and look forward to them creating jobs and economic opportunities here in Massachusetts."

Through the Massachusetts Life Sciences Center, Massachusetts is investing $1 billion over 10 years in the growth of the state's life sciences supercluster. These investments are being made under the Massachusetts Life Sciences Initiative, proposed by Governor Patrick in 2007, and passed by the State Legislature and signed into law by Governor Patrick in 2008.

"We are excited to welcome Leica Biosystems to the fast-growing Massachusetts life sciences community," said Susan Windham-Bannister, Ph.D., President & CEO of the Massachusetts Life Sciences Center. "With its cutting-edge cancer diagnostics technology and processes for histology and tissue processing, Leica Biosystems will be an important partner for the Commonwealth's R&D-focused organizations in both industry and academia."

Leica Biosystems is among a growing group of international companies that have recently picked Massachusetts as the place to expand their business in the U.S. "Massachusetts has become *the* destination for the world's most innovative companies across the entire life sciences spectrum," said Robert K. Coughlin, President & CEO of MassBio, a 600+ member life sciences trade association. "We are thrilled to welcome Leica Biosystems and know they will play a very important role in our world-class life sciences ecosystem." (Source: MassBio Website, 01 February, 2013)

Dune Medical Devices Wins FDA Approval for Advance in Breast Cancer Surgery

Framingham-based Dune Medical Devices announced that its breakthrough intra-operative tissue assessment tool for early-stage breast cancer surgery, the MarginProbe System, has received Premarket Approval (PMA) by the FDA. The technology significantly improves surgeons' ability to intra-operatively

identify "cancer on the margin" and significantly reduce pathologically positive margins following a patient's initial lumpectomy surgery.

FDA approval of the MarginProbe System was based on a 664 patient prospective, multi-center, randomized, double arm study to evaluate the effectiveness of MarginProbe in identifying cancerous tissue along the margins of removed breast tissue during initial lumpectomy procedures. MarginProbe, which uses electromagnetic "signatures" to identify healthy and cancerous tissue, was found to be over three times more effective in finding cancer on the margin during lumpectomy, compared to traditional intra-operative imaging and palpation assessment. This enabled surgeons to significantly reduce the number of patients with positive margins following initial surgery.

"Up to this point our ability to assess the microscopic margin status in the operating room has been limited. Frequently, early-stage breast cancers are detected by mammography. This can make the process of achieving negative margins more challenging," said Dr. Susan K. Boolbol, an investigator for the pivotal clinical trial and Chief of Breast Surgery at Beth Israel Medical Center. "Following their breast cancer surgery, telling a patient that they need more surgery can be an emotional issue for doctors and patients. This may result in tremendous anxiety and frustration. I believe that the MarginProbe System can help advance the field of breast surgery."

It is estimated that 30 to 60 percent of early-stage breast cancer patients who have an initial lumpectomy procedure will undergo a repeat surgery. This is because cancerous cells are found to be present on the rim or edge of the removed tissue, increasing the possibility that cancer still remains in the breast.

The 10 year old Framingham-based company will also be moving operations to the Boston Innovation District. (Source: Dune Medical Devices Website)

Alnylam & The Medicines Company Partner to Develop and Commercialize RNAi Therapeutics for Treatment of Hypercholesterolemia

The Medicines Company and Alnylam Pharmaceuticals, a leading RNAi therapeutics company, announced today that they have formed an exclusive global alliance for the development and commercialization of Alnylam's ALN-PCS RNAi therapeutic program for the treatment of hypercholesterolemia.

"This new alliance unites two organizations with a shared culture and commitment to innovation. In my view and past experience, there could be no stronger partner for our ALN-PCS program than The Medicines Company, which has demonstrated industry-wide leadership in the advancement of cardiovascular medicines to patients and remarkable success in its strategy of in-licensing, developing, and commercializing breakthrough products," said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. "For Alnylam, this new partnership enables the advancement of ALN-PCS, an important program within our 'Alnylam 5x15' product development and commercialization strategy focused on RNAi therapeutics directed toward genetically validated targets. We believe that the ALN-PCS program holds great promise for the development of a significant therapeutic option for patients with hypercholesterolemia, and that the unique mechanism of action for ALN-PCS could provide a differentiated and potentially best-in-class strategy for PCSK9 antagonism."

"Our focus on acute and intensive care medicine has led us to a leadership position with Angiomax (bivalirudin) and potentially with cangrelor in the management of patients in extreme risk as a consequence of the rupture of their vulnerable coronary artery plaque at and around the time of acute coronary syndromes. Meantime, we have made progress with MDCO-216 (ApoA-1 Milano), a turbocharged form of HDL-C ('good cholesterol') which has the potential to modify disease through reverse cholesterol transport," said Clive Meanwell, M.D., Ph.D., Chairman and Chief Executive Officer of The Medicines Company. "Now, this exciting collaboration with Alnylam - leaders in their field of RNAi - adds a second potentially disease modifying approach and more cutting edge technology to our portfolio. We have seen that PCSK9 gene silencing can substantially reduce LDL-cholesterol in patients and has epidemiological and disease mechanisms studies suggest this can further reduce the risks of the world's number one killer, coronary artery disease. Clearly we see the complementarity of approaches which increase 'good cholesterol' (HDL-C) and decrease 'bad cholesterol' (LDL-C). We look forward to working with our colleagues at Alnylam for whom we have the greatest respect and admiration based upon earlier collaborations particularly around Angiomax, which was invented by John Maraganore."

