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## Boston Area Chapter

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NEWSLETTER

May 2013, Volume XXIII, No. 3

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### President's Message: We're Number One!



Dear Fellow Boston Area Chapter Members,

Most of the President's Messages I have had the privilege to write have focused on the success of our Chapter. And this one is no different. However, sadly, this time I must begin by expressing my sorrow regarding the Boston Marathon bombings. I am writing this only three short days after this horrific occurrence, with the news accounts and images freshly in mind, and extend my heartfelt sympathy to all those directly or indirectly affected.

Furthermore, the tragedy has hit especially close to home. Kevin Chronley, New England Chapter President, was informed that close family members were at the marathon finish line and were severely injured. Our hearts go out to Kevin and his family. We wish them the best possible outcome and hope for justice for them and all the victims of this senseless and tragic event.

Moving on to Chapter business, although it is hard to celebrate in the wake of what has just happened, I want to call attention to the fact that we made it - our Chapter is now Number One! According to ISPE International, as of March 31, the Boston Area Chapter was tied with the New Jersey Chapter for the most Members in the world at 1241. In addition, our Member retention rate increased to 81.8 percent compared to 72.3 percent for New Jersey. Even better, our own records show that as of April 4, just four short days later, we had added another 13 members for a grand total of 1254 and climbing! So I am unofficially going out on a limb and declaring that we are Number One!

We couldn't have done it without the hard work of all those involved so I want to say a special thank you this month to everyone, past and present, who has helped our Chapter become the powerhouse it is today. Now for the latest update:

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- **Membership Growth**

Our goal this year is to add 50 new regular Members and 15 Young Professional Members. I am happy to report that we are back on track, with 8 regular and 10 Young Professional Members added since my last update, and our Member retention rate is up again as well at 81.8 percent. This is fantastic and attests to the fact that we continue to provide exceptional value to our members.

- **Student Chapter Growth and Development**

Our goal for Student Chapters this year is 50 new Student Members. As stated in the last newsletter, our student membership dropped slightly but was expected to skyrocket with our renewed focus on student outreach and the many student activities planned (see related article elsewhere in this issue). Thanks to the hard work of Past President Brian Hagopian, CPIP, and an active team of Chapter volunteers, we have not only recovered the Student Members we dropped, but are now 8 ahead for a total of 15 new student members! Way to go!

- **Educational Program Excellence**

What can I say, we continue to bring first class educational events to the membership and will continue to do so. As an example, our outstanding April program at WPI in Worcester attracted over 100 attendees with its dual-track educational presentations plus facility tour - a record for 2013!

Together we will 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. And here is a little tease - look for a very exciting announcement coming shortly!

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 Professionals™ (CPIPs). The latest additions are:

- Can Aktar, CPIP, Independent Consultant

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 imagination at work

- Scott D. Mackley, Project Manager, Commissioning Agents, Inc.
- Alan F. O'Driscoll, CPIP, Lead Process Engineer, Jacobs Engineering

Congratulations to Alan and Scott, who both participated in the CPIP Study Group held at Genzyme Framingham during the fall of 2012, and to Can, who qualified without the assistance of study group participation. Can, Scott, and Alan bring the total number of CPIPs from the Boston Area Chapter to 19. And we expect the spring study group now underway (see below) to add to this total. Good luck to the 28 Members participating!

#### Student Members Invited to Attend Educational Programs - for Free!

The Chapter Board of Directors has gone "all in" when it comes to providing pathways for students to become involved with ISPE. In its latest effort to encourage a high level of student participation, the Board of Directors has voted to allow student members to attend Chapter educational and related events for free! Simply join ISPE (at [www.ispe.org/join-or-renew](http://www.ispe.org/join-or-renew) at the \$20 student rate) and you can attend any and all Chapter educational events at no charge. Membership in the ISPE Boston Area Chapter truly does have its privileges!

#### \$2K Scholarships Available - Applications Due June 15

The next round of Joel Goldenberg Memorial Scholarship applications are due on

June 15. Individual scholarship awards of up to \$2,000 are available and this year's fund has been increased from \$10K to \$20K in anticipation of additional applicants. Boston Area Chapter student members and others are eligible. To see if you qualify, check out the "Scholarship Program" tab on the Chapter's website at [www.ispeboston.org](http://www.ispeboston.org) for more information and an application.

#### Spring CPIP™ Study Group Underway at Sunovion in Marlborough, MA

The Spring 2013 CPIP Study Group is off and running at Sunovion Pharmaceuticals in Marlborough, MA with 28 Members from the New England and Boston Area Chapters participating. This is the fifth study group sponsored by the Boston Area Chapter and the third led by John Spohn, CPIP, assisted by a team of area CPIPs. The course comprises nine, three-hour sessions and will wrap up on June 4.

To date, the Chapter's study groups have produced over 35 percent of the world's CPIPs, many of whom are practicing their craft locally. Since we last reported results, the Chapter has added two more CPIPs to the total (see above). We are proud of their achievements and look forward to adding several more new CPIPs from the current study group. Best of luck to those currently enrolled! For more information on CPIP™ please visit <http://www.ispe.org/certified-pharmaceutical-industry-professional>

#### 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*

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*Engineering* magazine, along with all other Member benefits. Contact the international ISPE office at [memberservices@ispe.org](mailto:memberservices@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](mailto: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 [www.ispeboston.org](http://www.ispeboston.org) to learn more about the many volunteer opportunities available.

#### Advertise on [www.ispeboston.org](http://www.ispeboston.org)

Did you know the Boston Area Chapter Website attracts over 8,000 visits monthly from the region's life sciences professionals? Now you can reach the same audience by advertising on [www.ispeboston.org](http://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](mailto:office@ispeboston.org).

#### Become a Chapter Sponsor Today - We've Just Made it Easier and Added a Discount!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at [www.ispeboston.org/sponsorship\\_application.html](http://www.ispeboston.org/sponsorship_application.html). In addition to all the information you need to know regarding the variety of sponsorship opportunities available, you can make your choices and pay by credit card online. And the more you spend, the bigger your discount, also calculated live, online. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

#### Upcoming Chapter Events - Mark Your Calendar

**Thursday, May 16, 2013**

**AUTOMATION: At the Crossroads with IT Interfaces**  
Genzyme Center, 500 Kendall Street, Cambridge, MA 02142

In January 2011, the FDA issued new Guidance for Industry on Process Validation, which replaced guidance issued over 20 years ago. The FDA Guidance is intended to align Process Validation practices with a "lifecycle" concept as well as with the principles outlined in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality Systems). This session will review the FDA Guidance just issued, and will summarize the efforts of ISPE's Process Validation Implementation Team, including some practical considerations for implementing the new approach. In addition, observations from establishing a Stage 3 "Continued Process Verification" program for legacy products will be shared, including challenges and lessons learned.

PRESENTATION ONE:

"Process Data Management and the Changing Role of the Automation Engineer"  
Speaker: Jordan Croteau, Automation Engineer, Biogen Idec

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**PRESENTATION TWO:**

"Implementing an Equipment Monitoring System with an Operations Information Infrastructure"

Speaker: Kenneth S. Kovacs, QA Business Systems Manager, Fujirebio Diagnostics, Inc.

Speaker: Glenn Restivo, Director of Business Development Life Sciences, Chemicals, Food, and Nutrition, M+W Automation

Register Today: [http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=295](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=295)

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**Wednesday, October 2, 2013**

**22nd Annual Product Show**

**Exhibitor Registration Now Available Online!**

ISPE + is the theme for this year's Show. It means being greater than the sum of our parts. Be a part of the greater sum and exhibit at the 22nd Annual Product Show at Gillette Stadium in Foxborough, MA. With an expanded exhibition area + education sessions + career fair + vendor show case + entertainment zone + after party + even more to be announced soon, this year's Show promises to be better than ever. Reserve your space today and become one of the great parts bringing members, educators and customers together.

