

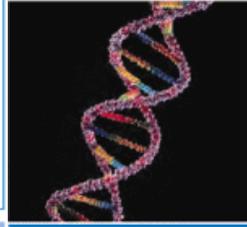


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Boston Area Chapter

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NEWSLETTER

March 2015, Volume XXV, No. 2

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President's Message: Exciting Chapter Activities Heat Up a Cold & Snowy Winter Season...



Dear Boston Area Chapter Members,

With the turning of the calendar and only a little snow fallen, I think we all hoped that spring would be around the corner and we would escape a terrible winter. Unfortunately after the last newsletter the New England area had over 100 inches of snow and record cold weather. We haven't hit the snow fall record in Boston but we are only a few inches away from a historic winter season. Spring isn't quite here yet!

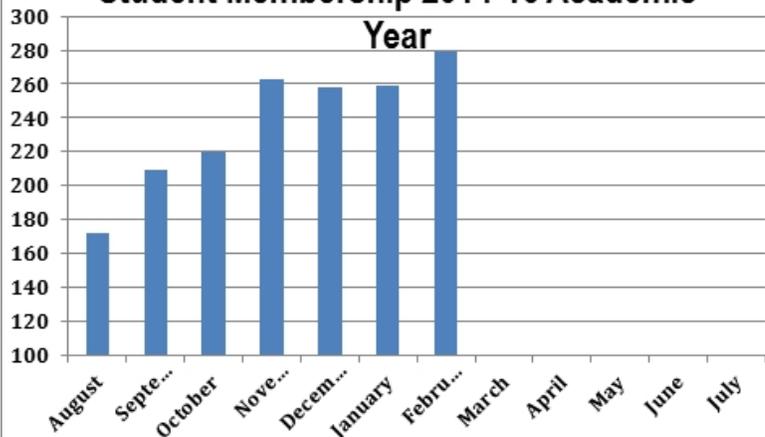
I was very fortunate to attend the Boston Area Chapter's Student Career Workshop at Northeastern University on February 7 where over 50 students braved the wintry weather to participate in a full day of workshops designed to help them improve their job hunting skills. Attendees included a number of participants from last year looking for a leg up in finding their next job! Among many other things, students learned how to develop an effective resume and an engaging elevator speech and how to get to know someone quickly at a business meeting. And for inspiration they were regaled with

stories from seasoned professionals who shared their life lessons. The Chapter would like to extend our thanks to Brian Hagopian, Dave Novak, Andre Walker, Katie Shannon, Paige Kane, Jen Duffy, Nidhi Maniar, Chris Ciampa, Stefani Takahashi, Jonathan Bean, Ayesha Iyer, Travis Maser and Zoey Shen for making this the most successful Career Workshop ever.

The Student Development Committee also hosted a very successful "Careers in Life Science" panel discussion at UMass Amherst on February 11. Over 50 students attended a lively session with lots of questions and discussions about jobs in the pharmaceutical and life sciences area. Thanks go to Joyce Chiu, Paige Kane, Andre Walker and Brian Hagopian for their participation in the panel discussion.

These Chapter-wide, student-focused activities and all the other activities at our 11 Student Chapters have led to a big increase in student membership this year. The Boston Area Chapter now boasts 279 student members - the most in the history of the Chapter!

Student Membership 2014-15 Academic Year



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And speaking of students, I would like to draw your attention to an important upcoming program, the Chapter's Annual Student Poster Competition. It will be held on Thursday, April 16 at WPI as part of the Chapter's April educational program. We already have double the number of entries from last year. Winners in the undergrad and graduate competitions will each receive a \$500 cash prize and a free trip to Philadelphia to compete at the International Student Poster Competition at the ISPE Annual Meeting in November. Winners of the international competition receive cash awards and have the opportunity to publish their research in Pharmaceutical Engineering as well as other Chapter/Affiliate publications.