PCSK9 (proprotein convertase subtilisin/kexin type 9) is a protein that regulates low-density lipoprotein (LDL) receptor levels on hepatocytes. Gain-of-function human mutations in PCSK9 are associated with hypercholesterolemia while loss-of-function mutations are associated with lower levels of LDL cholesterol and a reduced risk of cardiovascular disease. ALN-PCS is a PCSK9 synthesis inhibitor that reduces intracellular and extracellular levels of PCSK9 resulting in lowered plasma levels of LDL-C. MDCO-216 is a naturally occurring variant of a protein found in high-density lipoprotein, or HDL. It is a reverse cholesterol transport agent designed to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events.

Under this alliance, The Medicines Company and Alnylam intend to collaborate on the advancement of the ALN-PCS program. Alnylam's ALN-PCS program includes ALN-PCS02 - an intravenously administered RNAi therapeutic which has completed a Phase I trial; and ALN-PCSsc, a subcutaneously administered RNAi

therapeutic currently in pre-clinical development. Alnylam will continue the program for an estimated one to two years to complete certain pre-clinical and Phase I clinical studies.

The Medicines Company is responsible for leading and funding development from Phase II forward and commercializing the ALN-PCS program if successful. Under the terms of the agreement, The Medicines Company will make an upfront cash payment of $25 million to Alnylam. Alnylam may also receive potential development and commercial milestone payments of up to $180 million. Alnylam will be eligible to receive scaled double-digit royalties on global products sales of ALN-PCS products. (Source: Alnylam Website, 04 February, 2013)

Biogen Idec to Acquire Full Rights and Control of Tysabri from Elan

Biogen Idec announced the company has agreed to purchase Elan's interest in Tysabri (natalizumab) and upon closing will gain full strategic, commercial and decision-making rights to Tysabri. Upon the closing of the transaction, the previous collaboration agreement between the companies, whereby worldwide Tysabri profits were split 50/50, will be terminated along with the agreement's change of control provisions.

Under the terms of the agreement, Biogen Idec will use its existing cash reserves to make a payment of $3.25 billion to Elan upon the closing of the transaction and make future contingent payments to Elan in an amount equal to 12% of global net sales of Tysabri for the first twelve months, and thereafter, Biogen Idec will continue to make contingent payments of 18% on annual global net sales of Tysabri up to $2.0 billion and 25% on annual global net sales that exceed $2.0 billion. In 2014 only, the $2.0 billion threshold will be pro-rated for the portion of 2014 remaining after the first 12 months expires.

Biogen Idec anticipates the transaction will be approximately $0.20 to $0.30 accretive to 2013 GAAP earnings per share and $0.50 to $0.60 accretive to non-GAAP earnings per share, and will continue to be accretive thereafter, depending on the sales trajectory of Tysabri.

"This is a natural next step for Biogen Idec and Tysabri, and it underscores our deep, long-term commitment to improving the lives of MS patients around the world," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "Tysabri is a remarkably efficacious drug, and with the increased awareness of our risk stratification capabilities, we believe MS patients' use of Tysabri will continue to expand over the long-term. Full ownership will improve our ability to navigate its role as part of our leadership in MS. We appreciate Elan's tremendous partnership and the productive approach to our discussions that led to a transaction that benefits the shareholders of both companies. We expect a smooth transition to the closing of the transaction."

The transaction has been approved by the boards of directors of both companies and is subject to the customary review process under the Hart-Scott-Rodino Antitrust Improvements Act in the United States and other customary review processes. The transaction is expected to close by the end of the second quarter, assuming a standard regulatory approval timeframe. (Source: Biogen Idec Website, 06 February, 2013)

Ariad to Add HQ, Jobs in Kendall Square

Ariad Pharmaceuticals will build a new corporate headquarters and laboratory complex in Kendall Square, adding to a biotech building boom that is rapidly filling that part of Cambridge with jobs and modern buildings. The company, which recently won federal approval for its first major drug, will occupy most of two five-story buildings to be built on Binney Street by Alexandria Real Estate Equities Inc.

The new offices will allow Ariad to consolidate its operations and usher in an era of expansion following the launch of Iclusig, which won FDA approval last month as a treatment for chronic myeloid leukemia. The company is awaiting approval in Europe.

Ariad's workforce has more than doubled to about 300 employees since the start of 2012, and the company expects to add at least 100 jobs in Cambridge over the next two years.

Ariad's buildings will be part of a larger complex called Alexandria Center at Kendall Square, a 1.9-million-square-foot development that will eventually include four office and lab buildings, residences, stores, and restaurants. Tom Andrews, an Alexandria Real Estate executive, said the project will bring new life to vacant lots along the eastern end of Binney Street and upgrade the area with bike paths, a public park, and fresher landscaping.

"These improvements will really transform that corner of Kendall Square," Andrews said, adding that the Ariad buildings, to include at least one restaurant or retail shop, are scheduled to be completed in early 2015. The company has signed a 15-year lease to occupy about 60 percent of the 386,000-square-foot buildings at 75 and 125 Binney Street; much of the remainder will be available for lease by other technology or life sciences companies.

Several biotechnology companies are also moving forward with new office and laboratory complexes, including Novartis AG, Pfizer, Millennium Pharmaceuticals and Biogen Idec, which will occupy another building under construction at Alexandria Center. The rush of building activity is being fueled by the discovery of drugs to treat neurological disorders and chronic diseases such as cancer, ALS, and diabetes.

Ariad is working out of two buildings in the University Park development in Cambridge. Its founder and chief executive, Harvey J. Berger, said he is looking forward to consolidating them in Kendall Square in 2015. The new headquarters, designed by the architecture firm Payette, will feature glass terraces adjoining the buildings and textured panels and windows that will alternate in a manner to evoke DNA patterns. The complex will house Ariad's chemistry, biology, and pharmacology labs, as well as sales, marketing, and finance operations.