Exhibitors, Register Here:

[http://www.ispeboston.org/ProductShow/vendor\\_registration\\_page1.html?formName=Exhibitor%20Registration](http://www.ispeboston.org/ProductShow/vendor_registration_page1.html?formName=Exhibitor%20Registration)

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**Sneak Preview of Upcoming Events**

**Thursday, June 20, 2013**

Educational Program focusing on Validation

**Monday, July 29, 2013**

Annual Golf Tournament

**Thursday, September 19, 2013**

Educational Program focusing on CIP & SIP

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## Mother Nature Smiles on Chapter Ski Trip to Loon Mountain

*text & photos by Chris Opolski, Alexion Pharmaceuticals*

On March 1<sup>st</sup> forty-eight skiers and boarders braved another early morning start, boarded a bus or drove, and headed north to the White Mountains in search of powder skiing. It was another beautiful day for skiing with seasonable temperatures, blue skies, and a few clouds.

After getting off the bus and unpacking the ski equipment, Gene Dennen, our tour guide for the day, passed out tickets and wished us all happy skiing. It was one of the best March days of skiing at Loon Mountain in long time. The snow the region received earlier in the week and the cold temperatures kept the white stuff in great condition. The following picture includes a part of the group that managed to meet at the Camp III lodge.



One thing to remember is that none of us are professional skiers, or at least we don't think so after a day of skiing like we had in March. Fortunately we are a kind and generous bunch and we are always willing to help our fellow members, even when they "yard sale" across the mountain.





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After the long day of skiing and a few falls, the entire group met at the Bunyan Room to enjoy scrumptious appetizers and many cold beverages. There was much socializing, meeting up with old friends or meeting new ones, and of course chatting about the great skiing conditions. We were fortunate to be entertained by a local musician jamming and playing his guitar at the bar. Oh and there was a little bit of dancing too... sorry no pictures!!

So after a few long stops for provisions, the bus headed south while everyone enjoyed another fine ski trip appropriate movie. It was a long ride home back to Massachusetts and for some Rhode Island, but everyone arrived safe and sound with many fond memories.

A special thank you to our event sponsors. Without their continued support for events like the golf tournament or ski trip, none of these events would be possible. The sponsors were:

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And finally a huge amount of thanks goes out (again!) to Gene Dennen for the fabulous efforts organizing this year's ski event. He has coordinated this trip for many years and it's always a great time. And this time he got the weather just right! Thanks, Gene!

Hope to see you on the slopes next year! If you have any suggestions on how to make the ski trip better or would like to volunteer on the social committee or any other Boston Area Chapter committees please contact the Chapter at [office@ispeboston.org](mailto:office@ispeboston.org).

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## Newsletter Archive

## Subject Matter Experts Illuminate Science and Risk-Based C&Q

*by Armen Nahabedian, Pfizer, and Dan Ramsey, Commissioning Agents, with photos by Joyce Chiu, CPIP, Honeywell Safety Products and Brian Hagopian, CPIP, Clear Water Consulting*

On March 21, the Boston Area Chapter hosted an educational program entitled "The Science and Risk Based Approach to C&Q: The Road to ASME E2500." Distinguished speakers, Steve Wisniewski, Principle Compliance Consultant, Commissioning Agents, and Dave Dolgin, Senior Quality Program Manager, Quality Systems Group, AbbVie (formerly Abbott), combined their expertise to present a comprehensive introduction to the topic. For the first time, the event was held at the law offices of Goulston & Storrs on Atlantic Avenue in Boston, which proved to be superb venue for an educational program.



The Boston offices of law firm Goulston & Storrs provided an elegant venue for the March educational program.

Both speakers were integral to the development and publishing of the two recent ISPE documents - "ISPE Guide: Science and Risk Based-Approach for the Delivery of Facilities, Systems, and Equipment" and "Good Practice Guide - Applied Risk Management for C&Q" - and have extensive experience applying the approaches outlined in the documents. In addition, they have spoken extensively on the subject at local, national and international ISPE events. As a result, the audience was treated to polished presentations of the most up-to-date thinking and practices on the subject.

Steve Wisniewski outlined the content of the ISPE Guide on the science and risk-based approach. 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. Although the ASTM and ICH documents indicate the "What" in defining a science and risk-based approach to system verification, the "How" of practical and efficient implementation of the supporting work processes had not been fully described and associated best practices had not been developed. Steve brought the audience through the key elements of the guide, which 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 (QBD) concepts.



Chapter Members Alan O'Driscoll, Aarash Navabi and Andrew Mwase enjoy the networking reception preceding the presentations.

Dave Dolgin outlined how the ISPE C&Q Community of Practice (COP) formed a task team (which he led) to develop the "Good Practice Guide - Applied Risk Management for C&Q." The Good Practice Guide maps possible transition strategies for practitioners to take when moving from the traditional or "Baseline Guide 5" C&Q approach based on impact assessment to ICH Q9/ASTM quality risk management implementation. The task team was comprised of leading pharma and biotech companies all actively transitioning to the new approach. Each of the companies had made strategic decisions regarding the extent of implementation, with some choosing to apply only some of the key principles and others choosing a complete transition. For example, one company chose to apply all the principles outlined in the guides while continuing to use the nomenclature of IQ/OQ/PQ; while another moved to the general terminology of Verification Testing.

Following the formal presentations, both Steve and Dave were peppered with questions from the audience,

always a good sign that their presentations had been well-received. In a follow-up conversation I had with them several days later, both described being impressed by the depth of the questions and stated that the Boston Area Chapter companies seem to have the best grasp of science and risk-based approaches compared to other ISPE events they have spoken at or attended. This compliment underscores the vibrant biotech/pharma community in greater Boston and the value that ISPE and our local Chapter brings to the area by offering the most current and practical information available in the industry today.

In closing, the Chapter and the Educational Program Committee would like to thank our hosts, our distinguished speakers and our audience for combining to make this an enjoyable and extremely informative event.

## Chapter Leaders Seek to Aid Efforts to Bring Pharma Manufacturing to Massachusetts

*by Jack Campion, Genzyme*

Several members of the Boston Area Chapter Board of Directors attended a presentation of the Boston Foundation on March 26 reporting on the first 4.5 years of the Massachusetts Life Sciences Initiative as led by the Massachusetts Life Sciences Center (MLSC). The Chapter's Board is also seeking to collaborate with the Center on their efforts to bring new pharma manufacturing to Massachusetts. This gathering provided an excellent opportunity for Chapter leaders to meet key players from local industry and the MLSC as a first step toward this goal.

The one-billion-dollar 10-year Initiative supports development of biotechnology enterprises at all levels through a variety of programs including grants, loans, tax incentives and internship funding. Recipients have included entities ranging in size and type from Shire HGT to Dyax to UMASS Lowell. The Center funds research, development, educational, capital "infrastructure" and other projects.

The Initiative and the Center were studied by the Dukakis Center for Urban and Regional Policy at Northeastern University for their effectiveness at meeting the economic development objectives established at the outset. They were given generally high grades for accomplishments, efficiency and objectivity.

The MLSC has distributed about \$301 million in the first four years of its intended 10-year lifespan - less than the average annual output for a 10-year, billion-dollar program. This is in part due to lack of full funding by the legislature. Several presenters appealed for both full funding and extension of the Initiative beyond ten years.

The report entitled "Life Sciences Innovation as a Catalyst for Economic Development: The Role of the Massachusetts Life Sciences Center" and is available on the Boston Foundation's website: [http://www.tbf.org/~media/TBFOrg/Files/Reports/LifeSciences\\_%C6%92.pdf](http://www.tbf.org/~media/TBFOrg/Files/Reports/LifeSciences_%C6%92.pdf)

In addition to promoting "home-grown" firms, the MLSC actively works to recruit new life science companies into the Commonwealth. However, their emphasis is directed toward firms at early stages of drug development and less toward expansion of the manufacturing base. To bolster the incentives for companies to locate their new manufacturing in the Commonwealth, the Boston Area Chapter has a new initiative of its own.

