



## Boston Area Chapter

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## NEWSLETTER

July 2015, Volume XXV, No. 4

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### President's Message: Outgoing Chapter President Chris Opolski on His Long Career with ISPE



Dear Boston Area Chapter Members,

While I write this I am struck with sadness that this is my last letter as President of the Boston Area Chapter of the ISPE. It has been another widely successful year and I am proud to have been part of it. From our monthly educational programs to our many socials, the Product Show in October and our eleven Student Chapters, this organization is the best! I would like to end my tenure as President by offering a little history of my involvement in ISPE.

I became a member of the Boston Area Chapter initially to attend educational programs on different topics in the pharmaceutical field. Most of these were held in Cambridge or Waltham and I would go down after work, network with colleagues in the industry, then attend the educational session. After a few years of attending programs and of course the Product Show, I volunteered to be on the social committee to help plan different events. It was a lot of fun and totally different from the stuffy engineering world I lived in every day. So I helped plan golf tournaments, ski trips and holiday parties; I also learned what Dia de Muertos meant. But I didn't do it alone - it was only with the incredible help of volunteers and friends like Sylvia, Jim, Gene, Sully, Michelle and Fasha that these events were so successful. We as a group also believed it was important to give back to the community and those less fortunate so we made it part of our mission to have every social event raise money for a worthy cause. It is a tradition the Chapter continues today and something I am very proud to have been a part of.

After a few years of volunteering on the social committee, I was nominated to be a member of the Boston Area Chapter's board of directors. I also continued my work as board liaison to the social committee. Being on the board was a very gratifying experience: learning about the inner workings of a very successful volunteer organization, then helping to make the Chapter even better. After a few years on the board, I was elected to be the Chapter's treasurer, a position I held for two years, then Vice President and finally President.

My four years as a Chapter officer have been an incredible experience. One of the Chapter's most satisfying accomplishments during that time was the merging of the New England and Boston Area Chapters. The board understood that if we were going to successfully manage a much larger geographic region, the Chapter needed new ways to serve its Members. The Chapter formed the Geographic Outreach (GO) initiative to develop ways to provide live simulcasting of educational programs to Members in different regions served by the expanded Chapter. We wanted more than just a replay of the educational programs and opted to include the social and networking aspects the Boston Area Chapter's events are known for. To date we have formed two GO hubs in Providence, RI and Worcester, MA with more planned.

Finally I want to thank my friends and coworkers Rick, Mark, Jerry and Steve. I couldn't have been an active part of this organization without their support.

As this Chapter year comes to a close I want to thank Dan Ramsey, Tulsa Scott, Jim Stout, and Jillian Willard, all of whom are retiring from the board, for their many years of service to the Chapter. Thank you for all your help and guidance. And I would like to welcome incoming President Steve Kennedy, Vice President Jack Campion, Treasurer John Spohn and Secretary Janet Tice as well as all of the incoming directors.

The Chapter has some great things planned for the year ahead. I encourage you to take part in the educational, membership, and social opportunities. This is a great organization and I'm proud to be a part of it! I am honored to have served as President this past year and look forward to learning the secret handshake of the Past Presidents! Hope to see you at an event in the future.

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## Christopher Opolski

President  
ISPE Boston Area Chapter

### Chapter Bulletin Board

#### More Product Show Exhibit Space Added!

Due to unprecedeted demand, we have added 50 additional exhibit spaces and reopened Exhibitor Registration. To ensure that you are not shut out a second time, immediately go to [www.ISPEBoston.com/ProductShow](http://www.ISPEBoston.com/ProductShow) and click on Registration.

It is also your last chance to lock up one of the remaining marketing opportunities to promote your firm. No matter what your budget, there is an opportunity for your company to get in front of the attendees from sponsoring our After Party to being a trend setter and advertising your company logo on our mobile app. These are all close to being sold out, so don't delay. For a full list of promotional opportunities, go to [www.ISPEBoston.org/ProductShow](http://www.ISPEBoston.org/ProductShow).

#### Newsletter Ad Space Expanding - Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at (781) 647-4773 or [office@ISPEBoston.org](mailto:office@ISPEBoston.org).

#### Support Your Chapter - Become a Sponsor!

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 containing all the information you need to know to become a Chapter Sponsor.

We invite you to visit the sponsorship page at [www.ISPEBoston.org](http://www.ISPEBoston.org) to explore the full range of sponsorship options available. Using the sponsorship application as your worksheet, you can view your savings as you select various combinations of sponsorship options - the more you choose, the bigger your discount!

So don't delay, visit [www.ISPEBoston.org/Sponsorship](http://www.ISPEBoston.org/Sponsorship) and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or - if you'd rather - contact the Chapter office at (781) 647-4773 or [office@ISPEBoston.org](mailto:office@ISPEBoston.org) and we'll be happy to help!

### Upcoming Chapter Events - Mark Your Calendar

**Thursday, July 23, 2015**

#### ISPE Educational Programs 2016 Season Planning Committee

Waltham Woods, Waltham, MA

#### PROGRAM SUMMARY

This summer, the Boston Area Chapter will receive valuable input on educational programs of interest to our Members through a survey which will be launched in June. The Educational Program Committee would like YOUR help to finalize the educational program content for the upcoming Chapter year using the survey results. Please join us on Thursday, July 23, 2015 as the 2016 educational season is developed.

Schedule 5:30 PM - 8:30 PM Dinner, planning the 2016 programming year, and brief committee meeting

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

**Click below for full information and to register:**

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=561](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=561)

**Monday, August 17, 2015**

#### ISPE Summer Golf Tournament

Kernwood Country Club, Salem, MA

#### EVENT INFORMATION

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11:15AM - 12:30 PM - Registration, Lunch and Driving Range  
 12:30 PM - Shotgun Start - Scramble Format  
 6:00 PM - Reception/Cocktails/Dinner

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### Sneak Preview of Upcoming Events

**Thursday, September 3, 2015**

ISPE Boston Harbor Boat Cruise  
 Boston Harbor Hotel Dock, Boston, MA

**Wednesday, September 16, 2015**

ISPE Regulatory Compliance (joint meeting with New England PDA)  
 Hilton Boston/Woburn, Woburn, MA

### **Breaking News: More Product Show Exhibit Space Added!**

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### **Product Show Exhibit Space Sold Out!**

by Mark Levanites, Product Show Committee Chair

This year, exhibitor space for the 24th Annual Product Show on October 7th sold out in record time, cementing the Show's reputation as the one show that you must be at as an exhibitor to reach all your clients in the Northeast. Typically, the Show sells out in late August, but this year it sold out in late June - a full two months earlier than in previous years. This was due to a record number of companies pre-registering after last year's Show's huge success. Thank you to all the exhibitors that will help make this year's Show even better!