"It will be designed to foster collaboration between scientists and commercial folks," Berger said. "It doesn't matter what department you're in. There will be elegant collaboration space." That space will include common areas where employees can work together on laptops and teleconferencing rooms where they can interact with colleagues at the company's offices in Lausanne, Switzerland.

Berger said Ariad limited its search to Cambridge, considering University Park and other sites before settling on Alexandria Center. "It's all about being in the Cambridge scientific environment," he said. "That's where our roots are. We've been in Cambridge from day one. We gave no consideration to being in Boston. Berger said the company's job growth in Cambridge will boost its worldwide payroll to about 500. (Source: Casey Ross and Robert Weisman, The Boston Globe Online, 07 January, 2013)

Shire Acquires Lotus Tissue Repair

Shire plc, announced that it has signed an agreement to acquire Cambridge-based Lotus Tissue Repair, a privately held biotechnology company developing the first and only protein replacement therapy currently being investigated for the treatment of dystrophic epidermolysis bullosa (DEB). DEB is a devastating orphan disease for which there is no currently approved treatment option other than palliative care. Subject to customary government approvals, Shire will purchase the company for an upfront payment and certain contingent payments based on the achievement of certain safety and development milestones.

Epidermolysis Bullosa (EB) is a set of rare, genetic diseases characterized by the presence of extremely fragile skin and recurrent blister formation resulting from minor mechanical friction or trauma. DEB is one of the more severe of the genetic disorders that comprise EB. Severe cases of DEB may also include internal blistering of the mouth, esophagus, lower GI tract, upper airway and GU tract.

Shire's Human Genetic Therapies business will undertake the further development of Lotus Tissue Repair's lead product candidate, a proprietary recombinant form of human collagen Type VII (rC7), an intravenous protein replacement therapy for the treatment of DEB. The product is in late pre-clinical development and has the potential to be a first-in-class systemic therapy for the treatment of DEB. This acquisition expands Shire's commitment to finding treatments for EB, which also includes ABH001, Shire's Regenerative Medicine product currently being investigated as a dermal substitute therapy for the treatment of non-healing wounds in patients with EB.

Lotus Tissue Repair is a private company launched in 2011 by a proven team of biotechnology entrepreneurs, world-leading experts in rC7 protein replacement therapy for DEB and top-tier life sciences investor, Third Rock Ventures. (Source: Shire Website, 08 February, 2013)

Ipsen to Sell Drugs and Milford Manufacturing Facility

Ipsen and Inspiration Biopharmaceuticals announced they entered into an Asset Purchase Agreement (APA) whereby Baxter International (Baxter) agrees to acquire the worldwide rights to OBI-1, a recombinant porcine factor VIII (rpFVIII) in development for congenital hemophilia A with inhibitors and acquired hemophilia A, and Ipsen's industrial facility in Milford, MA. In addition, Ipsen and Inspiration Biopharmaceuticals announced they entered into an APA whereby Cangene Corporation agrees to acquire the worldwide rights to IB1001, a recombinant factor IX (rFIX) for the treatment of hemophilia B.

The sales are a result of a joint marketing and sale process pursued by Ipsen and Inspiration shortly after Inspiration filed for protection under Chapter 11 of the U.S. Bankruptcy Code on October 30, 2012. Ipsen has been providing Inspiration with Debtor-in-Possession financing (DIP) for an amount of up to $23.6 million to fund Inspiration's operations during the sale process. (Source: Ipsen Website, 24 January, 2013 & 06 February, 2013)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

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

FDA Approves Monoclonal Antibody to Treat Inhalational Anthrax

The FDA has approved raxibacumab injection to treat inhalational anthrax, a form of the infectious disease caused by breathing in the spores of the bacterium Bacillus anthracis. Raxibacumab also is approved to prevent inhalational anthrax when alternative therapies are not available or not appropriate.

Raxibacumab is a monoclonal antibody that neutralizes toxins produced by B. anthracis that can cause massive and irreversible tissue injury and death. A monoclonal antibody is a protein that closely resembles a human antibody that identifies and neutralizes foreign material like bacteria and viruses. Anthrax is a potential biological terrorism threat because the spores are resistant to destruction and can be easily spread by release in the air.

The FDA granted raxibacumab fast track designation, priority review, and orphan product designation. The drug demonstrated the potential to fill an unmet medical need, has the potential to provide safe and effective treatment where no satisfactory alternative therapy exists, and is intended to treat a rare disease, respectively.

Raxibacumab is the first monoclonal antibody approved under the FDA's Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to support FDA approval when it is not feasible or ethical to conduct trials in humans.

Raxibacumab was developed by Rockville, Md.-based Human Genome Sciences, in conjunction with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority. Human Genome Sciences has since been acquired by GlaxoSmithKline. (Source: FDA Website, 14 December, 2012)

FDA Approves New Orphan Drug For Cushing's Disease

The FDA has approved Signifor (pasireotide diaspartate) injection for the treatment of Cushing's disease patients who cannot be helped through surgery. Signifor is manufactured by Novartis Pharma Stein AG, Stein, Switzerland. The drug is administered subcutaneously twice daily, and will be dispensed with a Medication Guide, including instructions for patients and caregivers that describe the risks and adverse reactions people should be mindful of when using the product.