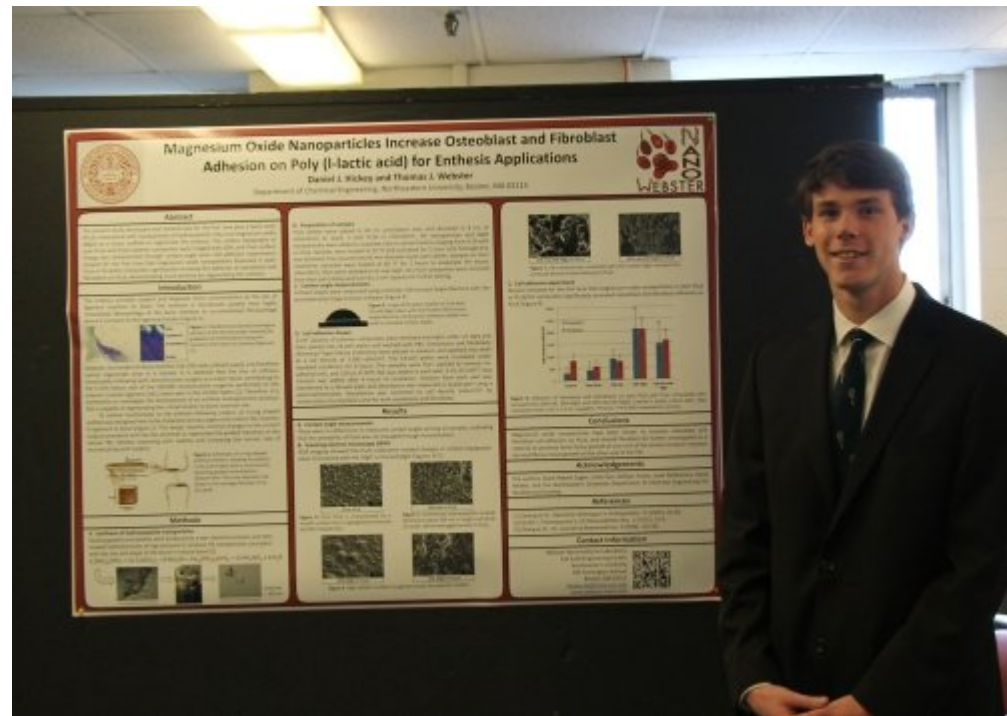
Working with the MLSC, the Chapter hopes to enhance the message and add to the "value proposition" delivered by the Center to prospective pharmaceutical manufacturers. We are convinced that the area's vast infrastructure of pharmaceutical professionals and service providers, especially as represented by the membership, educational and information resources of our distinguished Chapter, is a critical but unheralded asset to firms considering our area for the manufacture of pharmaceuticals. Chapter representatives will be presenting these ideas to MLSC officials later this month.

FDA Commissioner Margaret Hamburg said last month in Boston that the area is a "biotech supercluster second to none." The Chapter is acting to add our voice to the "harmonious chorus" working to sustain and extend this status as a global center for pharmaceutical innovation and production."

## Chapter Increases Investment in Students

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

How would you like to see what the future holds for ISPE and the local biotech industry? Well, it's easier than you think – just check out the many activities the Chapter has put in place for our Student Members. Students are the "pipeline to the future" and the Chapter is busily investing in this important group, with several programs designed specifically for students to be held this spring, including educational programs, plant tours, and career development events.



Northeastern's Dan Hickey was the proud winner of the graduate student competition. Congratulations, Dan!

The Chapter held its "first annual" Student Career Forum on March 30 at the Northeastern Alumni Center where students learned all about how to compose cover letters, focus a resume toward life sciences, make a good first impression during an interview, begin to build a network of contacts and develop a career path. The interactive session was moderated by Brian Hagopian, chair of the Student Development Committee.



Alison Neely from Biogen Idec led an open discussion where a few sample cover letters and resumes were critiqued for content and effectiveness. Furiously jotting notes, students took away many practical tips that they could use to improve their chances in the workplace.

Brian Hagopian from Clear Water Consulting led the group through making a positive first impression when interviewing. Next, Neda Zahid (AbbVie) and Sean Burgess (Integrated Builders), two of the Chapter's dedicated young professionals, starred in a role playing exercise where students got some real world experience on good and bad interviewing techniques. Lastly, students were taken out of their "comfort zone" during a group "networking exercise" where they were asked to meet and greet perfect strangers.

Carson Burrington from Kelly Scientific provided insights into resume presentation and networking. Veteran Chapter members Dan Ramsey from Commissioning Agents and Rick Pierro from Superior Controls shared insights on their respective career paths and the positive influence that ISPE played in their career development.

ISPE Student Members from Northeastern, Harvard, Boston University, and Worcester Polytechnic Institute all participated and many said this was one of the most informative career development events they had ever attended! As word begins to get out about the quality of the programs being offered by ISPE, more students will learn about the benefits of belonging to ISPE. Many thanks to all of the presenters who gave up their Saturday to help students!

The Career Forum was followed by the annual "Student Poster Competition" on April 13. Two winners were selected to represent the Chapter at the ISPE Annual Meeting in November. In the undergraduate category, Kassi Stein and Miglia Cornejo presented their research on production of cancer fighting drugs using plant roots. In the graduate category, Dan Hickey described his research into the use of nanoparticles to improve the adhesion of ligaments to bones after injuries like an ACL tear. They will be continuing their research over the summer and will present their work at the Product Show on October 2 prior to competing at Annual Meeting.

The Career Forum and Poster Contest kicked off a full slate of events for students planned by the Chapter for the rest of the spring semester. These include:

- Biotech 101 Educational Program at WPI - April 18
- Plant tour of AbbVie in Worcester - April 22
- Validation 101 Educational Program at Tufts Gordon Institute - June 20
- Boston Harbor Cruise

In addition, the Chapter is looking ahead to next fall and already has events planned for students, including:

- Bus transportation to Gillette Stadium for the Product Show on October 2
- Genzyme plant tour

The Chapter Board of Directors has gone "all in" when it comes to providing pathways for students to become involved with ISPE. Just last week, the Board showed its foresight and generosity by voting to allow Student Members to attend Chapter educational and related events for free! Simply join ISPE (at [www.ispe.org/join-or-renew](http://www.ispe.org/join-or-renew) at the \$20 student rate) and you can attend any and all Chapter educational events at no charge. Membership in the ISPE Boston Area Chapter truly does have its privileges!

And last – but by no means least - the next round of Joel Goldenberg Memorial Scholarship applications are due on June 15. Individual scholarship awards of up to \$2,000 are available and this year's fund has been increased from \$10K to \$20K in anticipation of additional applicants. Boston Area Chapter student members and others are eligible. To see if you qualify, check out the "Scholarship Program" tab on the Chapter's website for more information and an application.

For a complete calendar of upcoming events, visit the Chapter website at [www.ISPEBoston.org](http://www.ISPEBoston.org).

### YPs Fill Spring & Summer Calendar with Activities

*text by Dave Gallagher, GxP Automation with photos by Joyce Chiu, CPIP, Honeywell Safety Products*

Happy spring everyone! Hopefully the cold weather is finally gone for the year, and we can start looking forward to the spring and summer. With that said, the YPs kicked off the spring season with their first (and hopefully annual) social event at the Medieval Manor in Boston. The event had a great turnout with many YPs as well as regular Members. The evening began with a casual meet and greet at the bar, then migrated over to the main show where everyone shared an abundance of laughs as the king and his entertainers took us through the Dark Ages. It really was a "one-of-a-kind" type of entertainment as everyone feasted on six courses without fork, knife, or spoon! Special thanks to Sean Burgess of Integrated Builders for sponsoring and organizing the event.