Thousands of attendees fill the aisles in the exhibit area at last year's Product Show!

The Product Show Committee has not been resting on its laurels and has been working on many enhancements to make the exhibitor experience even better:

**New Product Show Website...** Coming in mid-July, look for the new Product Show Website. We have done a complete overhaul of the site with separate areas for Exhibitors, Career Fair and Attendees. You will find the new website easier to navigate and full of information that is pertinent to you as an exhibitor. Best of all for a select few firms, your company banner ad can appear on this site that every attendee will navigate to pre-register for the Show. Contact the Chapter office at (781) 647-4773 if you are interested.

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**New Training Videos Available...** We had great success with our Product Show training camps but we wanted to find a way to bring that information to a wider audience. The solution was to create five short videos that capture everything you need to know about exhibiting at the Product Show. These will be on our new website when we launch in mid-July.

**New Lead Retrieval System available...** As we mentioned in the last newsletter, this year we will be offering a new registration and lead retrieval system. We have selected ExpoTrac as our partner. The ExpoTrac system will provide us with a fast, efficient and convenient means of trade show registration. You, our exhibitors, will have access to the industry leading EZ-TRAC™ service to be able to quickly capture leads to help you make the sale! This is a mobile lead app for Apple & Android devices that allows you to customize your own qualifiers and enter lead data on your own device. You can then download your leads from a secure website. Information on purchasing licenses for the app will be on the new website and will be sent to exhibitors as we get closer to the Show.

**Product Show Guide Mobile App...** The Show Guide App has been updated and new content is being uploaded to align with the new website. Attendees will be reminded that there is no longer a hard copy of the Show Guide and to download the free app to their Apple & Android devices. There are still a few opportunities left for your firm to include a banner ad in the app, so contact the Chapter office at (781) 647-4773 if you are interested.

**Traffic Builders...** We think we have a couple of awesome traffic builders for this year's Show. First, we are holding a raffle that requires attendees to not only pre-register but also attend the Show in order to win. The prize? Two tickets to a New England Patriots game (courtesy of Superior Controls), lodging the night before the game at the Renaissance hotel and dinner at Davios. Second, we have invited Scott Zolak, Steve Grogan and the New Patriots Cheerleaders to join with us to promote awareness for a charity that we will be revealing in September. Attendees will have the opportunity to have photos taken with them during the Show for a donation to the charity. They will be set up in a pavilion in the West Clubhouse. Here is an opportunity for you to increase your visibility by providing the donation on behalf of your best clients.

**Hiring New Employees?** If your firm is hiring, then you need to be at the newly expanded Career Fair that is held in conjunction with the Product Show. An important part of your organization's success is recruiting and hiring the most qualified and experienced professionals in the biopharmaceutical field. The Career Fair, in partnership with CareerBuilder.com, provides you with the opportunity to meet hundreds of quality candidates in one day, and to fulfill your recruitment needs in an efficient and cost effective way. The Product Show attracts over 2500 of the best and brightest Life Science professionals, so take advantage of the high concentration of engineers and other professionals that want to meet you. We have doubled the number of free tables that are provided to hiring organizations and over half are already reserved. If your firm is interested in participating, please call the Chapter office at (781) 647-4773 for details on how to reserve a spot.

**After Party Update...** The After Party has a new venue this year - the new Optum Field Lounge in Gillette Stadium. This new space is located in the south end zone so you won't even have to leave the stadium. Our special guest for the evening will be none other than the man who snatched victory from the jaws of defeat - New England Patriot Malcolm Butler! So be sure to attend and wind down with colleagues and customers following the Show.



No travel necessary! This year, Gillette's new Optum Field Lounge will host the Product Show After Party.

We are always looking for enthusiastic members to join our Product Show Committee. If you want to be a part of this great team, let us know. Our next newsletter will be directed to the attendees. So for the exhibitors that registered for this year's show, thank you and we look forward to seeing you on October 7th!

## After a Brutal Winter, the Sun Shines for the Spring Golf Outing

by Dan Kenny, Northeast Engineering

The Boston Area Chapter hosted the Second Annual Spring Golf Outing on May 11th at Ledgemont Country Club in Seekonk, MA and we couldn't have asked for a better day. With the sun shining and the temps in the 80's, ISPE Members and guests from all over New England got together for a great day of golf and networking. As expected, the course was in amazing shape and the staff at Ledgemont bent over backwards to accommodate our every need.

Looking to improve on the buzz and success of last year's Spring Golf Outing, the Social Committee was able to do just that. With a full field this year, the day started with a hearty lunch buffet to make sure that no one went out on the course hungry. Once on the course, Past Presidents Dan Ramsey and Jim Grunwald set the pace by crushing the ball all over the course and making it difficult for others to keep up. While out on the course, the cheers of amazing shots and loud sighs of "almost-ins" were heard from the first hole to the last. As the last groups made it

## Newsletter Archive

into the clubhouse, the stories got better and better and the laughs got louder and louder over a beverage on the back deck overlooking the gorgeous landscape of the course.



Chapter Members from all over New England enjoyed a great day of golf and networking.

Once the last groups reached the clubhouse, everyone made their way to the dining room where a fantastic buffet with a full carving station awaited the golfers and guests. After dinner was served, the awards took center stage. Awards were handed out for first, second and third place foursomes, longest drive (men/women), straightest drive (men/women), and closest to the pin (men/women). There was also a putting contest held along with a number of amazing raffle prizes. Congratulations to all the winners!

### Winning Foursomes

- First - JC Cannistraro (Roland Oreste, Mike Johnson, Chris Kilday, Tom McCabe)
- Second - RW Sullivan (Paul Sullivan, Dan Paquette, Mike Shreve, Bruce Durkee)
- Third - Commissioning Agents (Jim Grunwald, Jerry Nadeau, Dan Ramsey, Geoff Wilkinson Jr.)

### Longest Drive

- Chris DePaula
- Tiffany Hubanks

### Straightest Drive

- Dan Paquette
- Suzanne Stuhler

### Closest to the Pin

- Dan Paquette
- Tiffany Hubanks

To end the event, there was a 50/50 raffle, with proceeds going to the Jimmy Fund which solely supports Boston's Dana-Farber Cancer Institute, raising funds for adult and pediatric cancer care and research to improve the chances of survival for cancer patients around the world.



Beautiful weather greeted Chapter Members and guests at Ledgemont Country Club in Seekonk.

The Social Committee would like to thank everyone who attended and helped make the tournament a big success. And we would like to extend a special thank you to all of the sponsors who made this event possible. Your support is greatly appreciated!