Cushing's disease is caused by over-production of cortisol, a hormone made by the adrenal glands. A tumor in the pituitary gland leads to overstimulation of the adrenal gland, which results in excess cortisol production. Cortisol regulates many important functions in the body, including response to stress and injury. Patients with Cushing's disease may have increased weight, glucose intolerance or diabetes, high blood pressure, easy bruising, and increased risk for infections. (Source: FDA Website, 14 December, 2012)

FDA Approves Gattex to Treat Short Bowel Syndrome

The FDA has approved Gattex (teduglutide) to treat adults with short bowel syndrome (SBS) who need additional nutrition from intravenous feeding (parenteral nutrition). SBS is a condition that results from the partial or complete surgical removal of the small and/or large intestine. Extensive loss of the small intestine can lead to poor absorption of fluids and nutrients from food needed to sustain life. As a result, patients with SBS often receive parenteral nutrition.

Gattex is an injection administered once daily that helps improve intestinal absorption of fluids and nutrients, reducing the frequency and volume of parenteral nutrition. It is the third FDA-approved drug to treat adults with SBS receiving nutritional support. Zorbtive (somatropin) and Nutrestore (glutamine) were approved in 2003 and 2004, respectively. Gattex is marketed by Bedminster, NJ-based NPS Pharmaceuticals; Zorbtive is marketed by EMD Serono, based in Rockland, MA and Nutrestore is marketed by Torrance, CA-based Emmaus Medical Inc.

To ensure that the benefits of Gattex outweigh the potential risks, the drug is being approved with a Risk Evaluation and Mitigation Strategy, consisting of a communication plan and training for prescribers. To study Gattex's long-term safety, the FDA is requiring a postmarket study of SBS patients treated with the drug in a routine clinical setting to further evaluate the drug's potential increased risk to cause colorectal cancer and other conditions. Patients in this study will be followed for at least 10 years. (Source: FDA Website, 21 December, 2012)

FDA Expands Tamiflu's Use to Treat Children Under 1 Year-old

The FDA has expanded the approved use of Tamiflu (oseltamivir) to treat children as young as 2 weeks old who have shown symptoms of flu for no longer than two days. The drug is not approved to prevent flu infection in this population. In addition, the safety and efficacy of Tamiflu to treat flu infection has not been established in children younger than 2 weeks old.

Tamiflu was approved in 1999 to treat adults infected with flu who have shown symptoms for no longer than two days. It has since been approved to treat flu in children ages 1 year and older who have shown symptoms of flu for no longer than two days, and to prevent flu in adults and children ages 1 year and older.

Although there is a fixed dosing regimen for patients 1 year and older according to weight categories, the dosing for children younger than 1 year must be calculated for each patient based on their exact weight. These children should receive 3 milligrams per kilogram twice daily for five days. These smaller doses will require a different dispenser than what is currently co-packaged with Tamiflu.

Tamiflu is distributed in the United States by South San Francisco-based Genentech, a member of the Roche Group. (Source: FDA Website, 21 December, 2012)

FDA Approves Varizig for Reducing Chickenpox Symptoms

The FDA has approved Varizig for reducing the severity of chicken pox (varicella zoster virus) infections in high risk individuals when given within four days after exposure. Varizig is a varicella zoster immune globulin preparation. Varicella zoster virus (VZV) causes chickenpox in children and shingles in adults. Varizig is the only FDA approved immune globulin for VZV after exposure available in the United States. It was designated as an orphan drug by the FDA and received a priority review.

Most people in the United States have immunity to VZV from vaccination or from having had chickenpox during childhood. However, people without immunity to VZV who are exposed to the virus may experience severe infections that are sometimes fatal. People most at risk include children or adults with weakened immune systems, pregnant women, and infants exposed during pregnancy or after birth. Occasionally, healthy people without immunity to VZV may contract severe infections. Antiviral treatments are not always effective and cannot be used in some cases.

Varizig is manufactured by Cangene Corporation in Winnipeg, Canada. (Source: FDA Website, 21 December, 2012)

FDA Approves Eliquis to Reduce Risk of Stroke & Blood Clots in Certain Patients

The FDA has approved the anti-clotting drug Eliquis (apixaban), an oral tablet used to reduce the risk of stroke and dangerous blood clots in patients with atrial fibrillation that is not caused by a heart valve problem. Eliquis is manufactured Bristol-Myers Squibb Company of Princeton, N.J. and marketed by BMS and Pfizer Inc. of New York.

Atrial fibrillation, one of the most common types of abnormal heart rhythm, is an abnormal, irregular, and rapid beating of the heart in which the heart's two upper chambers (atria) do not contract properly, allowing blood clots to form in them. These clots can break off and travel to the brain or other parts of the body.

Patients with prosthetic heart valves should not take Eliquis nor should patients with atrial fibrillation that is caused by a heart valve problem. These patients were not studied in clinical trial. As with other FDA-approved anti-clotting drugs, bleeding, including life-threatening and fatal bleeding, is the most serious risk with Eliquis. There is no agent that can reverse the anti-coagulant effect of Eliquis.

Eliquis will be dispensed with a patient Medication Guide that provides instructions on its use and drug safety information. Health care professionals should counsel patients on signs and symptoms of possible bleeding. (Source: FDA Website, 28 December, 2012)

Eliquis OK'd in Japan for Stroke Prevention

Bristol-Myers Squibb and Pfizer have announced that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved Eliquis (apixaban) for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). Eliquis is a novel anticoagulant that has demonstrated risk reductions versus warfarin in three important outcomes of stroke, major bleeding and all-cause death. Eliquis is an oral direct Factor Xa inhibitor, part of a novel therapeutic class.