A spirited musical intro to the Dark Ages provided entertainment during the feast.

On April 18, the YPs sponsored the introductory Biotech 101 portion of the evening's "dual-track" educational program which also included a presentation on process validation for the Chapter's more experienced Members. A tour of the WPI Bioengineering Center rounded out the evening. This type of event has had success in previous years due to its wide appeal and sold out early again this year. Biotech 101 described how biotech-based drugs are made, the typical systems required to maintain a robust biotech manufacturing facility and the critical quality attributes and process parameters associated with manufacturing a biotech drug. For YP Members new to the industry or seasoned veterans wanting to review

basic concepts, this behind-the-scenes look into drug manufacturing enhanced the understanding of how a single cell is turned into a lifesaving therapy.



One of the first YPs brave enough to venture onstage was YPC Chair Andrea Massa.

The YPs are also planning a variety of outdoor activities for the upcoming summer months. These include a Red Sox game, the annual softball challenge (hopefully the YPs can perform better against the seasoned vets than they did last year!) and the always-popular Boston Harbor cruise. There is also a possible bowling challenge on the radar if we can squeeze it into the summer schedule! Stay tuned for more updates in the coming months.





Medieval Manor...definitely NOT your typical ISPE gathering!

### Industry News in Brief

*by Janet Tice, GMP Piping*

**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.

#### **Bristol-Myers Squibb Announces 350 Jobs, Devens Expansion**

Bristol-Myers Squibb will expand its Devens facility, investing \$250 million and adding 350 workers, the company has announced. The firm said it will construct two new buildings totaling 200,000 square feet on its 89-acre campus. One will be dedicated to designing processes for early production of investigational biologics medicines. The other will house clinical manufacturing, where investigational medicines will be produced to support clinical trials.

"Biologics are increasingly important in the treatment of serious diseases and are a growing part of our company's pipeline of potential new therapies," said Lou Schmukler, president of global manufacturing & supply. "This initiative is designed to accelerate the development of new biologics medicines through the closer alignment of biologics research and development, and manufacturing."

The campus already has six buildings creating a 400,000-square-foot complex completed in 2009. It was

Bristol-Myers Squibb's first major investment in Massachusetts and, at \$750 million, its largest capital investment. It was designed to accommodate future expansion, the company said. Construction is expected to begin late this year and be completed in 2015. Until then, the company said it is leasing 30,000 square feet of lab space in Hopkinton.

According to BMS, the decision to expand reflects the initial success the company has had in Devens, as well as factors that initially drew it to the area such as "the abundance of biotechnology knowledge, education and training in the Boston area, which has created a large and well-qualified workforce, as well as the inception of the state's Life Sciences Initiative."

Through the initiative, \$1 billion is being invested in the life sciences industry in Massachusetts over a decade. (Source: Jacquelyn Gutc, WBJournal.com, 11 April, 2013)

### **Thermo Fisher's to Acquire Life Technologies for \$13.6 Billion**

Waltham-based Thermo Fisher Scientific, which has facilities in Franklin and Milford, will grow by nearly a third early next year when it acquires a California-based biotechnology manufacturer for \$13.6 billion. The intended purchase of Life Technologies is Thermo's largest deal since 2006 and is expected to increase its position in the DNA sequencing market. The deal is expected to close early next year.

After an acquisition-heavy 2011, Thermo only acquired one company in 2012 - transplant diagnostics firm One Lambda Inc. - in a \$925 million deal. The Life acquisition would be its largest transaction since 2006, when the \$12.8 billion merger of Fisher Scientific and Thermo Electronic created the company's current namesake.

More than 80 percent of Life's revenue comes from consumable products for the life science industry, including lab tools for gene expression, cellular research and sample preparation. Meanwhile, Thermo's leading revenue drivers are its analytical technologies and lab products and services divisions. Together, Thermo and Life would have more than \$16 billion in annual revenue, 50,000 employees across the world and the largest research and development budget in the industry, executives for each said on a conference call Friday.

"Very simply put this is a story about 2 industry leaders joining forces to create an even stronger industry leader," said Marc N. Casper, Thermo's president and CEO. "We look forward to adding 10,000 new colleagues to our team." Thermo said it expects to generate \$275 million in operating synergies by 2017, achieved by eliminating redundant public company reporting costs and consolidating some facilities (though it did not say which).

The acquisition of Life comes with the company's DNA sequencing technology, called Ion Torrent, which Life acquired in 2010 for \$375 million. Instead of using light to sequence DNA, Ion uses semiconductor technology to translate chemical signals into digital information, according to Life's website. The goal is to reduce sequencing costs. While Thermo has been a supplier of reagent for some sequencing companies, its purchase of Life will launch it squarely onto a short list of the biggest players in the rapidly evolving space. (Source: Matt Pilon, WBJournal.com, 16 April, 2013)

### **Pfizer to Relocate Alewife Workers to Kendall Square**

Pfizer has said it is planning to relocate the majority of its 530 employees at research facilities in Cambridge's Alewife neighborhood to Kendall Square sometime next year, joining roughly 400 Pfizer employees who are already working in Kendall Square. Pfizer said it plans to hire a broker to explore either

selling or subleasing four buildings in Cambridge, including three on Cambridge Park Drive in Alewife.

Pfizer said one reason for the move is that it is looking to make the most efficient use of its global real estate. Another reason: Pfizer wants to create a single, integrated research-and-development community that can easily access and collaborate with biomedical researchers and other partners.

In Kendall Square, meanwhile, a building at 610 Main St. is under construction. Pfizer expects that building to be ready for occupancy early next year. Most employees from Alewife will move there. Other Alewife employees will relocate to an existing Pfizer space at 700 Main St., though others could be transferred to a complex in Andover, Pfizer said. "We expect that there will be minimal impact to the size of Pfizer's workforce in the state of Massachusetts...", a Pfizer spokeswoman said. (Source: Chris Reidy, The Boston Globe, 12 April, 2013)

### **Moderna Therapeutics to License Technology to AstraZeneca**

AstraZeneca has announced an exclusive agreement with Moderna Therapeutics to discover, develop and commercialise pioneering messenger RNA therapeutics for the treatment of serious cardiovascular, metabolic and renal diseases as well as cancer. Messenger RNA therapeutics is an entirely new treatment approach that enables the body to produce therapeutic protein *in vivo*, opening up new treatment options for a wide range of diseases that cannot be addressed today using existing technologies.

Under the terms of the agreement, AstraZeneca will make an upfront payment of \$240 million. AstraZeneca will have exclusive access to select any target of its choice in cardiometabolic diseases, as well as selected targets in oncology, over a period of up to five years for subsequent development of messenger RNA. In addition, Moderna is entitled to an additional \$180 million for the achievement of three technical milestones.

Through this agreement, AstraZeneca has the option to select up to 40 drug products for clinical development and Moderna will be entitled to development and commercial milestone payments as well as royalties on drug sales ranging from high single digits to low double digits for each product. AstraZeneca will lead the preclinical, clinical development and commercialization of therapeutics resulting from the agreement and Moderna will be responsible for designing and manufacturing the messenger RNA against selected targets.

Moderna's unique approach uses proprietary messenger RNA containing naturally occurring nucleotide analogues, which are designed to stimulate the body's natural ability to produce intracellular and secreted therapeutic proteins without triggering an innate immune response. The secreted proteins will be released into the bloodstream to potentially restore function elsewhere in the body. Using messenger RNA also has the potential advantage of dramatically reducing the time and expense associated with creating therapeutic proteins using current recombinant technologies. (Source: Moderna Therapeutics Website, 21 March, 2013)

### **AstraZeneca to Establish Strategic R&D Centers, Add 80 Jobs in Waltham**

AstraZeneca has announced plans to invest in strategic research and development centers in the UK, the US and Sweden to improve pipeline productivity and to establish the company as a global leader in biopharmaceutical innovation. The proposals are designed to locate more of the company's scientists close to globally recognized bioscience clusters; bring teams together to improve collaboration and to create a more vibrant environment that puts science and the patient at the heart of everything the company does; and simplify the company's footprint to reduce complexity and eliminate unnecessary cost.