- A/Z Corporation
- Commissioning Agents
- Crosspoint Engineering
- JC Cannistraro
- Jenson Hughes
- New England Labs
- Northeast Engineering
- Sentrol
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- Structure Tone
- Superior Controls

### **"A Better Way to Deliver Fast-Track Projects" Draws Record Turnout at Biogen**

by Cheryl Huie, DPS Engineering, and Jack Campion, The Hart Companies, with photos by Joyce Chiu, Shire

The educational program held on May 21st provided Chapter Members with some terrific insights into a topic most of us have experienced - Fast Track Projects. Meeting manager Cheryl Huie of DPS assembled an all-star panel consisting of representatives from operating companies, an engineering firm and a construction firm. Together they represented the cross-section of key project stakeholders. Panelists included: Rich Quinby, Biogen Associate Director of Global Project Engineering (Owner); Tony Mejido, Sanofi Capex Procurement Director North America (Procurement); Jim Busam, Gilbane Vice President National Client Team (Construction Manager); Cory Siddons, DPS Senior Project Manager (Designer); and Eric Felz, Shire Associate Director of C&Q (Commissioning & Validation). Jack Campion of The Hart Companies served as moderator.



Attendees and speakers had a chance to "meet and mingle" during the networking reception.

Prior to the presentation, the group held a series of round tables which addressed questions such as: "How does a fast-track project differ from a non-fast-track one?", "What are the biggest concerns about delivering a fast-track project?", and "What can be done to minimize the impact if they occur?" What followed was a clear consensus on a few universal points, which was shared with the audience in an interactive format that allowed the audience to participate.



Panelists from operating companies, and engineering and construction firms represented a cross-section of key project stakeholders.

Some of the main points included:

- Having the right people at the table - Always having the right stakeholders/decision-makers in the room for key discussions; "front-loading" the project with information from all stakeholders; and having the owner's commitment - at a sufficiently high level - to apply the internal resources to make the project happen.
- "Before we go fast, we have to start slow" - For fast-track projects, planning is significantly more important. Decisions and financial commitments need to be locked down and made early in order to make tight schedules. If the project is not properly planned, rework, returns, and modifications to physical assets become very costly. Especially if changes are made in late-stage design, the cost in terms of re-engineering and extra time for approvals can significantly impact both the project schedule and the bottom line.
- Prequalification of vendors, suppliers, contractors, etc., as well as engaging Commissioning & Qualification during planning will also have a positive impact on the timeline.
- The Right Tools - Managing fast track projects can be challenging. Having tools such as Project Execution Plans, Collaboration Tools, Integrated Project Schedules, and BIM will help to guide the project through to success.
- Stakeholder engagement was emphasized - as embodied by the makeup of the panel itself - and the importance of each stakeholder's understanding of her/his role.



A topic of wide interest and an interactive format prompted a healthy exchange between the panel and the audience.

During the presentation, there was a healthy exchange of thoughts between the panel and the audience. The interweaving thread throughout the program was the importance of creating a "culture of collaboration." In the end, all agreed that approaching the project as a unified team was the safest way to deliver a fast track project.

The Chapter would like to thank the panelists; and Biogen, which provided a terrific venue for the program at its headquarters in Weston, MA.

### **Panelists Provide Insight on Tech Transfer During June Program at Genzyme**

*by Jonathan Ly, Barry-Wehmiller Design Group, and Norline Crossdale-Walker, Genzyme, with photos by Joyce Chiu, Shire*

The ISPE Boston Area Chapter educational program entitled "Tech Transfer: From Process Development to Product Manufacturing" was held on Thursday, June 18th at Genzyme Center in Cambridge. The program was planned and coordinated by Meeting Managers Jonathan Ly (Barry-Wehmiller Design Group), Zeke Johnston (AMAG Pharmaceuticals), Norline Crossdale-Walker (Genzyme), and Howard Sneider (CRB Consulting).

Following the traditional networking reception, the evening began with opening remarks by Boston Area Chapter President Christopher Opolski. The moderator for the event, Bhavi Mittal (Senior Scientist, Formulation Sciences - Takeda Pharmaceuticals), was introduced by Jonathan. He began the program with a comprehensive overview of the importance of

technology transfer in the pharmaceutical industry. He described the industry's shift toward the outsourcing model in manufacturing, which has brought about new technical challenges as well as business practices that the guest speakers discussed at the event.



The atrium at Genzyme Center provides a striking welcome for Chapter Members.

Gary Mills (Associate Director, Drug Product Development - Momenta Pharmaceuticals) came to us with over 27 years of experience in tech transfer and the utilization of contract manufacturing organizations (CMOs) in the commercialization of drug products. He presented on strategies and tips in selecting CMOs and building relationships from the contract sponsor point of view. Gary revealed two levels of due diligence within the scope of evaluating the status and capabilities of CMOs. His presentation spelled out qualities and attributes that process/product owners often overlook.

Claudia Buser (Director, Cell Banking Development - Genzyme) followed Bhavi's introduction. As an expert in cell culture process development with over 20 years of experience, Claudia presented on high level approaches to Phase III bioprocess development. She touched on concepts in process characterization, scale down model qualification, and establishment of design space. Moving forward with these concepts, Claudia described the governance structure of an internal tech transfer that often applied to external cases as well. She offered an excellent perspective on the requirements for a successful tech transfer from the process development point of view.



Moderator Bhavi Mittal and speakers (l to r) Claudia Buser, Gary Mills and Joe Cobb provided a comprehensive snapshot of the concepts behind successful tech transfers.

Joe Cobb (Director, Pharmaceutical Development - Metrics Contract Services/Mayne Pharma US) spoke as a representative from the CMO side of the business. Joe utilized his 22 years of contract manufacturing experience to provide case studies and narratives from tech transfer projects that he had been involved with in the past. He provided informative insight on the issues CMOs would face and some of the lessons learned from those experiences.

After the last presentation, the three speakers joined Bhavi for an open panel discussion on tech transfer topics that were presented, as well as for Q&As. The audience participation was outstanding, with questions on how Quality by Design (QbD) played a role in the tech transfer.



Educational programs are collaborative efforts between the Chapter's Educational Program Committee and industry experts, in this case, Meeting Managers (l to r) Jonathan Ly, Howard Sneider, Zeke Johnston and Norline Crossdale-Walker and the program's moderator and guest speakers.

Overall, the presentations provided a comprehensive and diversified snapshot of the concepts behind successful tech transfers in the pharmaceutical industry. Having a different speaker from each perspective of the industry and a large and exceptionally engaged audience combined to generate a great number of discussion points for the panel and stimulated open dialogue during the Q&A. This experience opens the doors to new ideas for future educational programming.

The Boston Area Chapter and Meeting Managers would like to thank the panelists, moderator and audience members for their valuable contributions to this program. And we would like to thank Genzyme for collaborating with us once again in providing an excellent venue for this event.

