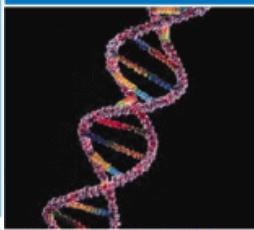




Boston Area Chapter

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NEWSLETTER

May 2016, Volume XXVI, No. 3

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Vice President's Message: Join Us to Celebrate Our Dedicated Volunteers and Their Many Contributions to the Chapter

My Fellow Members,

Volunteers made it happen! As we approach the Chapter's 25th anniversary in 2017, it is truly impressive to reflect on how far we have come. Not that many years ago we held a monthly educational program, a couple of social events each year and an Annual Product Show squeezed into the ballroom (and surrounding corridors) at the Newton Marriott (and before that, at the Howard Johnson's on Memorial Drive in Cambridge).

Today, a quick look at the calendar on the Chapter's website reveals dozens of events taking place in 2016, from educational programs, to networking socials, to special events geared to appeal to our Young Professional and Student Members, to our blockbuster Product Show at Gillette Stadium, the biggest and best one-day show serving our industry, bar none. And not only have we grown our membership to 1700, making our Chapter the largest in the ISPE family, we have extended our reach into areas well beyond the Boston area, regularly offering educational programs in Providence, Worcester and Portsmouth for the convenience of our far-flung Chapter Members.



And we have accomplished all of this without expanding our paid staff. How? Through the dedicated efforts of over a hundred Chapter volunteers who work together on the Chapter's nine committees to plan and execute this truly impressive schedule of activities every year. Their nonstop efforts and innovations enable the Chapter to thrive and prosper while fulfilling its mission of providing technical education, networking opportunities and career development for the region's pharmaceutical and biopharmaceutical industry professionals.

To honor our many volunteers and their contributions, the Chapter has declared this year's **Summer Social** on June 23 to be a "volunteer appreciation" celebration. The location is the Squantum Yacht Club in Quincy and the theme is "tropical isle" - so don your complimentary lei and join us for an evening of food, fun, and fellowship in recognition of the extraordinary efforts of our volunteers. After all, we couldn't succeed without them!

Future Biopharm Manufacturing Our April program at WPI, featured presentations and a panel discussion entitled "Biomanufacturing Science & Technology: Preparing for Tomorrow" along with the Annual Student Poster Competition. It was a perfect example of another ambitious Chapter offering. The event combined education, networking and an exciting opportunity for the best and the brightest among our Student Members to showcase their research. Congratulations to our winners:

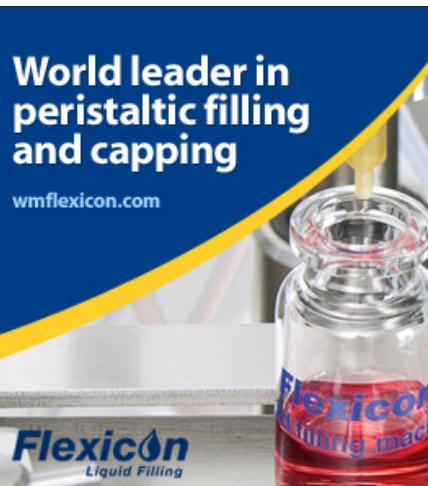
- Undergraduate Connor Williams of UMass Lowell and MIT ("NIR-Based Absorption Photometer Enables Real Time Monitoring of Optical Density in Yeast Fermentation"); and
- Graduate student John De La Parra of Northeastern ("Controlled Biosynthesis and Diversification of Plant-Derived Pharmaceuticals").

And kudos to James Carroll of Northeastern University and Middlesex Community College, and Shannon Guertin and Elaheh Kamaloo, both of WPI, all of whom made the judges' job especially difficult this year.

The winners were each awarded \$500 and an expense-paid trip to the ISPE Annual Meeting in Atlanta where they will compete against Poster Competition winners from ISPE Chapters and Affiliates around the globe. To quote one of the judges, "Listening to the students describe their research and answer tough questions with poise and professionalism leaves me feeling good about the future of our industry and the positive role our Chapter plays in that future." I would like to echo that view.

Looking forward to honoring our many Chapter volunteers with an evening of food, fun, and fellowship on June 23. Hope to see you there!

Warm Regards,



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Jack Campion
Vice President

Chapter Bulletin Board

Product Show Booths Selling Fast - Don't Delay or You May Miss Out!

From 1992 through 2016, the ISPE Boston Area Chapter Product Show has been "Connecting the Hub of Life Sciences for a Quarter Century." So join us on October 5, 2016 at Gillette Stadium in Foxborough, MA and help us celebrate our 25th Anniversary Product Show.

The ISPE Boston Area Chapter Product Show is the largest one-day show serving the life sciences industry in the world. Highlights include:

- Over 2500 life sciences professionals from the major manufacturing sites in the northeast
- Senior decision makers from operations, engineering, sourcing and compliance
- Attendees who are part of the decision process with open projects they are sourcing for
- Multiple opportunities to reconnect with current customers and prospect for new clients

Not to mention exciting educational programs, keynote address and special events throughout the day. Plus our famous After Party, this year at Splittsville in Patriots Place and featuring New England Patriots Defensive End Robert Ninkovich.

Booths and tables are going fast. Registration opened just a month ago and already 2/3 of the tables have been sold. So don't delay any longer. To reserve your exhibitor space, simply go to the ISPE Boston Product Show page and Register today.

Join the Product Show Committee and Contribute to the Show's Success

The Product Show Committee (PSC) organizes and coordinates all activities associated with the Boston Area Chapter Product Show, the largest one-day gathering of biotech and pharma professionals in New England. In addition to an exciting educational program and keynote address, the Show offers attendees an unparalleled opportunity to network with industry peers and the Chapter's Board of Directors. With over 375 exhibiting companies and well over 2,500 attendees each year, the Product Show has earned its reputation as ISPE's best local show.

The Product Show Committee is responsible for all aspects of the Show, including soliciting exhibitors, assisting in the coordination of the educational program, attracting attendees and providing a host of activities throughout the day. Committee members work closely with other Chapter committees such as the Educational Program Committee, Communications Committee, Young Professionals Committee and Student Development Committee to ensure a successful event.

The PSC is made up of a motivated group of volunteers including several members of the Chapter Board of Directors. Committee members have varied backgrounds and expertise. All have the opportunity to work together in a fast-paced environment, have fun and participate in something very special every year.

The Product Show's continued success relies on the participation and creativity of PSC members. Innovative and cutting edge ideas keep the Show new and fresh every year and ensure a high degree of participation from the local community. New Committee members who want to get involved are always welcome. To join this award-winning team, please contact any member of the committee or the Chapter Board of Directors, or the Boston Area Chapter administrative offices at office@ispeboston.org.

Chapter Mentoring Program Up and Running

Could you benefit from the experiences of others or can you share your experiences to help a fellow Member? If so, the Chapter's new Mentoring Program is the place for you. Mentoring is a positive experience as well as a growth opportunity for both the mentor and mentee. Check out the new "Mentoring Program" tab on the Chapter website to learn more: <http://www.ispeboston.org/mentoringdescription.html>. All you have to do is register and the Chapter will pair you up.

The mentoring program took almost a year to build and was a truly multidisciplinary effort by Membership Committee Chair Samir Gondalia, YP Committee Chair Chris Ciampa and Student Development Committee Co-Chair Brian Hagopian who worked together to develop and launch the program.

eNewsletter 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.

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 http://www.ispeboston.org/become_a_sponsor.html 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!