Under the plans, AstraZeneca's small molecule and biologics R&D activities will be concentrated in three strategic centers: Cambridge, UK; Gaithersburg, US; and Mölndal, Sweden. The proposals are expected to be fully implemented by 2016. The changes will lead to an estimated overall reduction of about 650



positions in the US; while around 170 will relocate to other AstraZeneca sites in the US or overseas. Wilmington, Delaware will remain the North America commercial headquarters, with a population of about 2,000 at the AstraZeneca site.

According to a report in the Boston Globe, over the next two years the global restructuring will add 80 jobs to the 460 currently at AstraZeneca's Waltham R&D center. (Source: AstraZeneca Website, 18 March, 2013 & Robert Weisman, The Boston Globe, 19 March, 2013)

### **GlaxoSmithKline to Close Sirtris Unit in Cambridge**

While other major pharmaceutical companies are scrambling for a spot in Kendall Square's hotbed of biotechnology, GlaxoSmithKline is closing the Cambridge headquarters of its Sirtris Pharmaceuticals subsidiary.

Glaxo bought Sirtris for \$720 million in 2008 to acquire research that captured the imagination of many as a potential high-tech fountain of youth. Now Sirtris's research - and a handful of its employees - will be folded into Glaxo's research and development operations in Philadelphia, spokeswoman Melinda Stubbee said Tuesday.

Sirtris scientists believe a group of enzymes, called sirtuins, are capable of fighting age-related diseases by playing a key role in vital cell processes like DNA repair and programmed cell death.

Just days ago, Sirtris cofounder David Sinclair released a study supporting his discovery of the anti-aging effects of a red wine chemical called resveratrol, which he says is one of the compounds that can activate the age-defying sirtuin enzymes.

Sinclair's claim has sparked a contentious debate in the science community for the last decade, but Glaxo said the red wine chemical is not a major focus moving forward. Stubbee said Glaxo is instead interested in developing Sirtris's research on other compounds that could activate sirtuins. Much has not been published yet, she said, but the company hopes to develop drugs to treat disorders including Type 2 diabetes, inflammatory disease, and cancer. "We're excited to take this research to the next stage of drug development," she said. "We hope to move this to the clinic within two to three years."

The Cambridge office employs about 60 staffers. But Glaxo said only a core group of employees will be reassigned to Philadelphia. Stubbee said Glaxo has appointed Sirtris's vice president of preclinical research, Jim Ellis, to lead research in Philadelphia. Chief executive George Vlasuk is also likely to take on a new role, she said.

Though the move is expected to leave no Glaxo employees in Cambridge, Stubbee said the company hopes to continue its connection to the Boston area. "We still have quite a few good, strong relationships with the tech community in Boston, and we're committed to continuing that presence through our work with Harvard and our office in Waltham," she said. (Source: Alyssa Edes, The Boston Globe, 13 March, 2013)

### **AIDS Research Center Unveils New \$30 Million Lab In Cambridge**

The Ragon Institute, a leading AIDS research center, recently unveiled its new \$30 million laboratory building in Cambridge Monday, where it aims to push ahead with efforts to develop an HIV vaccine and to study tuberculosis, which has affected hundreds of thousands of HIV patients in African and other developing countries.

The opening of the Ragon Institute's new home comes at a difficult moment for AIDS and other biomedical scientists, as they brace for possible cuts in their federal research grants driven by sequestration of the federal budget and shows the growing importance of private support.

The 75,000 square-foot facility near Kendall Square provides three times as much space as the institute's original offices, established four years ago at Massachusetts General Hospital's Charlestown campus, with a \$100 million gift from software magnate Phillip Terrence Ragon . The MIT graduate also gave the money for constructing and equipping the new lab, which is roomy enough for the staff of 175 to double over the next few years and still leave bench space for visiting scientists. (Source: Ragon Institute Website, 12 March, 2013)

### **Merck and Samsung Bioepis Enter Biosimilars Agreement**

Merck and Samsung Bioepis have entered into an agreement to develop and commercialize multiple pre-specified and undisclosed biosimilar candidate.

"The combination of Merck's global commercial presence with Samsung Bioepis' biologic development and manufacturing capabilities positions the two companies well to increase access to biosimilars to improve human health," said Rich Murray, Ph.D., senior vice president, biologics and vaccines research, Merck Research Laboratories.

Under the agreement, Samsung Bioepis will be responsible for preclinical and clinical development, process development and manufacturing, clinical trials and registration. Merck will be responsible for commercialization. Samsung Bioepis will receive an upfront payment from Merck, product supply income and will be eligible for additional payments associated with pre-specified clinical and regulatory milestones. Further financial terms were not disclosed.

"Samsung Bioepis has been building the capabilities needed to develop high-quality biosimilars," said Christopher Hansung Ko, Ph.D., CEO of Samsung Bioepis. "With this development and commercialization agreement, Samsung takes a significant step toward becoming a major player in the biopharmaceutical industry." Samsung Bioepis is a joint venture between Samsung Biologics and Biogen Idec which aims to develop affordable and high-quality biopharmaceutical and biosimilar products. (Source: Merck Website, 20 February, 2013)

### **Spring Bank's Hepatitis C Treatment Heads to Trial**

Approximately 170 million people worldwide are infected by the hepatitis C virus, including 4 million in the United States, according to the World Health Organization. After a decade of work and a recent infusion of \$10.5 million in equity capital, a Milford pharmaceutical firm is headed to clinical trial for its hepatitis C virus treatment, known as SB 9200.

The first of approximately 40 patients in the Phase 1 trial - which is taking place in Australia and New Zealand, will be dosed this month, said Douglas Jensen, co-founder, president and CEO of Spring Bank Pharmaceuticals. The trial will provide data on safety as well as anti-viral efficacy. The trial will take an estimated six to nine months, and if successful, will open up further financing options, Jensen said. If successful, commercialization is still about four years away, he said.

Spring Bank says its biotechnology platform is a new class of pharmaceutical rooted in nucleic acid chemistry, which has spawned RNAi and antisense therapeutics. Radhakrishnan "Kris" Iyer, the company's chief scientific officer, is a member of a core group of chemists whose work led to those therapeutics in the late 1980s. But while Spring Bank's small molecule nucleic acid hybrid platform shares some chemistry similarities with RNAi and antisense, it differs in several significant ways, Jensen said. For one, instead of targeting messenger RNA directly, its molecules are designed to selectively interact with nucleic acid binding sites on. Secondly, they combine a high degree of target selectivity and specificity with the drug-like

properties of classical pharmaceuticals, including oral delivery, good pharmacokinetics, low side effects and ease of manufacture, Jensen said. He added Spring Bank has a number of other treatments in its pipeline, including one for hepatitis B, and will be looking for partners for later-stage and commercial development. (Source: Matt Pilon, WBJournal.com, 05 March, 2013)

### **Westborough's RXi Buys RNAi Assets of OPKO Health**

Biotechnology firm RXi Pharmaceuticals of Westborough, which focuses on therapies using RNA-targeted technologies, announced the acquisition of assets of a Miami-based firm.

RXi said it will acquire all of OPKO Health Inc.'s assets that are related to RNA Interference (RNAi), including 12 patent families tied to biological targets. The molecules related to the patents are believed to play an important role in battling eye diseases, cancer, immune disorders and inflammatory diseases, RXi said.