The approval of Eliquis in Japan is supported by a Phase 3 trial which evaluated the safety and efficacy of Eliquis versus warfarin in 18,201 patients with NVAF, including 336 patients from Japan. Additionally, the safety and efficacy of Eliquis in Japanese patients were evaluated in a subanalysis of the study, which demonstrated results consistent with the overall study. The application for Eliquis for the prevention of ischemic stroke and systemic embolism was submitted in Japan on December 21, 2011. (Source: Pfizer Website, 26 December, 2012)

FDA Approves First Anti-Diarrheal Drug for HIV/AIDS Patients

The FDA has approved Fulyzaq (crofelemer) to relieve symptoms of diarrhea in HIV/AIDS patients taking antiretroviral therapy, a combination of medicines used to treat HIV infection. Fulyzaq is distributed by Salix Pharmaceuticals, based in Raleigh, N.C. under license from Napo Pharmaceuticals, Inc.

Diarrhea is experienced by many HIV/AIDS patients and is a common reason why patients discontinue or switch their antiretroviral therapies. Fulyzaq is intended to be used in HIV/AIDS patients whose diarrhea is not caused by an infection from a virus, bacteria, or parasite.

Derived from the red sap of the Croton lechleri plant, Fulyzaq is the second botanical prescription drug approved by FDA. A botanical drug product is often a complex mixture derived from one or more plant materials with varying degrees of purification. In 2006, the FDA approved the first botanical prescription drug, Veregen (sinecatechins), a treatment for external genital and perianal warts marketed by Florham Park, NJ-based PharmaDerm. (Source: FDA Website, 31 December, 2012)

FDA Approves New Seasonal Flu Vaccine Made Using Novel Technology

The FDA announced that it has approved Flublok, the first trivalent influenza vaccine made using an insect virus (baculovirus) expression system and recombinant DNA technology. Flublok is manufactured by Protein Sciences Corp, of Meriden, CT and is approved for the prevention of seasonal influenza in people 18 through 49 years of age.

Unlike current flu vaccines, Flublok does not use the influenza virus or eggs in its production. Flublok's novel manufacturing technology allows for production of large quantities of the influenza virus protein, hemagglutinin (HA) - the active ingredient in all inactivated influenza vaccines that is essential for entry of the virus into cells in the body. The majority of antibodies that prevent influenza virus infection are directed against HA. While the technology is new to flu vaccine production, it is used to make vaccines that have been approved by the FDA to prevent other infectious diseases.

Flublok contains three, full-length, recombinant HA proteins to help protect against two influenza virus A strains, H1N1 and H3N2, and one influenza virus B strain. (Source: FDA Website, 16 January, 2013)

FDA Approves Botox to Treat Overactive Bladder

The FDA has expanded the approved use of Botox (onabotulinumtoxinA) to treat adults with overactive bladder who cannot use or do not adequately respond to a class of medications known as anticholinergics. Botox is manufactured by Allergan Inc. based in Irvine, Calif.

Overactive bladder is a condition in which the bladder squeezes too often or squeezes without warning. Symptoms include leaking urine (urinary incontinence), feeling the sudden and urgent need to urinate, and frequent urination.

When Botox is injected into the bladder muscle, it causes the bladder to relax, increasing the bladder's storage capacity and reducing episodes of urinary incontinence. Injecting the bladder with Botox is performed using cystoscopy, a procedure that allows a doctor to visualize the interior of the bladder while Botox is being injected. (Source: FDA Website, 18 January, 2013)

FDA Approves Exjade to Remove Excess Iron in Patients with Genetic Blood Disorder

The FDA has expanded the approved use of Exjade (deferasirox) to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT), a milder form of thalassemia that does not require individuals to get frequent red blood cell transfusions. Over time, some patients with NTDT are still at risk for iron overload that can lead to damage to vital organs.

The FDA also authorized marketing of FerriScan as an imaging companion diagnostic for Exjade therapy in patients with NTDT. The agency previously cleared FerriScan for measuring liver iron concentration (LIC), but its use in Exjade clinical studies to select patients for therapy, and to manage therapy, defined its role as an imaging companion diagnostic necessary for Exjade's safe and effective use. FerriScan measures LIC non-invasively using magnetic resonance imaging.

Exjade is marketed by East Hanover, N.J.-based Novartis. FerriScan is marketed by Resonance Health, based in Australia. (Source: FDA Website, 23 January, 2013)

FDA Approves Gleevec for Children with Acute Lymphoblastic Leukemia

The FDA approved a new use of Gleevec (imatinib) to treat children newly diagnosed with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL). Gleevec is marketed by East Hanover, NJ-based Novartis.

ALL is the most common type of pediatric cancer, affecting approximately 2,900 children annually, and progresses quickly if untreated. Children with Ph+ ALL have a genetic abnormality that causes proteins called tyrosine kinases to stimulate the bone marrow to make too many immature white blood cells. This leaves less room for healthy white blood cells needed to fight infection.

Gleevec, a tyrosine kinase inhibitor, blocks the proteins that promote the development of cancerous cells. It should be used in combination with chemotherapy to treat children with Ph+ ALL.

Gleevec was granted accelerated approval in 2001 to treat patients with blast crisis, accelerated phase or

chronic phase Ph+ chronic myeloid leukemia (CML) who have failed interferon-alpha therapy. It has since been approved to treat several conditions, most recently regular approval to treat children newly diagnosed with Ph+ CML (2011) and regular approval to treat adults whose Kit (CD117)-positive gastrointestinal stromal tumors (GIST) have been surgically removed (2012). (Source: FDA Website, 25 January, 2013)

FDA Approves Three New Drug Treatments for Type 2 Diabetes

The FDA has approved three new related products for use with diet and exercise to improve blood sugar control in adults with type 2 diabetes: Nesina (alogliptin) tablets, Kazano (alogliptin and metformin hydrochloride) tablets, and Oseni (alogliptin and pioglitazone) tablets. All are distributed by Takeda Pharmaceuticals America, Inc., Deerfield, IL.