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Previous Issues

[March 2016, Volume... \(12\)](#)
[January 2016, Volume... \(15\)](#)
[November 2015, Volume... \(15\)](#)
[September 2015, Volume... \(14\)](#)
[July 2015, Volume XXV,... \(15\)](#)
[May 2015, Volume XXV,... \(12\)](#)
[March 2015, Volume... \(12\)](#)
[January 2015, Volume... \(13\)](#)
[November 2014, Volume... \(13\)](#)
[September 2014, Volume... \(17\)](#)
[July 2014, Volume... \(13\)](#)
[May 2014, Volume XXIV,... \(13\)](#)
[March 2014, Volume... \(13\)](#)
[January 2014, Volume... \(0\)](#)
[January 2014, Volume... \(11\)](#)
[November 2013, Volume... \(14\)](#)
[September 2013, Volume... \(17\)](#)
[July 2013, Volume... \(12\)](#)
[May 2013, Volume... \(12\)](#)
[March 2013, Volume... \(12\)](#)
[January 2013, Volume... \(11\)](#)
[November 2012, Volume... \(15\)](#)
[September 2012, Volume... \(16\)](#)
[July 2012, Volume... \(12\)](#)
[May 2012, Volume XXII,... \(13\)](#)
[March 2012, Volume... \(11\)](#)
[January 2012, Volume... \(10\)](#)
[November 2011, Volume... \(16\)](#)
[September 2011, Volume... \(15\)](#)
[July 2011, Volume XXI,... \(12\)](#)
[May 2011, Volume XXI,... \(16\)](#)
[March 2011, Volume XXI,... \(16\)](#)
[January 2011, Volume... \(13\)](#)
[November 2010, Volume... \(14\)](#)
[September 2010, Volume... \(16\)](#)
[July 2010, Volume XX,... \(13\)](#)
[May 2010, Volume XX,... \(16\)](#)
[March 2010, Volume XX,... \(15\)](#)
[January 2010, Volume... \(14\)](#)
[November 2009, Volume... \(11\)](#)
[September 2009, Volume... \(13\)](#)
[July 2009, Volume XIX,... \(11\)](#)
[May 2009, Volume XIX,... \(9\)](#)
[April 2009, Volume... \(11\)](#)
[February 2009, Volume... \(10\)](#)
[December 2008, Volume... \(13\)](#)
[October 2008, Volume... \(12\)](#)
[August 2008, Volume... \(10\)](#)
[June 2008, Volume... \(11\)](#)
[April 2008, Volume... \(10\)](#)
[February 2008, Volume... \(10\)](#)
[December 2007, Volume... \(13\)](#)
[October 2007, Volume... \(10\)](#)

Newsletter Archive

So don't delay, visit http://www.ispeboston.org/become_a_sponsor.html 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 and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Monday, May 9, 2016

ISPE Spring Golf Tournament

Ledgemont Country Club, Seekonk, MA

EVENT SUMMARY

Spring golf has sold out! Contact our office if you'd like to be added to the waitlist. Click on the link below for full details.

Click below for full information:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=647

Thursday, May 19, 2016

ISPE Single Use: From Toddler to Adolescent

Shire (Fortis Lecture Hall), Lexington, MA

PROGRAM SUMMARY

Attend the live program at Shire in Lexington, MA. This program will feature a networking reception including appetizers. As an added bonus, Shire is hosting a tour of Shire's Pilot Plant Facility with an emphasis on single use implementation. This is an ISPE MEMBER ONLY tour and has SOLD OUT but you may join the waitlist!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=578

Wednesday, May 25, 2016

ISPE Brainstorming Session For 2017 Educational Programming

Biogen, Cambridge, MA

EVENT SUMMARY

The Educational Program Committee of the ISPE Boston Area Chapter is sponsoring a free fun get-together with door prizes to brainstorm topics for the 2017-2018 season. If you have ideas for educational programs, speakers, or locations, please join us to share your thoughts. The session will begin with a networking reception and light dinner, and continue with a forum where attendees will offer their ideas and suggestions. All ideas will be voted on by the entire Boston area chapter membership via electronic survey. Results off the survey will be presented in July at which time you may volunteer to be a program manager or assist in another manner for a specific event. Please consider volunteering for the Educational Programs Committee to make these programs come to life!

Attendance is **free** (we want your ideas!), so please come and help us plan and brainstorm!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=652

Thursday, May 26, 2016

ISPE RE-SHOWING: Single Use: From Toddler to Adolescent

WPI Biomanufacturing Education and Training Center, Worcester, MA

Doherty's Ale House, Warwick, RI

Redhook Ale Brewery - Alemaker's Hall, Portsmouth, NH

EVENT SUMMARY

Join us at the WPI BETC at Gateway Park in Worcester, MA; Doherty's Ale House in Warwick, RI; or the Redhook Ale Brewery in Portsmouth, NH for a re-showing of the program recorded at Shire, May 19, 2016. A networking reception, including refreshments and appetizers, will be hosted before the presentation at each location.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=646

Thursday, June 16, 2016

ISPE Data Integrity: Part 11 is the Least of Your Problems

Crowne Plaza, Warwick, RI
WPI LSBC, Worcester, MA (Simulcast)
Redhook Ale Brewery, Portsmouth, NH (Simulcast)
Tufts Gordon Institute, Medford, MA (Simulcast)

EVENT SUMMARY

You are invited to attend a live program on Data Integrity with a focus on the recent FDA draft guidance for "Data Integrity and Compliance with CGMP." The event will be held at the Crowne Plaza in Warwick, RI, and simulcast at the WPI LSBC in Worcester, MA; the Redhook Ale Brewery in Portsmouth, NH; and the Tufts Gordon Institute in Medford, MA. Each venue will feature a networking reception with refreshments and a live Q&A after the presentation. Register now to stay up-to-date on the new FDA guidance!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=579

Thursday, June 23, 2016

ISPE Summer Social

Sc quantum Yacht Club, Quincy, MA

EVENT SUMMARY

Join the ISPE Boston Area Chapter for a Tropical Luau Beach Party to celebrate the start of Summer and Volunteer Appreciation Night! The event will feature: a raffle for Community Servings (www.servings.org), a live band, a BBQ feast & cash bar, and 1 drink ticket with admission. Abundant street parking can be found along Quincy Shore Drive!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=635

Sneak Preview of Upcoming Events - Save the Date!

Thursday, July 21, 2016

ISPE Young Professionals Red Sox Social
Fenway Park, Boston, MA

Monday, August 8, 2016

ISPE Summer Golf Tournament
Lake Winnipesaukee Golf Club, New Durham, NH

Thursday, September 8, 2016

ISPE Young Professional's Boston Harbor Boat Cruise, Boston, MA

Great Turnout Makes the Ski Outing One for the Record Book!

by Jim Grunwald, DPS, with photo by Kristen Dangelo, Boston Analytical

The 2016 edition of the Chapter's Annual Ski Outing is in the record book - we had a great day at Waterville Valley, NH on March 4. Attendees were blessed with fine weather and great camaraderie in an excellent setting for networking with peers and sharing news from the industry. Attendance for the day was 62, a great milestone for the event and the Chapter.

Started 16 years ago, the first Annual Ski Outing was attended by six skiers! They had a shared vision of starting something new in format that fostered fun and created a place for clients and service providers to enjoy each other's company. The idea was based on providing an informal environment in the great outdoors. This mission has surely been accomplished as all attendees thoroughly enjoyed the day and the networking.



As with many of our other Chapter initiatives, the Social Committee has a charitable bent. We are happy to announce that this year's Ski Outing raised \$1000 for the Dana Farber Cancer Institute and are very pleased to have had the support of our attendees in reaching this milestone.

A special thanks to all of our sponsors: A/Z Corporation, Albireo Energy, Boston Analytical, CAI, Commodore Builders, DPS, JENSEN HUGHES, Reflex Lighting, RW Sullivan, Sentrol, Superior Controls and TRIA; and finally to Kristen Dangelo of Boston Analytical and Jim Grunwald of DPS for organizing and running this event.

Looking ahead, the Social Committee has a very ambitious program for the balance of the spring and summer. Next up, on May 9, we have the Spring Golf Outing at Ledgemont Country Club in Seekonk. This will be followed by the Summer Social and Volunteer Appreciation with a tropical luau beach party theme at the Squantum Yacht Club in Quincy on June 23 and the ever-popular Summer Golf Outing at Lake Winnipesaukee Golf Club in New Durham, NH on August 8.

The Committee would like to invite Chapter Members to consider joining as a volunteer to help plan and coordinate these events. We have an excellent group of people dedicated to providing fun, uplifting and meaningful events for our Members. Just bring your energy and your ideas!