RXi will issue 50 million shares of its common stock to OPKO and will make milestone payments up to \$50 million for each product tied to the successful development and commercialization of products that use intellectual property acquired from OPKO. RXi would also make royalty payments to OPKO when products become commercialized.

"Together with its licensors and collaborators, OPKO was one of the early pioneers in the field of RNAi," said RXi President and CEO Dr. Geert Cauwenbergh. "We are honored to have the privilege to extend OPKO's ground breaking work, while at the same time deepening our product pipeline and broadening our technology platform and intellectual property position." (Source: WBJournal.com, 07 March, 2013)

### **Worcester Life Sciences Firms Get MassDevelopment Loans**

MassDevelopment said it's given equipment loans to two life sciences companies that started at Massachusetts Biomedical Initiatives incubators in Worcester. Blue Sky Biotech, a contract manufacturer of proteins and other biological products for pharmaceutical firms, received a \$300,000 loan to buy new laboratory equipment for its new space at Worcester Polytechnic Institute's Gateway Park at 50 Prescott St. Blue Sky also received funds from MassDevelopment in 2010 for the construction of its new labs and offices and will celebrate its 10th anniversary next month. Its new space is larger and helps accommodate the firm's workforce, which has grown, since 2003, from two employees to 39.

Meanwhile, Nemucore Medical Innovations Inc., which focuses on developing nanomedicines to treat ovarian cancer, received \$150,000 for lab equipment. Nemucore has leased 22,000 square feet at MBI's 55 Union St. facility and has been working with the organization to redevelop the space since 2010. Now in its sixth year, Nemucore is developing treatments that will combat multidrug-resistant ovarian cancer. (Source: Jacquelyn Gutc, WBJournal.com, 13 March, 2013)

### **Ipsen's Milford Operations to Continue under Baxter**

French pharmaceutical company Ipsen and its Cambridge-based partner, Inspiration Biopharmaceuticals, have closed a deal to sell their hemophilia drug program for \$185 million. But the employees at Ipsen's Milford facility have been offered employment by the purchasing company, Baxter International of Illinois, and Baxter expects to maintain operations in Milford for the foreseeable future, according to Bryan Kyhos, a Baxter spokesman.

The Maple Street facility is unique, according to Kyhos. It was designed specifically for the manufacture of

the company's hemophilia drug, known as OBI-1, which is being developed for the treatment of both acquired and congenital hemophilia, according to a statement by Ipsen. Baxter views the Milford facility as important to the continued development of the OBI-1 program, Kyhos said. There are approximately 80 employees at the Milford facility, and Kyhos said the workforce there will remain "approximately the same," now that the sale is final.

The Ipsen facility has been operating in Milford for about 30 years. Last summer, Ipsen reported it had about 150 employees in Milford when it was seeking tax incentives from the town through a planned \$42 million expansion. The company abandoned those plans and agreed, along with Inspirational Biopharmaceuticals, to sell the program to Baxter in January.

Ipsen officials could not be reached for comment, and Inspirational has filed for Chapter 11 bankruptcy protection. The two companies began pursuing the sale of the hemophilia program shortly after Inspirational filed for bankruptcy in October, Ipsen said. Ipsen provided financing to Inspiration to fund the sale process. Baxter paid \$50 million to Ipsen upfront, and will receive up to \$135 million in additional payments as sales milestones are met. (Source: Emily Micucci, WBJournal.com, 28 March, 2013)

### **Report Says State Incentives Boosted Life Sciences in Massachusetts**

At a public cost of more than \$22,000 per job, tax incentives authorized under a 2008 law to grow the Massachusetts life sciences sector created more than 2,500 jobs through June 2012, according to a report released Tuesday. The report, commissioned by The Boston Foundation, which played a role in developing the July 2008 law, estimated the jobs created through more than \$56 million in tax incentives pay an average salary of more than \$105,000 per year, with those salaries likely to spin off more than \$93 million in income and sales tax payments over the next five years.

Based on those projections, each dollar in tax incentives awarded under the law will generate \$1.66 in added tax revenue, according to the report, written by economists Barry Bluestone and Alan Clayton-Matthews of the Kitty and Michael Dukakis Center for Urban and Regional Policy at Northeastern University.

Between June 2008 and June 2012, the Massachusetts Life Sciences Center, which was created by the 2008 law, made \$301 million in investments, including more than \$186 million for capital projects and \$56.6 million in tax incentives to companies, \$23.3 million in academic research grants, \$22.9 million in company grants and accelerator loans for early-stage companies, \$6.9 million to fund internships at smaller Massachusetts life sciences firms, and nearly \$5 million in equipment and supply grants for schools and to fund other grants and competitions. The 10-year law authorized \$1 billion in investments and the report recommends forging ahead with those.

"All of our research suggests that the state will benefit from fully funding the remaining five years of the initiative in order to maintain the lead the life sciences have established in the Commonwealth," the report concluded. "This is particularly important as other states ramp up their investments in hopes of creating their own life-sciences ecosystems to entice the small and large firms Massachusetts has successfully attracted. California, Maryland, New Jersey, New York, Minnesota, and Florida are not resting on their laurels, but continue to spend state funds on their own life-sciences industries." (Source: WBJournal.com & State House News Service, 26 March, 2013)

### **Massachusetts No. 1 in Science & Technology**

Massachusetts is the top state in the country for science and technology assets, according to the Milken Institute, a nonprofit, nonpartisan think tank based in California. The institute has issued five science and



technology indices since 2002, and the Bay State has emerged as the top state in each. This year, the state had its highest score ever of 86.4. The next highest belonged to Maryland, which had a 79.4. The report said Massachusetts has "a critical mass in universities, research institutions and cutting-edge firms."

Milken's researchers use five equally weighted composites made up of 79 indicators to establish its rankings. The composites include research and development, risk capital and entrepreneurial infrastructure, human capital investment, technology and science workforce, and technology concentration and dynamism. The latter category measures how effective policy makers and others have been at parlaying regional assets into regional prosperity. (Source: Matt Pilon, WBJournal.com, 10 April, 2013)

### **Biogen Idec Wins FDA Approval for New Multiple Sclerosis Drug Tecfidera**

The FDA has approved Biogen Idec's Tecfidera (dimethyl fumarate) capsules to treat adults with relapsing forms of multiple sclerosis (MS).

"No drug provides a cure for multiple sclerosis so it is important to have a variety of treatment options available for patients," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "Multiple sclerosis can impair movement, sensation, and thinking and have a profound impact on a person's quality of life."

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. It is among the most common causes of neurological disability in young adults and occurs more frequently in women than men. For most people with MS, episodes of worsening function (relapses) are initially followed by recovery periods (remissions). Over time, recovery periods may be incomplete, leading to progressive decline in function and increased disability. MS patients often experience muscle weakness and difficulty with coordination and balance. Most people experience their first symptoms of MS between the ages of 20 and 40. (Source: FDA Website, 27 March, 2013)

### **Biogen Idec's Tecfidera Wins 15-Year Patent Protection**

Biogen Idec has announced that the U.S. Patent and Trademark Office has granted additional protection for Tecfidera (dimethyl fumarate), the company's oral drug for the treatment of multiple sclerosis (MS). The patent, which will expire in 2028, covers the dosing regimen of daily administration of 480 mg. This regimen was included in the marketing application for Tecfidera, which received approval from the FDA on March 27, 2013 (see above).

"The patent for this dosing regimen is recognition of the remarkable innovation Tecfidera represents for the MS community," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "The tremendous research investment required to study and validate the patented dosing regimen is an example of innovation that leads to meaningful benefits to patients."