### **Keeping Up With the YPs...**

*by Chris Ciampa, Thermo Fisher Scientific, with photo by Karima Erriahi, Thermo Fisher Scientific*

Hello all! It has been quite some time since we last checked in, as I was hibernating. Now that spring is in full effect, I am back with some great opportunities the YPs are hosting! But first let me bring you up to date, in case you missed our spring activities. YPs gathered in April at Sacco's Bowl Haven in Somerville for flatbread pizza and candlepin bowling (see companion article). And in early June, 50 Chapter Members had the opportunity to get out to the Fenway area for a meet up at "Who's on First" followed by a chance to see our beloved Red Sox take on the Minnesota Twins. Boston, fifth in the AL East at the time, won the game 1-0!



YPs cheered the Sox to a win over the Twins at Fenway in June.

During the summer months, YP events will enter a lull period as many folks will be traveling and planning their vacations. We are planning only one event during that time: a Pub crawl. Date and details are yet to be finalized, so please stay tuned!

The annual Boston Harbor cruise, our flagship YP event, is going to happen in early September. This is typically the biggest YP event of the year (other than the Product Show) and is a great opportunity for YPs and other Chapter Members to network and socialize. This is a fun event not to be missed - hope to see you there! And speaking of the Product Show, as always the YPs will be spearheading a number of activities designed just for us and our Student Members. Lastly, an educational session is being planned for late fall. It will focus on the "soft skills" needed to help YPs make their first big career move following their first entry level jobs. The date and details will be finalized in the coming months.

There is a lot happening with the YP organization at the international level, too. The Boston Area Chapter YPs participate in a monthly YP conference call for the purpose of sharing events best practices, etc. Our Chapter is known as one of the more active Chapters where YPs are concerned, with many fun events planned throughout the year. As Governor John Winthrop said when describing Boston in 1630: "as a city upon a hill, the eyes of all people are upon us," thus the Boston Area Chapter is a shining example in the ISPE organization! There is also a Community of Practice (COP) designed solely for YPs. Also, in the ISPEAK blog, a few YPs have had the opportunity to share their stories, including Boston Area Chapter YP Member Peter Tearchis from Pfizer. You can see the interview at <http://blog.ispe.org/?p=2225>

As always, we want to hear from you! If you have any suggestions, or would like to attend one of the regularly scheduled YP committee meetings, please don't hesitate to reach out to me or Jared Marshall. Thank you for tuning in and see you at an event soon!

### **Young Professionals and Students Enjoy Bowling and Flatbread Pizza**

*by Christopher Ciampa, Thermo Fisher Scientific, and Lucas Wafer, Pfizer*

On Thursday, April 30th, Boston Area Chapter Members gathered at Sacco Bowling/Flatbread Company in Davis Square. This venue has been a staple in the Somerville community ever since the Sacco family opened the bowling alley back in 1939. The venue is a mix of two companies: the Flatbread Company is known for delicious organic, nitrate-free pizzas and Sacco Bowling is the famous candlepin bowling alley. Flatbread's came into the picture around the late 1990s/early 2000s and offered pizza made with earth and fire (that is, in stone-based ovens). Flatbread's has since integrated its Somerville operations with Sacco Bowling to be able to offer the combination of pizza and bowling to the Somerville community.



*Chapter President Chris Opolski and VP Steve Kennedy joined YPs and students at Sacco's Bowl Haven in April.*

The April event drew quite a crowd with approximately 40 attendees, including many Young Professionals, the Chapter President himself, Chris Opolski, and Chapter Vice President Steve Kennedy. Student Members were provided free access to the event as part of their student membership, which also includes free attendance at the Chapter's educational programs. A few ISPE members from New Hampshire even made the trek to the social!

The event started with a networking session from 6-7pm that included unlimited pizza and salad. Folks also had the opportunity to sample hand-crafted, local beers, as Flatbreads keeps an excellent selection on tap. Afterwards, YP members had the opportunity to test out their bowling skills. Folks had a blast playing candlepin, many of whom even got strikes and spares!

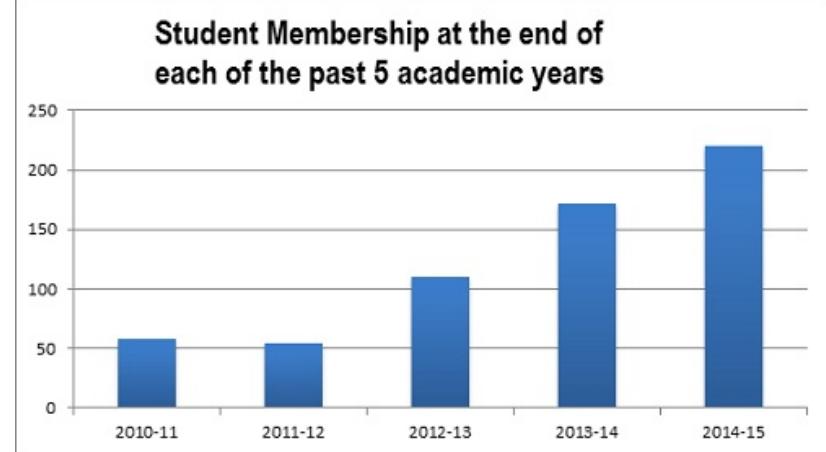
All in all, a great time was had by the Members that attended. This is an event we will be sure to host again in the following years since it was a hit!

### **Student Development: Help Us Plan for 2016 & Beyond**

*by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer.*

With the spring semester and academic year coming to a close and our Student Development Planning & Strategy Meeting approaching, this is a perfect time to reflect on the progress we have made. What have we accomplished over the past three years since the Chapter stepped up its efforts to involve students in the life science industry?

- The number of Student Chapters has more than doubled, from five to 11.
- The number of Student Members has increased by a factor of four, from about 50 to well over 200.
- More companies are taking advantage of our free job posting program with over 50 jobs posted this spring alone.
- More students are finding positions in the local life sciences industry than ever before.
- The Chapter is awarding \$25,000 per year in scholarships to Student Members.



None of this happened in a vacuum. The Chapter's board of directors deserves recognition and kudos for committing the financial resources needed to involve students at local colleges and universities in the life sciences industry. The Chapter actively sought out the most successful Student Chapters across the country and identified the key elements to success - active faculty involvement, active ISPE liaisons on campus, and availability of entry level jobs, to mention a few. We then sought out a dedicated and motivated group of Chapter volunteers to help spearhead on-campus efforts and implement programs at several college campuses, knowing that their efforts might take several years to generate results.

Perhaps the most telling metric of all happened this spring when we asked seven recent college grads (and former Student Members) now working in the local life sciences industry to act as mentors by attending our spring Career Workshop, an all-day event held on a Saturday in February. All seven agreed to attend and everyone was happy to "pay it forward" stating that the programs sponsored by the Chapter were excellent and had really helped them get a start in the industry.