Genzyme Hosts Presentation on Facility Expansions in Operating Plants

by Rose Mary Su, Acentech, with photos by Joyce Chiu, Shire

The ISPE Boston Area Chapter held a successful educational event this past February on the popular topic of how to renovate and expand an existing plant without shutting down. The presentation, entitled "Dancing through Traffic: Facility Expansions in Operating Plants," drew over 60 attendees to Genzyme in Cambridge.

The evening began with a networking reception at Genzyme's atrium space with great appetizers and drinks. It was great to see a lot of familiar faces as well as new faces in the crowd ranging from process engineers, facility managers, students and engineers to specialty consultants. Similar receptions were held at remote sites - WPI in Worcester and the Crowne Plaza in Warwick, RI - where attendees were able to watch a live telecast of the presentation. In addition, the Red Hook Brewery in Portsmouth, NH was pilot-tested for use as a remote site for future broadcasts. Thanks to Aaron Babcock of Zetawave Productions for coordinating with the Genzyme tech team to stream this presentation.



Veteran presenters and subject matter experts Rick Kotsky (right)...



...and John Spohn (second from right) found a few moments to chat with fellow Members during the networking reception.

The presentation was extremely informative while being entertaining at the same time. Presenters John Spohn and Rick Kotsky, both from Hargrove, are great speakers and have presented on this topic at past ISPE events. They opened with a video of a family of ducks and ducklings crossing a busy, six-lane interstate highway as an analogy to the plant renovation process. The audience was entertained but also got their message about how complicated and challenging a process this can be. The speakers took turns throughout the presentation, which kept the discussion lively, and their relaxed, conversational delivery made the wealth of information they presented easy to digest.

Undoubtedly there are a lot of challenges that come with the desire to avoid shutting down a plant in production while carrying out an expansion or renovation. The need for expansion or renovation can potentially interfere with production schedules, introduce unanticipated elements such as noise and vibration from construction and, as a result, increase the duration and cost of a project. The typical approach would be to move as quickly as possible to limit interruptions in current products. What the speakers wanted is for us to take a step back and understand the owner's needs and prioritize typical key concerns such as limiting production interruptions, developing a high-confidence schedule and eliminating adverse effects on processes under modification, products concurrently in-process and regulatory filings.

The speakers provided useful advice on how to keep both the operation and renovation running smoothly but one of the most important take-home messages is to consult experts that are familiar with the challenges and can raise potential concerns early in the planning and design stages so that surprises can be avoided and neither construction nor on-going production delayed or disrupted. They suggested a dramatic shift in the approach to the planning and implementation phases with a strong emphasis on thoughtful feasibility study, planning and evaluation of options as methods ensuring a successful renovation and expansion.

A lively question and answer session followed the presentation. The audience had many excellent questions for both presenters, attesting to the high level of interest in the subject matter. Not only did the presenters receive numerous questions from the audience in Cambridge, they also got questions from the

remote sites via Mailinator. These questions were relayed to the presenters by the meeting managers on behalf of the off-site attendees, a process which worked quite well, making it an interactive Q&A session for everyone, no matter where they were located.

This educational program is the last to be hosted by Genzyme Cambridge. We want to thank Genzyme for their generous support of the Boston Area Chapter over a period of several years. The Chapter would also like to thank our speakers for their wonderful presentations, our hosts at Genzyme and WPI, the meeting managers who coordinated the event, the staff at CAMI and everyone else who helped make the evening a great success. And lastly we would like to thank program sponsor Commissioning Agents (CAI) for their ongoing support for the Chapter's educational programs.

Members Gather at Shire for Pilot Plant Tour and Panel Discussion

by Stacy Price, Shire, with photos by Joyce Chiu, Shire

The Boston Area Chapter educational program, "Learning Through Doing: The Interplay of Pilot Plant, Product and Process," took place on Thursday, March 24 at Shire's Pharmaceutical Development and Pilot Plant facility in Lexington, MA. The discussion was both comprehensive and engaging, with the panel and moderator describing the pilot plant as a key step in scaling processes from development to manufacturing. They explained that if you look closely and leverage the capabilities and opportunities, the pilot plant can be a lot more than just material production. It is where operations are refined for larger scale production - which is not as easy as it may sound.

Between the pilot plant tour, the Young Professional's round table with the panelists and the panel discussion and Q&A session to follow, the evening promised - and delivered - lots of stimulating conversation on an important topic central to our industry.



YPs turned out in force to attend a round table with the panelists designed just for them.

While the 100+ attendees enjoyed an opening reception with conversation and appetizers, Elisa Pepicelli and Mirza Zukic from Shire guided attendees through Shire's Pilot Plant suites to see how toxicology and development material is made. Included were single use perfusion bioreactors, single use centrifugation and ATF (alternating tangential filtration) for cell separation, UF/DF and chromatography equipment.



Chapter Past Presidents Mark Sitzeske (l) and Andre Walker (r) share a light moment during the networking reception.

Following the reception and tour, Stacy Price of Shire opened the program by introducing the role of the pilot plant in the product life cycle and Moderator Brad Ebel of Shire introduced the five panelists: Bill Brazier of Amgen, Christof Schulz of Abbvie, Kelly Wiltberger of Biogen, David Sullivan of Pfizer and Shaun Grier of Shire. Each panelist then described their background, their role in the pilot plant and their respective companies.



Moderator Brad Ebel of Shire (l) introduced the five panelists (l to r): Christof Schulz of Abbvie, Bill Brazier of Amgen, Kelly Wiltberger of Biogen, David Sullivan of Pfizer and Shaun Grier of Shire.

Brad presented the data collected from a benchmarking study across the five company sites represented. The benchmarking was performed to understand the focus of biological processing pilot plants in the Boston area. Areas of commonality are that all companies focus on team supply and demonstration runs, use disposable systems, and are involved in technology development and design/scalability of processes. Areas of differences included the modality of product produced (monoclonal antibodies, enzymes, etc.), the degree to which operations range finding was performed, whether or not training was provided to manufacturing groups, and whether or not solution preparation services were included.

The pilot plant of the future was the next topic of conversation. Brad presented the "pilot plant of the future mission statement" developed at the Pilot Plant Industrial Network Forum:

"We are a cutting edge, variable scale Pilot Plant Facility with capabilities ranging across multiple technology and modality platforms. We aim to stay ahead of our customers' growing, diverse needs by continually seeking out and implementing the newest technologies and advances in industry to enable readiness for manufacturing whenever needed."

Agility is a key aspect of pilot plant success. One doesn't always know what's in store when processing new proteins at large scale for the first time. Dave articulated that pilot plants have a huge opportunity and responsibility in demonstrating processes and establishing robustness, training, and ensuring successful technology transfer and manufacturing as new technologies scale out and up. Kelly suggested that the facilities be designed to have flex spaces with a modular approach to utilities, equipment (portable vs. fixed) and automation support. Bill noted that in addition to pilot plant operations, a diversity of resource skills is required such as automation engineering expertise, scientific knowledge and quality system understanding.

GMP is a frequent consideration for pilot plants. It is usually desirable to have an in-house facility that can produce early clinical material for first in-human use. However, converting a pilot plant to a cGMP facility

carries with it serious considerations because the agility of a plant under cGMP typically decreases. The panelists had an open conversation about the need for phase appropriate GMP, in the level of equipment validation and quality system oversight, for example. Shaun noted that phase appropriate GMP is the key to efficiently and effectively transitioning from toxicology to Phase I clinical production since the cost of developing a drug doubles every nine years. Christof stressed that producing GMP product in the same space as non-GMP product will require resources to be fully versed and adaptable to the quality requirements for the production run at hand. During the Q&A following the discussion, the audience had many excellent questions for the panel, attesting to the high level of interest in the subject matter.

The Chapter would like to thank our moderator and each of our panelists for their engaging and educational discussion, the staff at Shire who coordinated the event and tour, event sponsor Commissioning Agents (CAI) and everyone who helped make this event a great success!

YPs Keep Busy with a Full Calendar of Events

by Christopher Ciampa, Thermo Fisher Scientific with photos by Brody Stara, Amgen, and Vaibhav Shah, University of Massachusetts

Now that the weather is finally warming up, we have some great YP programs coming up. Read on for a quick look at the events we have hosted recently as well as a taste of what the spring and summer have in store.