Alogliptin is a new active ingredient, while metformin hydrochloride and pioglitazone are already FDA-approved for the management of type 2 diabetes. As the most common form of the disease, type 2 diabetes affects about 24 million people and accounts for more than 90 percent of diabetes cases diagnosed in the United States.

People with type 2 diabetes are either resistant to insulin or do not produce enough insulin, resulting in high blood sugar levels. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney damage.

Nesina, Kazano, and Oseni were studied as stand-alone therapies (monotherapies) and in combination with other type 2 diabetes therapies, including sulfonylureas and insulin. They should not be used to treat people with type 1 diabetes or those who have increased ketones in their blood or urine (diabetic ketoacidosis). (Source: FDA Website, 25 January, 2013)

Federal Judge Approves Consent Decree with Ben Venue Laboratories

The FDA has announced that a federal judge has approved a consent decree of permanent injunction against Ben Venue Laboratories and three of its corporate officers for failing to comply with current good manufacturing practice requirements as required by federal law.

The action restrains Ben Venue Laboratories, a Boehringer Ingelheim Company, from manufacturing and distributing drugs from its Bedford, Ohio, facility until FDA determines that its operations are compliant with the Federal Food, Drug, and Cosmetic Act. Recent FDA inspections found several product quality problems, including particles in some sterile products and basic facility cleaning and maintenance issues. Poorly maintained equipment deteriorated to the point that it shed particles into injectable drugs.

Ben Venue has agreed to adhere to a strict timetable to bring the facility under compliance with regulatory requirements, or face substantial fines and other consequences as described in the decree. Under the decree, the FDA may order Ben Venue to stop manufacturing, recall products, and take other corrective action as necessary to ensure that patients receive safe and effective drugs. (Source: FDA Website, 31 January, 2013)

FDA Approves New Drug for the Chronic Management of Some Urea Cycle Disorders

The FDA has approved Ravicti (glycerol phenylbutyrate) for the chronic management of some urea cycle disorders (UCDs) in patients ages 2 years and older. Ravicti is marketed by Hyperion Therapeutics, based in South San Francisco, CA.

UCDs are genetic disorders that involve deficiencies of specific enzymes involved in the urea cycle, a series of biochemical steps normally required to remove ammonia from the blood. When protein is absorbed and broken down by the body, it produces nitrogen as a waste product. The urea cycle removes nitrogen from the blood and converts it to urea, which is removed from the body through urine. In people with UCDs, nitrogen accumulates and remains in the body as ammonia, which can travel to the brain and cause brain damage, coma or death.

Ravicti, a liquid taken three times a day with meals, helps dispose of ammonia in the body. It is intended for patients whose UCD cannot be managed by a protein-restricted diet or amino acid supplements alone. Ravicti must be used with a protein-restricted diet and, in some cases, dietary supplements.

Ravicti was reviewed under the agency's fast track program, designed to facilitate the development and expedite the review of drugs to treat serious diseases, fill unmet medical needs, and get important new drugs to patients earlier. Ravicti also was granted orphan product designation because it is intended to treat a rare disease. (Source: FDA Website, 01 February, 2013)

Generic Version of J & J Cancer Drug Doxil Expected to Help Resolve Shortage

The FDA has approved the first generic version of J & J's cancer drug Doxil (doxorubicin hydrochloride liposome injection).

Doxorubicin hydrochloride liposome injection is currently on the FDA's drug shortage list. For products on the shortage list, the FDA's Office of Generic Drugs is using a priority review system to expedite the review of generic applications to help alleviate shortages.

The generic is made by Sun Pharma Global FZE (Sun). Doxorubicin hydrochloride liposome injection is administered intravenously by a health care professional. Sun's generic will be available in 20 milligram and 50 milligram vials. (Source: FDA Website, 04 February, 2013)

FDA Offers New Guidance on Developing Drugs for Alzheimer's Disease

The FDA has issued a proposal designed to assist companies developing new treatments for patients in the early stages of Alzheimer's disease, before the onset of noticeable (overt) dementia.

Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks of daily living. In most people with Alzheimer's, symptoms first appear after age 60. Alzheimer's disease is the most common cause of dementia among older people.

The draft guidance titled, "Guidance for Industry, Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease," explains the FDA's current thinking about the way researchers can identify and select patients with early Alzheimer's disease, or those who are at risk of developing the disease, for participation in clinical trials. In recent years, the research community has tried to find ways to identify these patients using criteria that are based on biological indicators (biomarkers). Researchers have also tried to develop sensitive clinical measures that can detect subtle mental decline.

"This draft guidance is intended to serve as a focus for continued discussions between the FDA and pharmaceutical sponsors, the academic community, advocacy groups, and the public," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "The FDA is committed to vigorously addressing Alzheimer's disease and will work with industry to help develop new treatments in this early population as expeditiously as possible."

For drugs designed to treat patients with overt dementia, the FDA currently requires that treatments not only show an effect on abnormal thinking, but also how well patients function. The goal for these trials is to ensure that any beneficial effect on thinking is associated with a clinically meaningful outcome for the patient, e.g., improvement or lack of decline in how patients feel or function.

However, because patients with early Alzheimer's disease have little-to-no impairment of global functioning, it is difficult to assess changes in function in these patients. This can make it difficult to determine if a given treatment's effect is clinically important.