The Career Workshop held in February provided practical career advice with a focus on the local life sciences industry.

While the Chapter has a clear path forward, we also recognize the need for flexibility and are always looking for opportunities to improve. For this reason, we hold an annual strategic planning meeting during the summer months to brainstorm ideas for student development activities in the upcoming year. This year's meeting will be held at Waltham Woods on Wednesday, July 15 from 5:30 to 8:30. Please contact the ISPE office or email [brian@clear-water-consulting.com](mailto:brian@clear-water-consulting.com) if you are interested in attending and helping the Chapter plan for the future!

### **Industry News In Brief**

by Jillian Willard, Genzyme, a Sanofi Company

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.

#### **Alnylam Pharmaceuticals to Lease Lab and Office Space in Cambridge**

BioMed Realty Trust has announced that Alnylam has signed a 295,000 square foot lease at 675 West Kendall Street. Alnylam is leading the translation of RNAi as a new class of innovative medicines, with a core focus on RNAi therapeutics toward genetically defined targets for the treatment of serious, life-threatening diseases with limited treatment options for patients and their caregivers. This growing life science company will occupy all the rentable space available on the six floors of 675 West Kendall when the lease with the current tenant, Vertex Pharmaceuticals, ends in May 2018. (Source: Biomedrealty.com, 06 April, 2015)

#### **Thermo Fisher Scientific Acquires Advanced Scientifics (ASI)**

Thermo Fisher Scientific has announced it has acquired Advanced Scientifics, Inc. (ASI), a provider of single-use technologies for customized bioprocessing solutions, for \$300 million in

cash. ASI designs, manufactures and delivers customized single-use systems and equipment for the preparation, processing, storage and transportation of biopharmaceuticals. The company has 380 employees and operations in Pennsylvania and Mexico. Advanced Scientifics had approximately \$80 million in 2014 revenue and will be integrated into Thermo Fisher's Life Sciences Solutions Segment. (Source: Thermo Fisher Scientific Website, 05 February, 2015)

#### **FDA Approves Momenta Pharmaceuticals' Generic Drug for Treatment of MS**

Momenta Pharmaceuticals has announced that the FDA has granted marketing approval of Sandoz's Abbreviated New Drug Application for once daily Glatopa, a generic equivalent of daily Copaxone 20 mg. Glatopa is the first substitutable generic indicated for the treatment of patients with relapsing forms of multiple sclerosis (RRMS), a central nervous system disease characterized by inflammation and neurodegeneration. Glatopa was developed under a collaboration agreement between Momenta and Sandoz and is the second complex generic developed by Momenta together with Sandoz to receive FDA approval. Glatopa will be commercialized under the Sandoz brand.

Glatopa was determined by the FDA to be therapeutically equivalent to daily Copaxone 20 mg, with the same active ingredients, route of administration, strength and dosage form and Glatopa is now fully substitutable at the pharmacy level.

Under the terms of its collaboration agreement with Sandoz, Momenta is eligible to receive up to \$140M in milestone payments upon the achievement of certain U.S. regulatory, commercial and sales-based milestones for Glatopa, including a \$10M payment earned upon sole FDA approval of the ANDA, and another \$10M milestone payment upon first commercial sale. Sandoz is currently evaluating launch timing. (Source: Momenta Pharmaceuticals Website, 16 April, 2015)

#### **FDA Grants Priority Review for Boehringer Ingelheim's Anticoagulant Reversal Agent**

Boehringer Ingelheim Pharmaceuticals has announced that the FDA has granted Priority Review to the Biologics License Application (BLA) for idarucizumab, which is being investigated to specifically reverse the anticoagulant effect of dabigatran, the active ingredient in Pradaxa in patients needing emergency intervention or experiencing an uncontrolled or life-threatening bleeding event. The application includes phase I data showing the potential for idarucizumab to provide immediate reversal of the anticoagulant effect of dabigatran, the active ingredient in Pradaxa.

The idarucizumab BLA will be reviewed under Accelerated Approval and is the first review for a reversal agent in the novel oral anticoagulant (NOAC) class. If approved, Pradaxa will become the first NOAC with a complimentary product capable of reversing the anticoagulant effects for emergency intervention.

A Priority Review designation is granted when a drug, if approved, exhibits the potential to offer a significant improvement in the safety or effectiveness of the treatment of serious conditions when compared to standard applications. The FDA instituted its Accelerated Approval program to allow for earlier approval of drugs that both treat a serious condition and fill an unmet medical need based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Additionally, the FDA granted Breakthrough Therapy Designation for idarucizumab in June 2014. (Source: Boehringer Ingelheim Pharmaceuticals Website, 03 March, 2015)

#### **Sarepta Therapeutics to Submit Rolling NDA for Eteplirsen**

Cambridge-based Sarepta Therapeutics has announced that the company held a pre-New Drug Application (NDA) meeting with the FDA regarding its lead product candidate, eteplirsen, for the treatment of Duchenne muscular dystrophy (DMD). Sarepta has agreed with the FDA to initiate a rolling NDA submission and will submit the non-clinical and CMC components of the NDA by the end of this week. As previously announced, Sarepta plans to submit the final component of the NDA by mid-year 2015.

Sarepta Therapeutics is a biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics for the treatment of rare, infectious and other diseases. The company is primarily focused on rapidly advancing the development of its potentially disease-modifying DMD drug candidates, including its lead DMD product candidate, eteplirsen. Sarepta is also developing therapeutics for the treatment of drug-resistant bacteria and infectious, rare and other human diseases. (Source: Sarepta Therapeutics Website, 19 May, 2015)

#### **Alexion to Acquire Synageva**

Alexion Pharmaceuticals and Synageva BioPharma have announced that they have entered into a definitive agreement in which Alexion will acquire Synageva for consideration of \$115 in cash and 0.6581 Alexion shares for each share of Synageva, implying a total per share value of \$230 based on the nine day volume-weighted average closing price of Alexion stock through 05 May, 2015.

The transaction has been unanimously approved by both companies' Boards of Directors, and is valued at approximately \$8.4 billion net of Synageva's cash. Alexion expects to achieve annual cost synergies starting this year and growing to at least \$150 million in 2017. In addition, the transaction is expected to be accretive to non-GAAP earnings per share in 2018.

Like Alexion, Synageva's pipeline includes many treatments for rare diseases. After the acquisition, Alexion will have a clinical pipeline with eight product candidates in clinical trials for eleven indications. The programs include Synageva's SBC-103, an investigational enzyme replacement therapy in an ongoing Phase 1/2 trial for patients with mucopolysaccharidosis IIIB (MPS IIIB), a genetic and progressive rare metabolic disease. SBC-103 was granted Fast Track designation by the FDA in January 2015.