At the end of March we had our first-ever YP roundtable, which was hosted as part of the educational program at Shire and brought the evening's panelists together with a group of about 20 YPs. The panelists were project engineers and seasoned professionals from operating companies such as Shire, Pfizer, Amgen, and Biogen. It was very informal and gave the panelists and attendees an opportunity to get to know each other and share information. Jillian Willard facilitated the discussion and got to ask the tough questions (such as what is tech transfer and why it's important for pilot plants to do it effectively). Everyone enjoyed the discussion, which was very lively and informative.

Since this first-of-its-kind event was so successful, we will use it as a "best practice" when organizing future educational events. A big thank you to the attendees, the panelists and everyone who helped make the event a success!

We held two social events in April. Based on the success of the bowling social last year, we headed back to Sacco's in Davis Square on April 7 for candlepin bowling and flatbread pizza. The format was similar to last year: an hour of networking and dinner (pizza/salad/dessert and beer on tap) followed by two hours of bowling. And again - in spite of the heavy downpour that day - the turnout was excellent



Pizza and beer at The Flatbread Company provided the energy needed for an evening of candlepin bowling at Sacco's in Somerville.

The second event - a Providence Bruins game - was another first. It was held south of Boston to attract Members of the former New England Chapter (which merged with the Boston Area Chapter in 2013). Although attendance was light, the event was a big success - the buffet was excellent, the atmosphere was great and the Bruins won! Word-of-mouth is sure to guarantee a healthy turnout for this event next year.



Chapter board member Jared Marshall with friend at the Providence Bruins game.

The theme for April's educational program was "Biomanufacturing Science & Technology, Preparing for Tomorrow." It was hosted at WPI and broadcast live to three remote sites (Cambridge, Portsmouth and Providence) as part of the Chapter's "GO" initiative. Attendance was good with students, young professionals and industry veterans all well-represented. Three speakers (Parrish Galliher, Philippe de Vilmorin and Prakash Rai) gave in-depth presentations which were followed by a panel discussion, with questions from the audience at WPI and all three remote sites. This year's Annual Student Poster Competition was held in conjunction with the educational program. Congratulations to our winners: Connor Williams, UMass Lowell (undergraduate); and John de la Parra, Northeastern (graduate); and thanks to our judges - two of whom were past winners - who worked hard to narrow the excellent field down to two.

As an aside - we are looking to partner up again with WPI again this fall - as they are having a 5-day seminar on bioreactors. We are exploring the possibility of an evening event in conjunction with the seminar so that students and YPs can see the bioreactors. More to come on this in the future...

Our annual Red Sox outing is in the works for Thursday, July 21. Come watch our fellow Sox take on the Minnesota Twins! There will be a pre-game event, most likely at "Who's on First," reopening after extensive renovations as "The Bullpen." The name may have changed but you can expect the same great food and pre-game venue!

Looking toward the end of 2016, we are planning a dual track educational program for November. One suggestion for the YP track is "Regulatory 101: Jargon for Engineers." It will be hosted in the Boston area, preferably at a local college site. We are hoping to have two speakers in tag-team approach, one from a consulting company and one from an operating company. We have a few months before the topic needs to be locked down, so if you have other suggestions, please let me know.

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 (christopher.ciampa@gmail.com). Happy Spring and go Red Sox!

Students Reap the Many Benefits of ISPE Membership

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

The Chapter's Student Members benefit in so many ways from their involvement with ISPE. Here are just a few of the advantages that membership offers this spring:

- Over 75 new postings for internships, co-op's and full time positions
- Two Shire plant tours in March
- On-Campus Career Fairs attended at UNH, UMass Lowell and WPI
- Student Poster Contest on April 20
- Scholarship Applications due June 1

The Chapter has been extremely busy helping students find employment, whether it's a summer internship, co-op or full time position. The Chapter offers local life science companies a free job posting service to help them fill vacancies. Check out the "[Jobs and Internships](#)" section of the Chapter website and "like" the [Chapter's Facebook page](#) to receive notifications when new positions are posted. We have already reached our goal of posting 75 positions and we're adding more every week! Remember, you have to be an ISPE Member to access these positions.

Chapter Student Members attended a great plant tour at Shire on March 30. Students were treated to a presentation describing the activities that happen inside Shire's disposables facility which was followed by

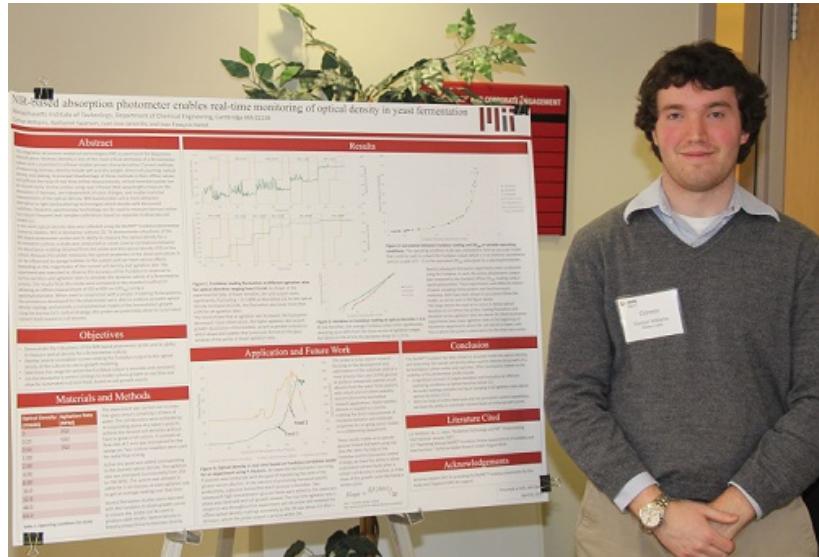
an informative tour of Shire's upstream and downstream processing operations. Students learned a tremendous amount about Shire's "first in class" disposables facility and operations and got an up-close look at some of the advantages and challenges of utilizing disposable technology.



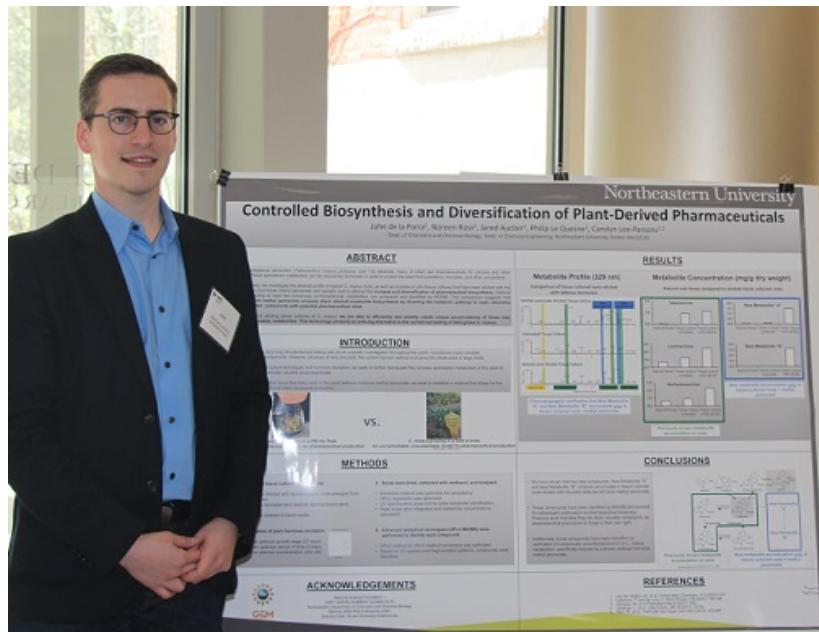
Thanks to Shire for hosting a behind-the-scenes plant tour for the Chapter's Student Members.

The Chapter's outreach efforts continued this spring with participation at three on-campus Career Fairs at UNH, UMass Lowell and WPI. Chapter representatives met with faculty, students, career center staff and administrators to strengthen bonds and build new relationships while working to show students the benefits of belonging to an active professional network like ISPE.