The FDA proposal is part of U.S. Department of Health and Human Services' efforts under the National Plan to Address Alzheimer's Disease, which calls for both the government and the private sector to intensify efforts to treat or prevent Alzheimer's and related dementias and to improve care and services. (Source: FDA Website, 07 February, 2013)

FDA Approves Pomalyst for Advanced Multiple Myeloma

The FDA approved Pomalyst (pomalidomide) to treat patients with multiple myeloma whose disease progressed after being treated with other cancer drugs. Multiple myeloma is a form of blood cancer that primarily affects older adults and arises from plasma cells in the bone marrow. According to the National Cancer Institute, approximately 21,700 Americans are diagnosed with multiple myeloma and 10,710 die yearly from the disease.

Pomalyst is a pill that modulates the body's immune system to destroy cancerous cells and inhibit their growth. It is intended for patients who have received at least two prior therapies, including lenalidomide and bortezomib, and whose disease did not respond to treatment and progressed within 60 days of the last treatment.

"Pomalyst is the third drug in a class of immunomodulatory agents that includes lenalidomide and thalidomide, and is the second drug approved in the past year to treat multiple myeloma," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in FDA's Center for Drug Evaluation and Research. "Treatment for multiple myeloma is tailored to meet individual patient's needs, and today's approval provides an additional treatment option for patients who have not responded to other drugs."

In July 2012, FDA approved Kyprolis (carfilzomib) to treat multiple myeloma. Similar to Kyprolis, Pomalyst is being approved under the agency's accelerated approval program, which provides patients earlier access to promising new drugs while the company conducts additional studies to confirm the drug's clinical benefit and safe use. The therapy was also granted orphan product designation because it is intended to treat a rare disease or condition.

Pomalyst carries a Boxed Warning alerting patients and health care professionals that the drug should not

be used in pregnant women because it can cause severe life-threatening birth defects, and that the drug can cause blood clots.

Pomalyst, lenalidomide and thalidomide are marketed by Celgene, based in Summit, NJ. Kyprolis is marketed by South San Francisco, CA-based Onyx Pharmaceuticals. (Source: FDA Website, 08 February, 2013)

J & J's TB Drug Sirturo Receives FDA Approval

The FDA has approved Sirturo (bedaquiline) as part of combination therapy to treat adults with multi-drug resistant pulmonary tuberculosis (TB) when other alternatives are not available.

TB is an infection caused by Mycobacterium tuberculosis and is one of the world's deadliest diseases. It is spread from person to person through the air and usually affects the lungs, but it can also affect other parts of the body such as the brain and kidneys. According to the CDC, nearly 9 million people around the world and 10,528 people in the United States became sick with TB in 2011.

Multi-drug resistant TB occurs when M. tuberculosis becomes resistant to isonazid and rifampin, two powerful drugs most commonly used to treat TB. Sirturo is the first drug approved to treat multi-drug resistant TB and should be used in combination with other drugs used to treat TB. Sirturo works by inhibiting an enzyme needed by M. tuberculosis to replicate and spread throughout the body.

Sirturo carries a Boxed Warning alerting patients and health care professionals that the drug can affect the heart's electrical activity, which could lead to an abnormal and potentially fatal heart rhythm. The Boxed Warning also notes deaths in patients treated with Sirturo.

Sirturo is being approved under the FDA's accelerated approval program, which allows the agency to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. This program provides patients earlier access to promising new drugs while the company conducts additional studies to confirm the drug's clinical benefit and safe use.

The FDA also granted Sirturo fast track designation, priority review and orphan-product designation. The drug demonstrated the potential to fill an unmet medical need, has the potential to provide safe and effective treatment where no satisfactory alternative therapy exists, and is intended to treat a rare disease, respectively.

Sirturo's manufacturer, Janssen Therapeutics, will distribute the drug from a single source and will provide educational materials to help ensure the drug is used appropriately. Janssen Therapeutics, a division of Janssen Products LP, is based in Titusville, NJ. (Source: FDA Website, 31 December, 2012)

FDA Seeks Additional Data on Novo Nordisk's Diabetes Drugs Tresiba and Ryzodeg

Novo Nordisk has announced that on 8 February 2013 it received a Complete Response Letter from the FDA regarding the New Drug Applications (NDAs) for Tresiba (insulin degludec) and Ryzodeg (insulin degludec/insulin aspart). A Complete Response Letter is issued by the FDA when the agency determines that an application cannot be approved in its current form.

In the letter, the FDA requests additional cardiovascular data from a dedicated cardiovascular outcomes trial before the review of the NDA can be completed. Novo Nordisk is evaluating the content of the Complete Response Letter and will work closely with the FDA to provide the requested data. Novo Nordisk does not expect to be able to provide the requested data during 2013.

In the letter, the FDA also states that approvals for Tresiba® and Ryzodeg® cannot be granted until the violations cited in the previously announced Warning Letter, dated 12 December 2012, have been resolved.

The NDAs for Tresiba and Ryzodeg were submitted by Novo Nordisk to the FDA in September 2011. In November 2012, at an FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting, a panel of independent scientific experts unanimously recommended that a cardiovascular outcomes trial should be conducted and voted eight to four in favor of approving the products with a post-approval cardiovascular outcomes trial commitment.