In addition, Alexion will have more than 30 pre-clinical programs across a range of therapeutic modalities, including 12 from Synageva's novel drug discovery platform. At least four pre-clinical candidates from the combined pipelines are expected to enter the clinic by year-end 2016.

Alexion will also have expanded manufacturing capabilities with three Synageva upstream facilities. Synageva brings to Alexion a proprietary manufacturing technology, known as the expression platform, an integrated system of proprietary vectors that can be used to produce proteins with human-like glycosylation patterns, creating additional therapies with better targeting capabilities and the potential for greater efficacy.

The acquisition also includes Synageva's Kanuma, which is under Priority Review with the FDA and has been granted accelerated assessment of its Marketing Authorization Application (MAA) by the European Medicines Agency (EMA). Kanuma has been granted Breakthrough Therapy Designation by the FDA for LAL Deficiency presenting in infants. Regulatory decisions in the U.S. and Europe are expected in the second half of 2015. (Source: Alexion Website, 06 May, 2015)

#### **bluebird bio Aiming for Accelerated Approval for LentiGlobin BB305**

Cambridge based bluebird bio, Inc., a clinical-stage company developing gene therapies for severe genetic and rare diseases and T cell-based immunotherapies, announced that it has met with regulatory authorities in Europe and the United States to discuss potential approval pathways for its LentiGlobin BB305 product candidate for the treatment of beta-thalassemia major. These discussions have resulted in general agreement from both agencies regarding bluebird bio's development plans, which could potentially result in accelerated approvals.

Bluebird bio will be one of the first companies to participate in the European Medicines Agency's (EMA) Adaptive Pathways (formerly referred to as Adaptive Licensing) pilot program, which is part of the EMA's efforts to improve timely access for patients to new medicines. Based on several discussions involving the EMA, European Health Technology Assessment (HTA) agencies and patient advocacy organizations as part of this program, bluebird bio believes it is possible to seek conditional approval for the treatment of adults and adolescents with beta-thalassemia major on the basis of the totality of clinical data, including that from an ongoing study. Conversion to full approval will be subject to the successful completion of two clinical trials, supportive long-term follow-up data and "real-life" post-approval monitoring data.

In addition, bluebird bio has reached general agreement with the FDA on the design of two of its planned clinical trials. Based on its discussions with the FDA, bluebird bio believes that data from these trials, together with data from the ongoing beta-thalassemia major clinical studies, could form the basis for a Biologics License Application (BLA) submission for LentiGlobin BB305.

The FDA has already granted Breakthrough Designation for LentiGlobin BB305, which grants additional FDA guidance through the development and review of a drug candidate. If the LentiGlobin BB305 product candidate demonstrates acceptable efficacy and safety in these patient populations, these planned clinical trials could support an accelerated approval, with post-approval confirmatory evidence to be provided with longer-term follow-up of these trials. (Source: bluebird bio Website, 19 May, 2015 & 02 February, 2015)

#### **Retrophin Agrees to Sell Priority Review Voucher to Sanofi for \$245 Million**

San Diego-based Retrophin, Inc. has announced an agreement to sell its Rare Pediatric Disease Priority Review Voucher ("Pediatric PRV") to Sanofi. Retrophin received the Pediatric PRV when Cholbam™ was approved by the FDA for the treatment of pediatric and adult patients suffering from bile acid synthesis disorders due to single enzyme defects, and for patients with peroxisomal disorders (including Zellweger spectrum disorders).

Upon closing of the transaction, Retrophin will receive a payment of \$150M, followed by two equal installments of \$47.5M in 2016 and 2017. The company will receive a total consideration of \$245M in cash from Sanofi in exchange for the Pediatric PRV. The voucher was awarded by the FDA under a provision that encourages development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. Sanofi has not disclosed how it will use the PRV. The transaction is subject to customary closing conditions and clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

The Rare Pediatric Disease PRV program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. A Pediatric PRV may be issued to the sponsor of a rare pediatric disease product application and would entitle the holder to priority review of a single New Drug Application or Biologics License Application, which reduces the target review time and could lead to an expedited approval. The sponsor receives the voucher upon approval of the rare pediatric disease product application. (Source: Retrophin Website, 27 May, 2015)

#### **Padlock Therapeutics Licenses GSK Intellectual Property and Assets**

Cambridge-based Padlock Therapeutics has announced that the company has entered into an agreement to license intellectual property and a collection of assets targeted at protein-arginine deiminases (PADs) from GSK. Padlock plans to use these assets to expand its proprietary chemistry portfolio in an effort to create new treatments for autoimmune disease by targeting the PAD enzymes. Clinical applications under evaluation at Padlock include rheumatoid arthritis, systemic lupus erythematosus, and multiple sclerosis.

Under the terms of the agreement, Padlock will receive exclusive rights to a package of assets including intellectual property, selected compounds in several chemical series, assays, data and crystal structures developed by GSK scientists. In return, GSK will receive an undisclosed equity grant and board observer rights. Per the transaction, GSK receives no option to license or acquire Padlock assets nor does Padlock owe any future milestone or royalty payments.

The protein-arginine deiminases (PADs) are a family of enzymes that post-translationally modify arginine side chains on proteins to the related amino acid citrulline. In some patients, these citrullinated proteins are immunogenic - in other words, in these patients PAD enzymes produce the autoantigens that drive disease. Inhibiting PADs in these patients may provide an innovative,

alternative approach to treating patients who suffer from rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, and other destructive autoimmune diseases. (Source: Padlock Therapeutics Website, 28 May, 2015)

### **FTC Reaches \$1.2B Settlement in Suit Charging Cephalon with Blocking Generic Competition**

The Federal Trade Commission has reached a settlement resolving the Commission's antitrust suit charging Cephalon, Inc. with illegally blocking generic competition to its blockbuster sleep-disorder drug Provigil. The settlement ensures that Teva Pharmaceutical Industries, Ltd., which acquired Cephalon in 2012, will make a total of \$1.2B available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid because of Cephalon's illegal conduct. Provigil is a prescription drug approved to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shift-work sleep disorder. In the year before generic entry, Provigil sales in the United States exceeded \$1 billion.

The settlement stems from a 2008 FTC lawsuit, which charged that Cephalon unlawfully protected its Provigil monopoly through a series of agreements with four generic drug manufacturers in late 2005 and early 2006. The FTC alleged that Cephalon sued the generic drug makers for patent infringement and later paid them over \$300 million in total to drop their patent challenges and forgo marketing their generic products for six years, until April 2012. This type of settlement, in which the generic drug firm agrees not to market its product for a period of time and the brand name drug manufacturer pays the generic - whether in monetary or non-monetary form - is commonly referred to as a "reverse-payment" patent settlement. In 2013, in *FTC v. Actavis*, the Supreme Court confirmed that reverse payments can violate antitrust laws.