This spring's Annual Poster Contest was held on Wednesday, April 20 at WPI's Biomanufacturing Education and Training Center in conjunction with the Chapter's April educational program. Students who did research and prepared a poster for one of their classes, had a chance to share their work, polish their presentation skills, compete for one of two \$500 cash awards and meet a hundred or so local ISPE members who can open a door or two on the employment front!



Winning undergrad Connor Williams of UMass Lowell ("NIR-Based Absorption Photometer Enables Real Time Monitoring of Optical Density in Yeast Fermentation")



Winning grad student John De La Parra of Northeastern ("Controlled Biosynthesis and Diversification of Plant-Derived Pharmaceuticals")

And lastly, the Chapter's Scholarship Program wants to help you pay for the cost of your education. Twice a year, the Chapter awards \$12,500 in scholarships as part of the Chapter's commitment to giving back and investing in you. The next application deadline is June 1. Applying is easy and your chances of receiving a scholarship are much higher than you might expect. You can [apply online here](#), but don't wait until the last minute. A written reference is one of the requirements and must be submitted online before the deadline, in addition to your completed application. If you miss the June deadline, don't despair - the next deadline is November 1.

If you need any further convincing of the benefits of being part of an active professional network, check this out: <https://vimeo.com/148636910>. And remember, students can attend the Chapter's educational programs and YP social events for free! Hope to see you on campus or at an ISPE event soon!

Congratulations to the Chapter's Annual Poster Competition Winners!

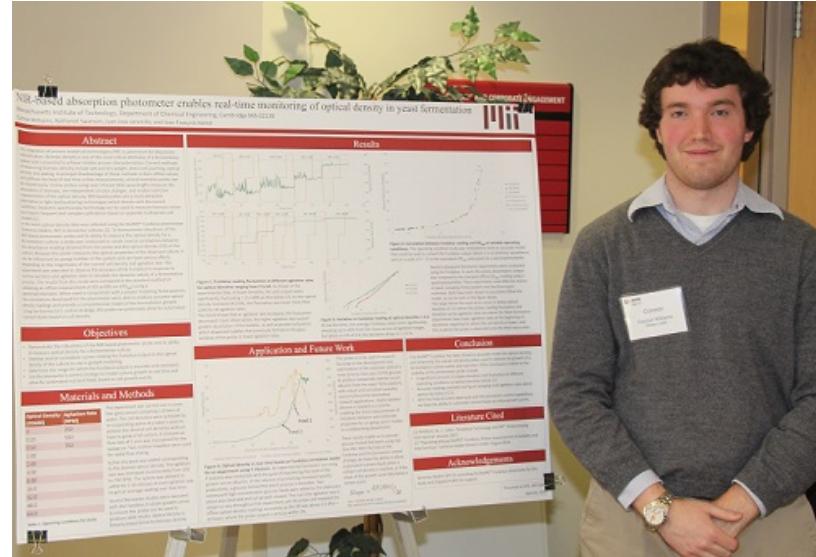
by Janet Tice, GMP Piping, with photos by Brian Hagopian, Clear Water Consulting

Congratulations to our 2016 Poster Competition winners!

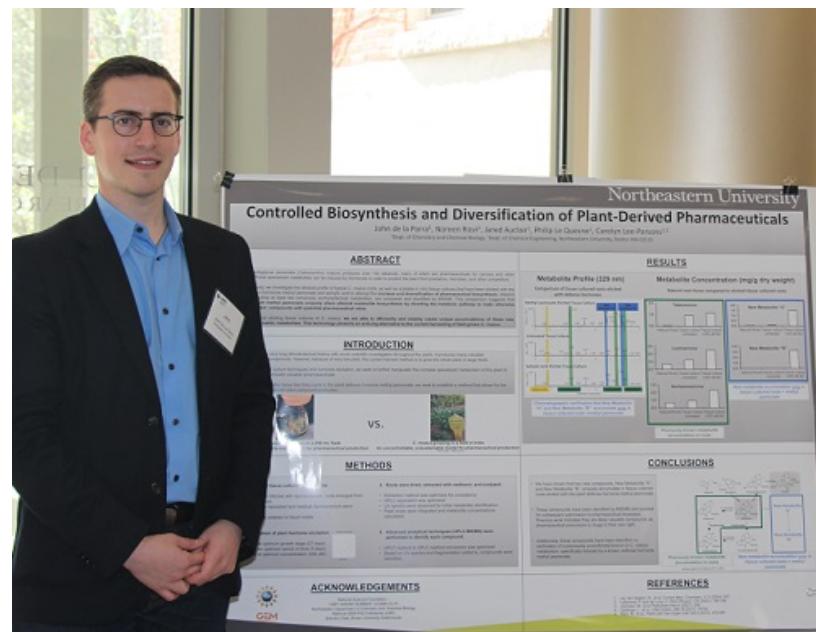
- Connor Williams of UMass Lowell ("NIR-Based Absorption Photometer Enables Real Time Monitoring of Optical Density in Yeast Fermentation") in the undergraduate category
- John De La Parra of Northeastern ("Controlled Biosynthesis and Diversification of Plant-Derived Pharmaceuticals") in the graduate category

And kudos to James Carroll of Northeastern and Middlesex Community College, and Shannon Guertin and Elaheh Kamaloo, both of WPI, all of whom made the judges' job especially difficult this year.

The winners were each awarded \$500 and expense-paid trips to the ISPE Annual Meeting in September where they will compete against winners from ISPE Chapters and Affiliates around the globe. Our Chapter has brought home the "gold" several times, most recently in 2015. Let's hope our track record continues for Connor and John in 2016!



Poster contest winner Connor Williams of UMass Lowell ("NIR-Based Absorption Photometer Enables Real Time Monitoring of Optical Density in Yeast Fermentation") in the undergraduate category.



Poster contest winner John De La Parra of Northeastern ("Controlled Biosynthesis and Diversification of Plant-Derived Pharmaceuticals") in the graduate category.

As a Poster Competition judge for three years in a row, let me say it is truly a privilege to be introduced to several of the best and brightest among our Student Members, and listen to them describe their research and respond to tough questions with poise and professionalism. And beyond their poise and professionalism, there is even more - passion and enthusiasm for the work itself and for the opportunity to explain it to a new audience. It's an experience that always leaves me feeling good about the future of our industry and the positive role that our Chapter plays in that future.

Many thanks to this year's judges, Immediate Past President Chris Opolski, and former ISPE International Poster Competition winners Dawn Eriksen (2006) and Sydney Shaw (2015), both of whom were able to provide valuable insights based on their prior experience. And finally, thank you to Student Development Committee Co-Chairs Paige Kane and Brian Hagopian for continuing to nurture one of the Chapter's most enduring and gratifying traditions.

Industry News In Review

by Jillian Willard, Genzyme, a Sanofi Company

Industry News In Review, a regular feature of the Boston Area Chapter Newsletter, presents a review of recent 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 Chapter Members.

FDA Approves First US Biosimilar Monoclonal Antibody

The FDA has approved Celltrion's Inflectra (biosimilar infliximab) across all eligible indications of the reference product, Remicade® (infliximab). Inflectra is the first and only biosimilar monoclonal antibody (mAb) therapy, and only the second biosimilar, to be approved in the US. Inflectra is indicated for reducing

signs and symptoms in patients with rheumatoid arthritis, adult ulcerative colitis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and adult and pediatric Crohn's disease.

Hospira, now a Pfizer company, entered into an agreement with Celltrion and Celltrion Healthcare in 2009 for several potential biosimilar products, including Inflectra. Pfizer holds exclusive commercialization rights to Inflectra in the US and certain other jurisdictions. (Source: Pfizer Website, 05 April, 2016)

Pfizer/Allergan Merger Terminated After US Updates Tax Laws

Pfizer has announced that the merger agreement between Pfizer and Allergan has been terminated by mutual agreement of the companies. The decision was driven by the actions announced by the US Department of Treasury on April 4, 2016, which the companies concluded qualified as an "Adverse Tax Law Change" under the merger agreement. In connection with the termination of the merger agreement, Pfizer has agreed to pay Allergan \$150 million for reimbursement of expenses associated with the transaction. (Source: Pfizer Website, 06 April, 2016)

Lexington's ImmuneXcite Closes \$8.6M Financing

ImmuneXcite, a privately-held biotech company based in Lexington, has announced the completion of an \$8.6 million Series A-1 financing. Investors included Cormorant Asset Management, Sanofi-Genzyme BioVentures, and Partners Innovation Fund. ImmuneXcite plans to use the funding to complete studies that will enable selection of a lead program to advance into clinical trials.