Tresiba and Ryzodeg are approved in Japan, the EU and Mexico and under regulatory review in a number of countries throughout the world. The Complete Response Letter is not expected to significantly impact Novo Nordisk's expectations for the company's financial results for 2013. (Source: Novo Nordisk Website, 10 February, 2013)

New Members

Sergio O. Alvarez-Romero, *Student,* Worcester Polytechnic Institute

Mr. Jonathan Michael Bean, *Facilities Engineer,* Massachusetts Maritime Academy

Michael Burke, *Validation Specialist,* Genzyme

Mrs. Anne M. Butterworth, *Manager, QC Microbiology,* Lantheus Medical Imaging

Mr. Miguel Chavarria, *Sr. Technical Manager,* Genentech

Mr. John H. Concannon, *Senior Project Manager,* Integrated Builders

Kyle Cousin

Laura E. Crowell, *Student,* Tufts University

Mr. Gabriel A. Dakowicz, *Validation Eng,* IPS

Selena Di Maio, *PhD Candidate,* Northeastern University

Mr. Bruce L. Doran, *President,* Diagnosys LLC

Mr. Michael Englert, *Sr Supervisor Instrumentation,* Pfizer

Steven J. Ferris, *Director of Quality,* Pharmalucence, Inc.

Joe S. Fitzpatrick, *BIM Manager,* DPS Biometics

Mr. Gary M. Garfield, *Principal Engineer,* URS Corporation

Mr. Daryl J. George, *Junior Field Engineer,* CrossPoint Engineering

Maria Del Lourdes Gomez-Lara, *Student,* Worcester Polytechnic Institute

Christopher R. Gould-Kelley, *Project Engineer,* Architectural Environments, Inc.

Geoffrey Grove, *Product Manager,* SOTAX

Khiem Le

George Y. Lee, *Senior Associate Scientist,* Pfizer

Ms. Christie Martin, *Product Manager,* Mettler-Toledo

Ms. Jennifer M. Morgan, *Supply Chain Lead,* Pfizer

Thomas O'Brien, *Group Manager,* RoviSys

Mr. Mark A. Omobono, *Process Engineer,* Genzyme Corporation

Mr. Srini Paluri, *Global Strategic Account Leader,* Emerson Process Management

Mr. Steve A. Payne, *Sales Manager Pharma,* M. Braun, Inc.

Ms. Theresa S. Pinnell, *Manager, Business Developement,* ProPharma Group

Mr. Andre Porto, *Student,* Umass Amherst

Mr. Roman Vincent Rodriguez, *Group Product Manager,* EMD Millipore

Ms. Sowmya Selvanathan, *Process Engineer,* Genzyme Corp

Mr. Phil Seymour, *Operations Manager,* Waltham Services

Tim Southwick, *Senior Consultant,* Eliassen Group

Kassi Stein, *Student,* Northeastern University

Mr. David J. Sullivan, *Sr. Manager Bioprocess R&D,* Pfizer

Mr. John E. Thomas, *Co-Owner,* NextGen Energy Solutions

Mr. Justin D. Tousignant, *President,* Black Bear Coatings & Concrete

Ms. Kang Wu, *Assistant Professor,* University of New Hampshire

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

Mr. Richard P. Capobianco

Mr. Raymond J. Cardin, PharMax Consulting LLC

Mr. Michael S. Cheney, Biogen Idec

Ms. Denise R. Connelly, Genzyme Corp

Dr. Charles L. Cooney, Massachusetts Institute of Technology

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

Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. Daniel J. Dumont, Dynamic Systems Inc

Mr. John H. Evers, Lantheus Medical Imaging

Mr. Henry Fitzgerald

Mr. William R. Fraga

Dr. Dan M. Gee, gTechBio

Dr. Roy F. Greenwald, DENS Partners, Inc.

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

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

Mr. David C. Hardy

Mr. Edwin L. Harmon, III, Genzyme Corp

Mr. David G. Harney, Microfluidics

Ms. Shelly Henderson, NNE Pharmaplan

Mr. Stephen R. Higham, PE, Genzyme Corp

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

Mr. Thomas R. Jerome

Mr. Robert W. Juffras, MS, Olympus Biotech

Mr. Jerome E. Justin, Shire HGT

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

Peter F. Levy, PL Consulting, LLC

Dr. Richard V. Levy, PDA

Mr. Dwight C. Long, Integra Companies Inc

Mr. Frank J. Manning, VNE Corp

Mr. Daniel J. Mariani, M+W Group

Mr. H. Stafford McCoart, Stafford Technical Sales

Dr. Robert C. Menson, PhD, Menson & Associates Inc

Mr. Hank Moes

Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc

Mr. Thomas W. Moss, Applied Process Solutions, Inc

Mr. Armen J. Nahabedian, Pfizer

Mr. Christopher R. Perley, Biotech Ops Consultants

Mr. Stephen R. Potter, Baxter

Mr. Richard D. Priester, Strategic Facility Planning LLC

Dr. John J. Prior, Genzyme Corp

Mr. Thomas A. Ramundo, New England Controls Inc

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Mr. Robert J. Sheehan

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

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

Mr. James D. Vogel, PE, The BioProcess Institute

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

15 Year Anniversary

Mr. Thomas E. McLaughlin, Process Energy Measurements Corp

Mr. Timothy C. Myott, Cubist

10 Year Anniversary

Mr. Kevin Caffrey, Abec Inc

Mr. Michael W. Mietzner, Lonza Biologics Inc.

Mr. Wilburn M. Miller, Lonza Biologics Inc

Mr. Jeffrey D. Neault, Shire

5 Year Anniversary

Mr. Liam M. Casey, New England Controls

Ms. Jennifer M. Duffy, Shire

Mr. Jason W. Kuc, Spirax Sarco Inc

Mr. Joseph Naughton, RF Walsh Project Management

Mr. Krishnan Ramanathan, Enerquip, LLC

Mr. John P. Seffernick, New England Controls

Ms. Catherine Simard, Shire HGT

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