As part of the settlement, Teva also has agreed to a prohibition on the type of anticompetitive patent settlements that Cephalon used to artificially inflate the price of Provigil. Teva is the largest generic drug manufacturer in the world, and this prohibition applies to all of its U.S. operations. (Source: Federal Trade Commission Website, 28 May, 2015)

### **Mass Innovation Labs Launches Co-working Lab Space in Kendall Square**

Mass Innovation Labs has announced the launch of 124,000 square foot accelerated commercialization space (ACS) in the heart of Kendall Square. An ACS is designed to provide comprehensive solutions for growing life science companies, including research model facilities, co-located CRO services, and operational needs under one roof. Mass Innovation Labs is comprised of first-class chemistry and biology laboratories alongside office space and is located at 675 West Kendall Street in Cambridge.

One of the company's partners, Charles River Laboratories, recently opened Charles River Accelerator and Development Lab (CRADL), an onsite turnkey facility to provide customized vivarium space and scientific support. CRADL offers a flexible option for biopharmaceutical companies to launch or expand research capabilities, with the added benefit of access to Charles River's premier portfolio of integrated drug discovery resources.

CRISPR Therapeutics, a biopharmaceutical company focused on translating CRISPR-Cas9 gene-editing technology into transformative medicines for serious human diseases, is the first tenant to join Mass Innovation Labs and CRADL. (Source: PM Business Wire, 04 May, 2015)

### **Mylan Board Rejects Unsolicited \$40B Offer from Teva, Increases Offer for Perrigo**

Mylan has announced that its Board of Directors has unanimously rejected the unsolicited expression of interest from Teva Pharmaceutical to acquire Mylan, which was announced by Teva on 21 April, 2015. Executive Chairman Robert J. Coury stated multiple reasons for rejection of the offer in a letter to Teva CEO Erez Vigodman. These reasons included that the \$40B offer undervalued the company, and concern over the strength and capabilities of Teva as a company. The board felt that any offer for the company would need to be well over \$100 a share, much higher than the \$82 a share offered by Teva.

The letter stated that "Teva faces the looming loss of significant revenue from the end of exclusivity for the Copaxone franchise, and has seen years of consistent and significant underperformance, even while enjoying the benefits of Copaxone. Further, Teva has faced a constantly changing and flip flopping strategy, rotating leadership, shareholder outrage and a flat to negative growth outlook." The letter added that, "In the past three years Teva has underperformed peers and the S&P 500 index by 223 percent and 12 percent, respectively."

The announcement also reiterated Mylan's interest in acquiring Perrigo, an Irish manufacturer of over the counter products. Two days later, Mylan increased its offer for Perrigo to \$232.23 per Perrigo share, Abbott Laboratories' announced intention to support Mylan's offer to acquire Perrigo and vote in favor of this acquisition at Mylan's upcoming shareholder meeting. Abbott is currently Mylan's largest shareholder, owning 14.5 percent of Mylan's outstanding shares. (Sources: Mylan Website, 27 April, 29 April & 16 June, 2015; Teva Pharmaceuticals Website, 21 April, 2015)

### **Philips Signs Pact with MIT, Will Move North America Research Center to Cambridge**

Royal Philips announced it has signed a five-year research alliance with the Massachusetts Institute of Technology (MIT) aimed at developing innovative HealthTech solutions to address society's most pressing challenges in healthcare, as well as digital connected lighting systems to address the need to make cities more livable and sustainable. With a total budget of \$25M for the five-year term, this is the largest research alliance undertaken by the company in the region.

Philips also plans to move the company's research center to Cambridge, allowing Philips to collaborate with other institutes and partner companies. The move to Cambridge, within close proximity of the MIT campus, will allow Philips researchers to collaborate readily with MIT faculty and Ph.D students on jointly defined research programs, as well as participate in open innovation projects.

Joint teams will work on advancements in HealthTech, for example to help improve the

management of cardiovascular disease and the diagnosis and treatment of various types of cancer, focused on improving patient outcomes, while reducing costs. Through the alliance, Philips will gain access to MIT's experts and clinical partners, allowing the company to better explore applications for population health management through the use of high-resolution imaging, healthcare informatics and data analytics. (Source: Philips Website, 19 May, 2015)

#### **Voyager Therapeutics Raises \$60 Million**

Cambridge-based Voyager Therapeutics, a gene therapy company developing treatments diseases of the central nervous system (CNS), has announced the successful completion of a \$60M Series B financing. Investors included Brookside Capital, Partner Fund Management, Wellington Management Company, Casdin Capital and two undisclosed blue chip investment funds.

Proceeds from the financing will be used to advance the company's product pipeline, which includes five clinical and preclinical programs, as well as its industry-leading adeno-associated virus (AAV) product engine. The company's pipeline is focused on CNS diseases, including Parkinson's disease, a monogenic form of amyotrophic lateral sclerosis (ALS), Friedreich's ataxia and Huntington's disease.

Voyager has broad strategic collaborations with Genzyme, a Sanofi company, and the University of Massachusetts Medical School (UMMS). Founded by scientific and clinical leaders in the fields of AAV gene therapy, expressed RNA interference and neuroscience, Voyager Therapeutics was launched in 2014 with funding from leading life sciences investor Third Rock Ventures. (Source: Voyager Therapeutics Website, 13 April, 2015)

### **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 Amgen Drug for Heart Failure**

The FDA has approved Amgen's Corlanor (ivabradine) to reduce hospitalization from worsening heart failure. Corlanor is approved for use in certain people who have chronic heart failure caused by the lower-left part of their heart not contracting well. The drug is indicated for patients who have symptoms of heart failure that are stable, a normal heartbeat with a resting heart rate of at least 70 beats per minute and are also taking beta blockers at the highest dose they can tolerate.

Corlanor will be dispensed with a patient Medication Guide that provides instructions for its use and important drug safety information. Health care professionals should counsel patients about the risk of harm to an unborn baby, and women should not become pregnant while taking Corlanor. (Source: FDA Website, 15 April, 2015)

#### **First Generic Version of Copaxone Approved by FDA for Patients with MS**

Sandoz has received FDA approval to market generic glatiramer acetate in a 20 mg/1 ml daily injection for treatment of multiple sclerosis (MS). 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.

The FDA applies the same rigorous and reliable standards to evaluate all generic drug products. As needed, the agency requires appropriate information to demonstrate sameness for complex active ingredients, such as glatiramer acetate. For this approval, FDA scientists established a thorough scientific approach for demonstrating active ingredient sameness that takes into consideration the complexity of glatiramer acetate. (Source: FDA Website, 16 April, 2015)

#### **FDA Approves First Generic Versions of Abilify for Schizophrenia and Bipolar Disorder**

The FDA has approved the first generic versions of Abilify (aripiprazole). Generic aripiprazole is an atypical antipsychotic drug approved to treat schizophrenia and bipolar disorder. Alembic Pharmaceuticals, Hetero Labs, Teva Pharmaceuticals and Torrent Pharmaceuticals have received FDA approval to market generic aripiprazole in multiple strengths and dosage forms.