In association with this financing, Eric Furfine, Ph.D. was appointed Chief Scientific Officer, acting Chief Executive Officer and will serve as a member of the Board. In addition, the company further expanded its Board of Directors with the addition of Jim Geraghty and John Edwards, who will serve as Executive Chairman. Ann DeWitt from Sanofi-Genzyme BioVentures will also join the board. In addition, Ifat Rubin-Bejerano, ImmuneXcite's scientific co-founder and inventor of the company's technology platform has been named Head of Research.

ImmuneXcite is developing immuno-oncology products that utilize the power of both the innate and adaptive immune response. The foundation of the company's technology is its mAbXcite platform. The technology is based on ImmuneXcite's research, which identified a unique fungal carbohydrate responsible for stimulating the innate immune system, the immune system's first response against fungal infections. By attaching a fungal sugar known as beta-1,6-glucan to cancer-targeting monoclonal antibodies, the mAbXcite therapies activate complement and neutrophils to kill tumors. Subsequently, the neutrophils recruit other immune cells, including T-cells, which further limit tumor growth and metastasis. (Source: ImmuneXcite Website, 30 March, 2016)

PTC Therapeutics to Reduce Workforce by 18 Percent

PTC Therapeutics has announced that it is reducing its workforce by approximately 18 percent, which will primarily affect employees and contractors in the US. This reduction is part of PTC's program intended to reduce operating expenses following the company's receipt of a Refuse to File letter from the FDA for Translarna (ataluren) for the treatment of nonsense mutation Duchenne muscular dystrophy (nmDMD). PTC plans to work with the FDA to determine the best path forward to bring Translarna to patients in the US. PTC plans to complete this workforce reduction by June 30, 2016. (Source: PTC Therapeutics Website, 23 March, 2016)

Bristol-Myers Squibb to Acquire Padlock Therapeutics, Inc.

Bristol-Myers Squibb Company (BMS) and Padlock Therapeutics have announced that they have signed a definitive agreement under which BMS will acquire all of the outstanding capital stock of Padlock, a private, Cambridge-based biotechnology company. Padlock Therapeutics is currently developing medicines to treat destructive autoimmune diseases. The acquisition will give BMS full rights to Padlock's Protein/Peptidyl Arginine Deiminase (PAD) inhibitor discovery program focused on the development of treatment approaches for patients with rheumatoid arthritis (RA). Padlock's PAD discovery program may also lead to treatments for systemic lupus erythematosus (SLE) and other autoimmune diseases.

PADs are a family of enzymes that produce autoantigens which play an active role in the development and progression of RA and other autoimmune diseases. Inhibiting PADs offers the potential to prevent progression of autoimmune diseases early in their evolution. In identifiable high risk patients with pre- and early-RA, PAD inhibition could prevent disease development and resulting joint destruction. PAD4 inhibition in combination with current standard of care therapies may increase and maintain the durable remission rates in RA patients with rapidly progressive disease.

The transaction includes upfront and near term contingent milestone payments of up to \$225 million and additional contingent consideration of up to \$375 million upon the achievement by BMS of certain development and regulatory events. The transaction has been approved by the boards of directors of both companies and by the stockholders of Padlock. Bristol-Myers Squibb and Padlock anticipate the transaction will close during the second quarter of 2016. (Source: Bristol-Myers Squibb Website, 23 March, 2016)

Amarin Granted Rights to Promote Off-Label Use of Drug

Amarin Corporation has announced that settlement terms have been reached to resolve litigation to promote the off-label use of their drug Vascepa (icosapent ethyl) based on first amendment rights. Under the terms, the FDA and the US government have agreed to be bound by the 07 August, 2015 judicial declaration that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa capsules. Amarin's expanded promotion of Vascepa, initiated following the August 2015 judicial declaration, continues as planned. The key settlement terms include agreement by the FDA to provide Amarin with an optional preclearance provision through 2020 for new off-label claims.

Vascepa capsules are a single-molecule prescription product consisting of 1 gram of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a GMP manufacturing process. Vascepa is currently approved as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

Amarin is in the middle of an ongoing cardiovascular outcomes study. This study is designed to test whether Vascepa, when added to statin therapy, will significantly reduce cardiovascular risk compared to

statins alone in high-risk patients with elevated triglyceride levels. The study is expected to conclude in 2017 with results anticipated to be published in 2018. An interim review by the independent data monitoring committee of the efficacy and safety results of the trial is expected to occur during 2016. (Source: Amarin Website, 08 March, 2016)

Sarepta Therapeutics will Move all Operations to Massachusetts

Sarepta Therapeutics, a developer of RNA-targeted therapeutics, announced a long term plan to move all of its operations to Massachusetts, as part of a strategic plan to increase operational efficiency. Over the course of the year, Sarepta plans to close their facility in Corvallis, Oregon, which primarily focused on early-stage research and research manufacturing. As part of the consolidation, research activities and some employees will transition to Sarepta facilities in Andover and Cambridge. The consolidation efforts are planned to occur in four waves - in May, October, November, and December of this year - with an estimated completion date of December 30, 2016. (Source: Sarepta Website, 08 March, 2016)

AbbVie and Boehringer Ingelheim to Collaborate on Development of Monoclonals

AbbVie and Boehringer Ingelheim announced a global collaboration to develop and commercialize BI 655066, an anti-IL-23 monoclonal biologic antibody in Phase 3 development for psoriasis. AbbVie and Boehringer Ingelheim also are evaluating the potential of this biologic therapy in Crohn's disease, psoriatic arthritis and asthma. In addition to the anti-IL-23 antibody, AbbVie gains rights to an anti-CD-40 antibody, BI 655064, currently in Phase 1 development. Boehringer Ingelheim will retain responsibility for further development of BI 655064, and AbbVie may elect to advance the program after completion of certain undisclosed clinical achievements.

Under the terms of the license agreement, AbbVie will make an initial upfront payment of \$595 million. Boehringer Ingelheim will be eligible to receive additional development and regulatory milestone payments and royalties on net sales, the terms of which were not disclosed. In the initial period, the companies will share the responsibility for future development of BI 655066. AbbVie will be solely responsible for commercialization of BI 655066, while Boehringer Ingelheim will retain an option to co-promote the compound in asthma. (Source: Abbvie Website, 07 March, 2016)

FDA to Allow Expedited Review and Approval of Generics for Single Source Drugs

In March, the FDA Office of Generic Drugs revised its policy for the review of generic medicines for drugs with only a single source. The policy already allowed for expedited review of generics if no other generic version of the same reference listed drug (RLD) has yet been brought to market under an approved ANDA. This policy was expanded to allow expedited review of submissions for drug products for which there is only one approved drug product listed in the Prescription Drug Product List (the "active section") of FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

Expedited review gives a submission heightened review priority within the FDA. Expedited review may be granted following a request from the applicant or at the FDA's initiative. Submissions that do not receive expedited review are reviewed in the order in which they are received.

This update in policy comes after companies like Turing Pharma received media and regulator attention about its decision to raise the price of a recently acquired drug, Daraprim from \$17.63 per pill to \$750 per pill. Daraprim is primarily used to treat a parasitic infection called toxoplasmosis that most often affects patients with compromised immune systems. It is the only approved treatment for toxoplasmosis in the US. In addition, there has been no pharmaceutical innovation or research in the treatment of toxoplasmosis for over 50 years. (Source: FDA Website, 11 March, 2016)

Ariad Announces Reduction in Workforce as Part of Strategic Review

Cambridge-based Ariad Pharmaceuticals has announced that it is reducing approximately 25 percent of its headquarter positions. The reduction includes approximately 90 positions in the US and Europe. No customer-facing positions within Ariad's commercial or medical affairs organizations are included in this action.