The European Patent Office also recently determined that Biogen Idec's application for a patent covering the same dosing regimen of Tecfidera is allowable. Once granted, this patent would also expire in 2028. The Tecfidera dose regimen patents add to the growing portfolio of granted patents covering the drug. (Source: Biogen Idec Website, 19 March, 2013)

### **Kadcycla Wins FDA Approval & Royalty Income for ImmunoGen**

Waltham-based ImmunoGen, a biotech company that develops anticancer therapeutics using its TAP technology, has announced that the FDA has granted marketing approval to Genentech's Kadcyla for the treatment of people with HER2-positive metastatic breast cancer who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy.

"This is a big day for the patients with this cancer and for ImmunoGen," commented Daniel Junius, Immunogen President and CEO. "In clinical testing, the findings with Kadcyla in this patient population have been impressive, and we're delighted the product can now be used by practicing oncologists across the US. In addition to its importance from a medical perspective, commercialization of Kadcyla also marks the start of ImmunoGen earning royalty income."

FDA approval of Kadcyla triggers a \$10.5 million milestone payment to ImmunoGen. The Company also earns royalties on commercial sales of Kadcyla. Genentech is prepared to launch the product imminently.

Mr. Junius continued, "The efficacy and tolerability seen with Kadcyla underscores the transformative potential of our technology. Kadcyla is the most advanced of ten compounds with our TAP technology already in the clinic, with more in earlier stages of development. We are hopeful that in the future many different types of cancers will be routinely treated with TAP compounds."

ImmunoGen conceived of the idea of attaching the Company's DM1 maytansinoid cell-killing agent to Genentech's trastuzumab antibody to achieve a highly effective, HER2-targeted anticancer agent. In 2000, Genentech licensed from ImmunoGen exclusive rights to use the Company's maytansinoid TAP technology to develop anticancer products targeting HER2. In 2006, Genentech advanced the compound that became known as Kadcyla into clinical testing. Genentech has implemented a broad Kadcyla clinical development program that has continued to expand subsequent to Genentech's acquisition by Roche. Today, multiple Phase III trials are underway or planned evaluating Kadcyla for a number of HER2-positive breast cancer indications. The compound also is being evaluated for the treatment of HER2-positive gastric cancer.

In addition to Kadcyla, nine other compounds with Immunogen's TAP technology are in clinical testing for the treatment of an array of cancer types. Three of these compounds are wholly owned by ImmunoGen: IMG901, in Phase II testing for the treatment of small-cell lung cancer; IMG853, in Phase I testing for the treatment of ovarian, lung, and other cancers that over-express folate receptor 1; and IMG529, in Phase I testing for the treatment of non-Hodgkin's lymphoma.

Immunogene expects to advance a fourth TAP compound, IMG289, into the clinic in 2013. IMG289 targets EGFR and is a potential treatment for cancers that overexpress this target, including many head and neck and non-small cell lung cancers. (Source: Immunogen Website, 22 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 Chief Addresses MassBio Annual Meeting

Margaret Hamburg, MD, head of the Food and Drug Administration, addressed the MassBio Annual Meeting on March 15 and said the federal agency is working to expedite the approval of safe new drugs, but across-the-board federal budget cuts threaten to hamper its efforts. She added that she is hoping Congress will

enable the FDA to access user fees the industry pays for the agency's operating expenses.

Dr. Hamburg noted that Massachusetts has a "biotech supercluster that's second to none" and the top five hospitals funded by the National Institutes of Health. However, she added that even successful biotech clusters face daunting pressures: foreign competition; rising product development costs; the challenge of securing venture capital; the looming patent cliff; uncertainties surrounding tax policy; increasingly complex reimbursement policies; and a reduction in R&D budgets -- both "Big Pharma" and government science agencies like NIH and FDA that are under the budget knife.

For a complete transcript of Dr. Hamburg's remarks, please visit the FDA website at: <http://www.fda.gov/NewsEvents/Speeches/ucm343949.htm>

### **FDA Approves Genetech's Kadcyla for Late-Stage Breast Cancer**

The FDA has approved Kadcyla (ado-trastuzumab emtansine), a new therapy for patients with HER2-positive, late-stage (metastatic) breast cancer. HER2 is a protein involved in normal cell growth. It is found in increased amounts on some types of cancer cells (HER2-positive), including some breast cancers. In these HER2-positive breast cancers, the increased amount of the HER2 protein contributes to cancer cell growth and survival.

Kadcyla is intended for patients who were previously treated with trastuzumab, another anti-HER2 therapy, and taxanes, a class of chemotherapy drugs commonly used for the treatment of breast cancer. It is being approved with a Boxed Warning alerting patients and health care professionals that the drug can cause liver toxicity, heart toxicity and death. The drug can also cause severe life-threatening birth defects, and pregnancy status should be verified prior to starting Kadcyla treatment.

"Kadcyla is trastuzumab connected to a drug called DM1 that interferes with cancer cell growth," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Kadcyla delivers the drug to the cancer site to shrink the tumor, slow disease progression and prolong survival. It is the fourth approved drug that targets the HER2 protein."

Referred to as T-DM1 during clinical research, Kadcyla was reviewed under the FDA's priority review program, which provides for an expedited six-month review of drugs that may provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. Other FDA-approved drugs used to treat HER2-positive breast cancer include trastuzumab (1998), lapatinib (2007) and pertuzumab (2012).

Kadcyla, trastuzumab and pertuzumab are marketed by South San Francisco, California-based Genentech, a member of the Roche Group. Lapatinib is marketed by GlaxoSmithKline, based in Research Triangle Park, NC. (Source: FDA Website, 22 February, 2013)

### **Affymax & Takeda Pharmaceuticals Recall of Anemia Drug Omontys**

The FDA is alerting health care providers and patients of a voluntary nationwide recall of all lots of Omontys Injection by Affymax of Palo Alto, CA and Takeda Pharmaceuticals of Deerfield, IL. The recall is due to reports of anaphylaxis, a serious and life-threatening allergic reaction.

Anemia is common in adult patients who have chronic kidney disease (CKD) and who are on dialysis. Omontys, approved by the FDA in March 2012, is an erythropoiesis-stimulating agent (ESA) that aids in the formation of red blood cells. Additional ESA products are available to treat anemia, including Procrit, Epogen, and Aranesp.

According to the companies, serious and fatal hypersensitivity reactions have been reported in some patients receiving their first dose of Omontys, given by intravenous injection. The reactions have occurred within 30 minutes following the dose. There have been no reports of reactions following subsequent dosing, or in patients who have completed their dialysis session.

The FDA has been notified by Affymax of 19 reports of anaphylaxis from dialysis centers in the United States. Three of the anaphylaxis cases resulted in death. Other patients required prompt medical intervention and in some cases hospitalization. Some of the reports included patients who were able to be resuscitated by doctors. However, anaphylaxis is life-threatening and resuscitation efforts are not always successful.

Affymax and Takeda are investigating these adverse reactions. (Source: FDA Website, 24 February, 2013)

### **FDA Approves Stivarga for Advanced Gastrointestinal Stromal Tumors**

The FDA has expanded the approved use of Stivarga (regorafenib) to treat patients with advanced gastrointestinal stromal tumors (GIST) that cannot be surgically removed and no longer respond to other FDA-approved treatments for this disease.

GIST is a tumor in which cancerous cells form in the tissues of the gastrointestinal tract, part of the body's digestive system. According to the National Cancer Institute, an estimated 3,300 to 6,000 new cases of GIST occur yearly in the United States, most often in older adults.

Stivarga, a multi-kinase inhibitor, blocks several enzymes that promote cancer growth. With this new approval, Stivarga is intended to be used in patients whose GIST cancer cannot be removed by surgery or has spread to other parts of the body (metastatic) and is no longer responding to Gleevec (imatinib) and Sutent (sunitinib), two other FDA-approved drugs to treat GIST.

Stivarga was reviewed under the FDA's priority review program, which provides an expedited six-month review for drugs that may provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. The drug was also granted orphan product designation because it is intended to treat a rare disease.