Generic prescription drugs approved by the FDA have the same high quality and strength as brand-name drugs. Generic prescription drug manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs. (Source: FDA Website, 28 April, 2015)

#### **Orphan Drug from Wyeth Approved for Rare Lung Disease**

The FDA has approved Rapamune (sirolimus) to treat lymphangioleiomyomatosis (LAM), a rare, progressive lung disease that primarily affects women of childbearing age. This is the first drug approved to treat the disease. Rapamune is made by Wyeth Pharmaceuticals, a subsidiary of Pfizer.

LAM is characterized by an abnormal growth of smooth muscle cells that invade lung tissues, including the airways, and blood/lymph vessels that cause destruction of the lung, resulting in airflow obstruction, and limiting the delivery of oxygen to the body. LAM is a very rare disease. According to the U.S. National Library of Medicine, only between two and five women per million women worldwide are known to have the disease. (Source: FDA Website, 28 May, 2015)

#### **FDA Approves Implantable Device to Help Reduce Symptoms of Parkinson's**

The FDA has approved the Brio Neurostimulation System, an implantable deep brain stimulation device to help reduce the symptoms of Parkinson's disease and essential tremor, a movement disorder that is one of the most common causes of tremors. The Brio Neurostimulation System can help some patients when medication alone may not provide adequate relief from symptoms such as walking difficulties, balance problems, and tremors.

An estimated 50,000 Americans are diagnosed with Parkinson's disease each year, according to the National Institutes of Health, and about one million Americans have the condition. The neurological disorder typically occurs in people over age 60, when cells in the brain that produce a chemical called dopamine become impaired or die. Dopamine helps transmit signals between the areas of the brain that produce smooth, purposeful movement. (Source: FDA Website, 12 June, 2015)

#### **FDA Approves New Device to Assist the Blind**

The FDA allowed marketing of a new device that, when used along with other assistive devices, like a cane or guide dog, can help orient people who are blind by helping them process visual images with their tongues.

The BrainPort V100, manufactured by Wicab, Inc. of Middleton, WI, is a battery-powered device that includes a video camera mounted on a pair of glasses and a small, flat intra-oral device containing a series of electrodes that the user holds against their tongue. Software converts the image captured by the video camera in to electrical signals that are then sent to the intra-oral device and perceived as vibrations or tingling on the user's tongue. With training and experience, the user learns to interpret the signals to determine the location, position, size, and shape of objects, and to determine if objects are moving or stationary.

According to the National Institutes of Health's National Eye Institute (NEI), in 2010 more than 1.2 million people in the United States were blind. NEI projects that number of Americans who are blind will rise to 2.1 million by 2030 and 4.1 million by 2050.

The FDA reviewed the data for the BrainPortV100 through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally-marketed device. (Source: FDA Website, 18 June, 2015)

#### **New Members**

**Nedim Emil Altaras**, Seres Therapeutics, Inc.

**Patrick B. Archer**, BWT Pharma & Biotech, Inc.

**Gordon A. Argall**, Alexion Pharmaceuticals

**Michael T. Bergin**, Pharmacuetical Quality

**Mark S. Berglund, P.E.**, Baxalta

**Kellie D. Ciano**, SBB Testing

**Edward Dyakiw**, Alexion Pharmaceuticals, Inc

**Michael Forth**, Suffolk Construction

**John Frenz**, Alnylam Pharmaceuticals

**Steven Frye**, Shire

**Sandra Gibbons**, Shire

**Brandy Gill**, Immunogen

**William Greenrose**, Deloitte

**Stephen M. Hall**, Clorox

**Michael Healy**, Citra Labs (A Biomet Biologics Company)

**Ben Higgitt**, Cognition Corporation

**Michael D. Hobbs, Jr.**, Organogenesis Inc

**Mike Ingalls**, Shire

**Andrea D. Jones**, Softworld Inc.

**Olga Kazatchenko**, Genzyme

**Claude Kinard**, Sequence Quality and Compliance Services

**Anna S. Kokensparger**, Momenta

**Frank Koza**, Shire

**Andrew Krenning**, Siemens Building Technologies

**Nicole Labrecque**

**Kevin LaPlante**, Design Group Facility Solutions

**Patrick Mahan**

**Maura Maloney**, Ironwood Pharmaceuticals

**Derek Masser**, Non-Metallic Solutions  
**Chris Masterson**, Ipsen Pharmaceuticals  
**John Morton**, HITCO  
**Glen F. Nonemaker**, Genzyme  
**Dr. Jose Manuel Otero**, Seres Therapeutics, Inc.  
**Ashley Owens**, Berkshire Sterile Manufacturing  
**Brijesh Patel**, Shire  
**James Pentleton**, Shire Pharmaceuticals  
**Kevin D. Pham**, Shire Pharmaceuticals  
**Jonathan Platt**, Amgen  
**Michael T. Puntin**, Berkshire Sterile Manufacturing  
**Elizabeth A. Richmond**, Vertex Pharmaceuticals Inc.  
**Isabel Rodriguez**, IRP Consulting  
**Jon P. Roland**, Saint-Gobain  
**Debra J. Sawyer**, Shire  
**Bryan Scrocca**, Precision Cleanrooms  
**Ted Smith**, HITCO  
**Laura Stoneman**, Northeastern University  
**Nathan A. Storie**, Design Group  
**Rose Mary Su**, Acentech  
**Scott Tereshak**, Lend Lease

### Member Anniversaries

#### **Over Twenty Years**

- Fred H. Arbogast, Critical Process Filtration Inc. (22 years)
- James V. Blackwell, PhD, MBA, The Windshire Group, LLC (21 years)
- Nicholas J. Casale, Biogen Idec (21 years)
- Shelly Henderson, HCA (23 years)
- Tom J. Routliffe, Medimmune (23 years)

#### **Twenty Years**

- H Steven Kennedy, PE

#### **Fifteen Years**

- Mark J. Keegan, Selecta Biosciences, Inc.
- Anthony J. Meenaghan, Serono Laboratories Inc
- Christopher J. Opolski, SPEC Process Engineering and Construction

#### **Ten Years**

- Anthony Giragosian, MassBiologics
- Rexford Hayes, ICQ Consulting Inc.
- Christopher H. White, Alexion Pharmaceuticals

#### **Five Years**

- Andrew Gee, Boehringer Ingelheim Pharma
- Joe McCreight, Thermo Scientific BPP & Cell Culture
- Suesan Randlett, Gamma Supplies, LLC
- Andre J. Zdunczyk, Bausch + Stroebel Machine Company, Inc.