This reduction in workforce is one of five key areas of Ariad's ongoing strategic review. In addition, the review also includes an evaluation of commercial maximization initiatives, geographical presence, R&D portfolio, and business development opportunities to support the overall strategic direction. Ariad plans to provide further details on the progress of the strategic review in the second quarter of 2016. (Source: Ariad Website, 29 March, 2016)

Gilead Sciences Acquires Nimbus Therapeutics' Program for Liver Diseases

Gilead Sciences and Nimbus Therapeutics have announced that they have signed a definitive agreement under which Gilead will acquire Nimbus Apollo, a wholly-owned subsidiary of Nimbus Therapeutics, and its Acetyl-CoA Carboxylase (ACC) inhibitor program. Nimbus Therapeutics will receive an upfront payment of \$400 million, with the potential to receive an additional \$800 million in development-related milestones over time.

The Nimbus Apollo program includes the lead candidate NDI-010976, an ACC inhibitor, and other preclinical ACC inhibitors for the treatment of non-alcoholic steatohepatitis (NASH), and for the potential treatment of hepatocellular carcinoma (HCC) and other diseases. NDI-010976 was granted Fast Track designation by the FDA in February 2016. Upon completion of the acquisition, Nimbus Apollo will become a wholly-owned subsidiary of Gilead. Nimbus Therapeutics will retain ownership of its other research and development subsidiaries. Gilead will be solely responsible for future development and commercialization of NDI-010976 and other ACC inhibitors.

Nimbus Therapeutics is a biotech company headquartered in Cambridge. It uses computational chemistry to design treatments for diseases. The focus on metabolic diseases, cancer and immune-inflammatory disorders reflects the mechanistic relationship between these disorders. Nimbus is structured as a series of independent C corporations, each of which houses distinct research and development programs. This model enables Nimbus to make investment and partnership decisions on an asset versus pipeline basis. (Source: Gilead Sciences Website, 04 April, 2016)

Radius Health Submits NDA to FDA for Osteoporosis Treatment

Waltham-based Radius Health has announced that it has submitted a New Drug Application (NDA) to the FDA for abaloparatide-SC 80 mcg, an investigational, once-daily treatment for postmenopausal women with osteoporosis. Clinical trials have met the primary and secondary endpoints essential for submission of the NDA, including the primary endpoint of reduction of vertebral fractures as well as key endpoints of reduction of nonvertebral, clinical, and major osteoporotic fractures.

Radius Health submitted a Marketing Authorization Application (MAA) for the investigational drug abaloparatide-SC in Europe on November 17, 2015, which is currently undergoing regulatory review. If approved, abaloparatide-SC would be the first new bone anabolic treatment option in Europe since 2003 and the first in the US since 2002 for postmenopausal women with osteoporosis.

Radius develops therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Abaloparatide is Radius' lead product candidate. The Radius clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in multiple applications including cancer. (Source: Radius Health Website, 30 March, 2016)

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 First Coagulation Factor-Albumin Fusion Protein for Hemophilia B

The FDA has approved Idelvion, Coagulation Factor IX (Recombinant), Albumin Fusion Protein, for use in children and adults with Hemophilia B. Idelvion is the first coagulation factor-albumin fusion protein product to be approved, and the second Factor IX fusion protein product approved in the US that is modified to last longer in the blood. Idelvion is manufactured by CSL Behring, headquartered in King of Prussia, Pennsylvania.

According to the CDC, Hemophilia B is a rare inherited bleeding disorder that prevents blood from clotting normally. The disorder primarily affects males and, rarely, females. People with Hemophilia B can experience repeated episodes of potentially serious bleeding, mainly into the joints, which can be damaged by the bleeding. (Source: FDA Website, 04 March, 2016)

FDA Expands Use of Xalkori to Treat Form of Non-Small Cell Lung Cancer

The FDA has approved Pfizer's Xalkori (crizotinib) to treat people with advanced (metastatic) non-small cell lung cancer (NSCLC) whose tumors have an ROS-1 gene alteration. Xalkori is the first and only FDA approved treatment for patients with ROS-1 positive NSCLC.

Xalkori is an oral medication that blocks the activity of the ROS-1 protein in tumors that have ROS-1 gene alterations. This effect on ROS-1 may prevent NSCLC from growing and spreading. The FDA granted the Xalkori expanded use application breakthrough therapy designation and priority review status. (Source: FDA Website, 11 March, 2016)

FDA Approves New Treatment for Inhalation Anthrax

The FDA has approved Anthim (obitoxaximab) injection to treat inhalational anthrax in combination with appropriate antibacterial drugs. Anthim is also approved to prevent inhalational anthrax when alternative therapies are not available or not appropriate.

Inhalational anthrax is a rare disease that can occur after exposure to infected animals or contaminated animal products, or as a result of an intentional release of anthrax spores. It is caused by breathing in the spores of the bacterium *Bacillus anthracis*. When inhaled, the anthrax bacteria replicate in the body and produce toxins that can cause massive and irreversible tissue injury and death. Anthrax is a potential bioterrorism threat because the spores are resistant to destruction and can be spread by release in the air.

Anthim is a monoclonal antibody that neutralizes toxins produced by *B. anthracis*. Anthim was approved under the FDA's Animal Rule, which allows efficacy findings from adequate and well-controlled animal studies to support FDA approval when it is not feasible or ethical to conduct efficacy trials in humans.

Anthim carries a Boxed Warning alerting patients and health care providers that the drug can cause allergic reactions (hypersensitivity), including a severe reaction called anaphylaxis. Anthim was developed by Elusys Therapeutics, Inc. of Pine Brook, New Jersey, in conjunction with the US Department of Health and Human Services' Biomedical Advanced Research and Development Authority. (Source: FDA Website, 21 March, 2016)

FDA Approves Eli Lilly's New Psoriasis Drug

The FDA has approved Eli Lilly's Taltz (ixekizumab) to treat adults with moderate-to-severe plaque psoriasis. Psoriasis is a skin condition that causes patches of skin redness and flaking. Psoriasis is an autoimmune disorder that occurs more commonly in patients with a family history of the disease, and most often begins in people between the ages of 15 and 35.

Taltz's active ingredient is an antibody (ixekizumab) that binds to a protein (interleukin (IL)-17A) that causes inflammation. By binding to the protein, ixekizumab is able to inhibit the inflammatory response that plays a role in the development of plaque psoriasis. Taltz is administered as an injection. It is intended for patients who are candidates for systemic therapy, phototherapy (ultraviolet light treatment) or a combination of both.

Because Taltz is a medicine that affects the immune system, it is being approved with a Medication Guide to inform patients that they may have a greater risk of an infection, or an allergic or autoimmune condition. (Source: FDA Website, 22 March, 2016)

FDA Approves Cinqair to Treat Severe Asthma

The FDA has approved Cinqair (reslizumab) for use with other asthma medicines for the maintenance treatment of severe asthma in patients aged 18 years and older. Cinqair is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines. The drug is administered once every four weeks via intravenous infusion by a health care professional in a clinical setting prepared to manage anaphylaxis. Cinqair is manufactured by Teva Pharmaceuticals in Frazer, PA.

Asthma is a chronic disease that causes inflammation in the airways of the lungs. During an asthma attack, airways become narrow making it hard to breathe. Severe asthma attacks can lead to asthma-related hospitalizations because these attacks can be serious and even life-threatening. According to the Centers for Disease Control and Prevention, as of 2013, more than 22 million people in the US have asthma, and there are more than 400,000 asthma-related hospitalizations each year. (Source: FDA Website, 23 March, 2016)

FDA Approves AbbVie Drug for Chronic Lymphocytic Leukemia

The FDA has approved AbbVie's Venclexta (venetoclax) for the treatment of patients with chronic lymphocytic leukemia (CLL) who have a chromosomal abnormality called 17p deletion and who have been treated with at least one prior therapy. Venclexta is the first FDA-approved treatment that targets the B-cell lymphoma 2 (BCL-2) protein, which supports cancer cell growth and is overexpressed in many patients with CLL.