Stivarga was approved in September 2012 to treat colorectal cancer. It is marketed by Bayer HealthCare Pharmaceuticals, based in Wayne, NJ. Gleevec is marketed by East Hanover, NJ-based Novartis, and Sutent is marketed by New York City-based Pfizer. (Source: FDA Website, 25 February, 2013)

### **FDA Approves TOBI Podhaler for Lung Infection in Cystic Fibrosis Patients**

The FDA has approved TOBI Podhaler (tobramycin inhalation powder) for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*, a bacterium that causes lung infections.

Cystic fibrosis is a genetic disease that affects about 30,000 pediatric and adult patients in the United States. Cystic fibrosis causes the body to produce thick, sticky mucus that builds up in the lungs and blocks airways. The buildup of mucus makes it easy for bacteria like *P. aeruginosa* to grow and cause a chronic lung infection that, over time, can severely damage the lungs. Many patients with cystic fibrosis are treated with antibiotics using a nebulizer machine.

TOBI Podhaler, a plastic, handheld inhaler device, contains a dry powder formulation of tobramycin, an antibiotic used to treat *P. aeruginosa* infection. The powder is inhaled twice daily using the Podhaler device for 28 days. Patients should then stop TOBI Podhaler therapy for 28 days before resuming again. TOBI



Podhaler is marketed by East Hanover, NJ-based Novartis. (Source: FDA Website, 22 March, 2013)

### **FDA Approves Botulism Antitoxin**

The FDA has approved Botulism Antitoxin Heptavalent to treat patients showing signs of botulism following documented or suspected exposure to botulinum neurotoxin. The product is derived from horse plasma and contains a mixture of antibody fragments that neutralize all of the seven botulinum nerve toxin serotypes known to cause botulism.

Botulism is a rare but serious illness caused by ingesting or inhaling a botulinum nerve toxin, or by exposure arising from toxin secreted by Clostridium bacteria in a wound or the intestine. Patients with botulism develop severe muscle weakness that progresses from the head to the rest of the body. If untreated, the illness may progress to total loss of muscle function and inability to breathe. This heptavalent antitoxin is the only product available for the treatment of botulism in adults, and for cases of infant botulism caused by nerve toxins other than types A and B.

The product is manufactured by Cangene Corporation, based in Winnipeg, Canada. It was developed with support from the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. The antitoxin will be maintained in the Strategic National Stockpile and distributed through the CDC's Drug Service. (Source: FDA Website, 22 March, 2013)

### **FDA Approves Invokana for Type 2 Diabetes, First in New Class of Diabetes Drugs**

The FDA has approved Invokana (canagliflozin) tablets, used with diet and exercise, to improve glycemic control in adults with type 2 diabetes. Invokana is manufactured for Janssen Pharmaceuticals of Titusville, NJ.

Type 2 diabetes is the most common form of the disease, affecting about 24 million people and accounting for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney damage.

"Invokana is the first diabetes treatment approved in a new class of drugs known as sodium-glucose co-transporter 2 (SGLT2) inhibitors," said Mary Parks, M.D., director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research. "We continue to advance innovation with the approval of new drug classes that provide additional treatment options for chronic conditions that impact public health."

Invokana works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels. Its safety and effectiveness were evaluated in nine clinical trials involving over 10,285 patients with type 2 diabetes. The trials showed improvement in hemoglobin A1c levels (a measure of blood sugar control) and fasting plasma glucose (blood sugar) levels. (Source: FDA Website, 29 March, 2013)

### **US Patent & Trademark Office Grants Pfizer Reissue Patent for Celebrex**

Pfizer has announced that the US Patent & Trademark Office has granted Pfizer a reissue patent covering methods of treating osteoarthritis and other approved conditions with celecoxib, the active ingredient in Celebrex®. The reissue patent will expire on December 2, 2015, which includes six months of pediatric

exclusivity. The basic patent for celecoxib expires on May 30, 2014, which also includes six months of pediatric exclusivity.

Pfizer filed suit against Teva Pharmaceuticals, Mylan Pharmaceuticals, Watson Laboratories, Lupin Pharmaceuticals, and Apotex for infringement of the reissue patent. Each of these generic companies previously filed an abbreviated new drug application with the United States Food and Drug Administration seeking approval to market a generic form of celecoxib in the United States beginning in May 2014, prior to the December 2, 2015 expiration of the reissue patent. (Source: Pfizer Website, 05 March, 2013)

## New Members

**Sebastian Arevalo**, *Sales Engineer*, Eppendorf North America

**Mr. James R. Baker**, *Validation Engineer*, Genzyme

**Justin A. Barbas**, *Student*, Northeastern University

**Ms. Samantha Barrett**, *Student*, Wentworth Institute of Technology

**Nicholas Bayhi**, *Student*, Tufts University

**James Chris Bedi**, *Process Engineer*, Genzyme Corporation

**Ms. Tuhina Bhattacharya**, *Student*, Worcester Polytechnic Institute

**Amanda Bishop McFarland**, Genzyme

**Mr. Bielinsky A. Brea**, *Student*, WPI

**Mr. Edward Butler**, *Senior Engineer*, Shire

**Dr. Terri A. Camesano**, *Professor*, Worcester Polytechnic Institute

**Benjamin Chiang**, *Process Engineer*, Genzyme Corp.

**Mr. Ralph Codio**, *Plumber*, Organo Genesis

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**Ms. Katherine Cook**, K. Adina Consulting

**Miglia Cornejo**, *Student*, Northeastern University

**Caitlin Lee Cutter**, *Process Engineer*, Genzyme

**Mr. Maxwell Andrew Dandridge**, *Process Engineer*, Genzyme

**Mrs. Deirdre Day**, *Strategic Account Manager*, Avnet

**Michael Delaney**, *Prod. Support Team Lead*, Emergent Bio Defence

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**Thomas J. Izbicki**, *Facilities-Maintenance Mgr*, Lonza Biologics Inc.  
**Mr. Manish Jain**, *Assoc. Director*, MST, ImmunoGen, Inc.  
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**Ms. Callie King**, *Student*, Worcester Polytechnic Institute  
**Mr. Derek Lee**, *Student*, Tufts University  
**Ms. Melinda Lei**, *Student*, WPI  
**Ms. Theresa J. Logan**, *Student*, Worcester Polytechnic Institute  
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**Sue Marrichi**, Shire HGT  
**Ms. Sarah A. McNulty**, *Assistant Manager of QA*, Integra Companies Inc  
**Mark R. Melilli**, *Process Engineer*, DPS Biometrics Inc  
**Matthew Meyer**, *Student*  
**Dr. Gerard James Morgan**, *Recruitment*, DPS Biometrics  
**Mr. Nolan S. Murphy**, *Project Engineer*, Design Group  
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**Zhiyuan Shen**, *Graduate Student*, Worcester Polytechnic Institute

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**Ms. Lauren E. Tice**, *Student*, Worcester Polytechnic Institute

**Kellie L. Waterman**, *Student*, Worcester Polytechnic Institute

**Mr. Thomas P. Weiss**, *SR. Mechanical Engineer*, CRB Consulting Engineers

**Mr. Nigel R. Williams**, *Vice President, Quality*, Lantheus Medical Imaging

**Mr. Stephen E. Wilson**, *Process Engineer*, Genzyme

**Mr. Alan Wong**, Livzon Mabpharm, Inc

## 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!

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**Mr. Richard P. Capobianco**

**Mr. Raymond J. Cardin**, PharMax Consulting LLC

**Mr. Michael S. Cheney**, Biogen Idec

**Dr. Charles L. Cooney**, Massachusetts Institute of Technology

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**Mr. Daniel J. Dumont**, Dynamic Systems Inc  
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**Mr. John Najim**, Proteon Therapeutics

**Mr. Christopher Osmena**, Castle Hill Technologies

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