According to the National Cancer Institute, CLL is one of the most common types of leukemia in adults, with approximately 15,000 new cases diagnosed each year. CLL is characterized by the progressive accumulation of abnormal lymphocytes, a type of white blood cell. Patients with CLL who have a 17p deletion lack a portion of the chromosome that acts to suppress cancer growth. This chromosomal abnormality occurs in approximately 10 percent of patients with untreated CLL and in approximately 20 percent of patients with relapsed CLL.

Venclexta is indicated for daily use after detection of 17p deletion is confirmed through the use of the FDA-approved companion diagnostic Vysis CLL FISH probe kit.

The FDA granted the Venclexta application breakthrough therapy designation, priority review status, and accelerated approval for this indication. These are distinct programs intended to facilitate and expedite the development and review of certain new drugs in light of their potential to benefit patients with serious or life-threatening conditions. Venclexta also received orphan drug designation, which provides incentives such as tax credits, user fee waivers and eligibility for exclusivity to assist and encourage the development of drugs for rare diseases. Venclexta is manufactured by AbbVie and marketed by AbbVie and Genentech USA. The Vysis CLL FISH probe kit is manufactured by Abbott Molecular. (Source: FDA Website, 11 April, 2016)

New Members

Mark Adams, Alexion Pharmaceuticals

Chad Beesley, Sanofi

Sunita Behera, Middlesex Community College

Daniel Bendell, BS, ITIL, Assurance Technology Management

Steve Butler, Troemner

Loe Cameron, Pall Life Sciences

Michael Cammarata, Pfizer

Cara Catinella, DPS Engineering

Lai Man Cheung, BS, Skellig Automation

Anthony Chiarello, BS-MBA, TC Consulting

James Cummins, BSc

Patrick Cusson, DPR Construction - Cambridge

Michael DeFuria, Sanofi Genzyme

Anthony DiGiulio, Community College of Rhode Island

Renee Driscoll, A/Z Corporation

McDesmond Duru, Bothwell Engineering Inc

Dawn Eriksen

Daniel Faria, BWT Pharma & Biotech, Inc.

Michael S. Fedorenko, University of Rhode Island

Adam Feinstein, High Purity New England

Patrick R. Fenton, Genzyme

Joshua T. Ferreira, Davol Inc

Gregory Robert Fischer, ICQ Corp.

Timothy John Flannery, Community College of Rhode Island

Bert Frohlich, Shire
Gregory Gonzalez, Amgen Ltd
Pablo Gramajo, Amgen
Robert Guarino, Hart Design Group
Shannon Guertin, WPI
Matthew Hancur, Webb Bio-Pharm
Michael Hetzel, Baxalta
Madan Kambam, Regeneron Pharmaceuticals Inc.
Daniel Kelley, DPS Engineering
Eric Lahti, Biotech Builders Group
James Levin, DVM, DACLAM, Perkins + Will
Gregory Lewis, STV|DPM
Joseph Loiselle, Avid Engineers
Daniel Madru, Margulies Perruzzi Architects
Kerron Matthews, Middlesex Community College
Amy Mei, EMD Millipore
Bethany Mitchell, Sentinel Process Systems Inc
Melissa Walsh Mobley, Worcester Polytechnic Institute
Jonathan Morris, University Of Massachusetts - Amherst
Joe Murphy, Ironwood Pharmaceuticals
Michael Patrick Murphy, ICQ Corp.
William J. Murray, TFS, Inc
Kevin Neenan, University of Rhode Island
Jenny Nguyen, EMD Millipore
Angel Nieves, Sanofi
James J. O'Donnell, Nitto Denko Avecia, Inc.
Darrell Kevin Orozco, University of New Hampshire
Jeffrey Pearson
Jim Pericles, Alexion Pharmaceuticals
Huancheng Qiao
Gregory Nicholas Riehle, BS, Process Design Solutions, LLC
Jascha Rosenbaum, M.Sc.Eng, Integra Companies
Chelsea Sanborn, CHEG, The RoviSys Company
Daniel Saragnese, Catalent Pharma Solutions
Bryan Sasbon, Ropack Pharma Solutions
Heather Scott, Thermo Fisher Scientific
Marc Shaffer, Mar Cor Purification
Bisma Siddiqui, University of Massachusetts Dartmouth
Matthew Patrick Sitzcoske, High Purity New England
Jamie Snopkowski, ChemE, RoviSys
Michael Solony, BWT Pharma & Biotech, Inc.
Andrea Sonan, DPS Engineering
Kassi Stein, MIT
Eric Stoltz, Worcester Polytechnic Institute
Paul Szafrir, DPS Engineering
Dean Taylor, Cimetrics Inc
Jeannie Thacker, TRIA
Nate Turner, Margulies Perruzzi Architects
Justin Watkins, Community College of Rhode Island
Susan Wiggins

Member Anniversaries

Over Twenty Years

- Michael S. Cheney, Biogen Idec (27 years)
- Donald Cole, Hart Passivation Services, Inc. (26 years)
- Daniel D. Crosby, Bristol Myers Squibb (21 years)
- Greta W. Davis, Lantheus Medical Imaging (26 years)
- Thomas Douville, Koltaan Pharmaceuticals (21 years)
- Michael J. Denault, Denault Associates (21 years)
- John H. Evers, Lantheus Medical Imaging (26 years)
- Michael J. Fisher, Genzyme, Sanofi (22 years)
- Raymond Foley, DPS Engineering (21 years)
- Joshua Froimson, AbbVie Bioresearch Center (22 years)
- Paul F. Herbert, Alkermes Inc (22 years)
- Doyle R. Johnson, Jr., BS, MS, MBA, Hargrove Life Sciences LLC (21 years)
- Richard V. Levy, PhD, PDA (27 years)
- David P. MacKay, Pfizer (21 years)
- Stephen P. Miraglia (23 years)
- Robert S. Mitchell, CPIP (21 years)
- David Monette (22 years)
- Peter Mosgrove, Mettler-Toledo Thornton Inc (24 years)
- Russell B. Parry (24 years)
- Thomas C. Ransohoff, BioProcess Technical Consultants Inc (25 years)
- Stanley E. Rotkiewicz, Jr., Genzyme Corporation (24 years)
- Peter J. Sbrollini, MBA, Brandt Industrial, Inc. (21 years)
- Alexander E. Smith, Jr., M+W U.S., Inc. (26 years)
- Michael J. Sweeney, Hart Design Group (23 years)
- David A. Wilson, Abbott Bioresearch Center (24 years)

Twenty Years

- Paul C. Farrell, Hach Ultra Analytics
- Mark P. Laroche, Superior Controls Inc
- Lucy Lavallee, Leo Pharma AS
- James P. Mirisola, Oliver M Dean Inc
- Albert G. Prescott

Fifteen Years

- Sam K. Aghdam, Genzyme
- Beth Ann Billotto, Regeneron Pharmaceuticals Inc
- Alan N. Brinton, Rhodes Technologies
- John C. Giner, P.E.
- Peter R. Hansen, MSc, Pharm-Assist
- John K. Sicurella, BS, Sanofi Genzyme

Ten Years

- Christopher Brown, Lantheus Medical Imaging
- Stavroula Meimeteas
- Charles E. Mirabal, Validation, Shire
- Edward V. Sargent, MPH, PhD, DABT, E V Sargent LLC
- John F. Shaw, J.F. Shaw Co Inc
- Michael J. Wojcik, MECO
- Timothy M. Zetts, Top Line Process Equipment Co

Five Years

- Rebecca C. Boduch, Organogenesis Inc
- Eric D. Briggs, Siemens Industry Inc.
- Charles C. Cotter, Jr.
- Steven J. Gattuso, Shire
- William E. Gittler, Airgas Northeast Inc
- Martin Quinn, Pfizer Inc
- Antonio Hernandez-Cardoso, United States Pharmacopeial Convention
- Douglas J. Lantigua
- Emery Otruba, Evergreen Engineering
- Ben M. Potenza, EquipNet Inc
- Andrew Roberts, Shire
- Paul C. Stuart, Pfizer, Inc

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