One good thing about all the snow New England has received in the past month is the incredible ski conditions at our local ski areas. There will be plenty of snow for the Chapter's upcoming Annual Ski trip to Waterville Valley in New Hampshire this Friday, March 6. We already have 56 skiers registered! Look for lots of great stories and photos in the next newsletter.

We have a lot of great programs coming up in the next few months. So either attend the live event in person at the meeting location or visit one of our new GO hubs in Warwick, RI or Worcester, MA and view the simulcast. All locations feature a networking reception and light dinner prior to the educational program. On March 19 the program "Risky Business: How Quality Systems and Risk Blend" will be held at Shire Human Genetic Therapies in Lexington, MA in combination with a facility tour. On April 16 at WPI's Gateway Park in Worcester, MA the topic will be "Downstream Processing, How it is Done and How to do it Faster and Better," a dual-track program with both introductory and advanced level presentations. And be sure to come early for the Annual Poster Competition and support our Student Members.

I hope all of you get through the winter season without too many snow or ice-related problems and look forward to spring and warmer weather!

Sincerely,

Christopher Opalski

President
ISPE Boston Area Chapter

PS. If the weather doesn't improve soon, I am going to suggest the next GO Hub be located in Florida!

Chapter Bulletin Board

Scholarship Program Announces Winners

The Chapter's Joel Goldenberg Memorial Scholarship Program has awarded scholarships to the following Chapter Student Members:

D. Ezra Aurian-Blajeni	UMass Amherst
Valmik Doshi	MCPHS University
Michael Foshey	UMass Dartmouth
Megan Harless	Northeastern University
Luiza Korobkova	UMass Amherst
Paige Kane	Dublin Institute of Technology (DIT)
Raymond Lawton	UMass Dartmouth
Aislinn Mulligan	MCPHS University
Sydney Shaw	Northeastern University

Congratulations to all of our winners! And remember, you can't win if you don't apply! Visit the Chapter's website for all the details at www.ISPEBoston.org/scholarship.

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.

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

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter 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 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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So don't delay, visit 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 and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Thursday, March 20, 2015

Risky Business: How Quality Systems and Risk Blend

Shire Human Genetic Therapies, Lexington, MA

OR

Simulcast to the Crowne Plaza Hotel, Warwick, RI

AND in a new simulcast location

WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

EVENT INFORMATION:

Attend the live program at Shire Human Genetic Therapies in Lexington, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs at all locations will feature a networking reception including appetizers.

PROGRAM SUMMARY:

Have you ever wondered about how risk approaches integrate across different quality systems? What does the FDA think of risk assessments? Do they just justify not doing work or are they a tool to quantify the risk associated with decisions and focus work on the most impactful portions of the business. How should risk be viewed, especially when looking across different quality systems? Is risk in a silo or do we integrate risk across different quality systems? Why is risk in change control so different than deviations? Come ready to hear some thoughts from an FDA speaker and then bring questions for our panel of an FDA speaker and industry expert.

TOUR:

The ISPE Boston Area Chapter is also glad to present a rare opportunity to tour Shire's 400 Shire Way manufacturing facility in Lexington utilizing single-use technologies at commercial scale.

Membership has its privileges!

This tour is open only to ISPE Members and will fill up fast! So register early!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=472

Thursday, April 16, 2015

Downstream Processing: How it's Done and How to do it Faster & Better

WPI Biomanufacturing Education and Training Center (BETC) at Gateway Park, Worcester, MA

OR

Simulcast to the Crowne Plaza Hotel, Warwick, RI

EVENT INFORMATION:

Join ISPE at WPI's Gateway Park for this dual track event that has something for everyone. Attend the live program or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will feature a networking reception including appetizers. Tours of the BETC facility will be offered during the reception hour or cheer on the Student Poster Contestants during the final phase of judging.

TRACK 1:

Downstream Processing Techniques and Single Use Applications

This interactive presentation will introduce participants to the unit operations typically carried out to purify a cell culture product. Understanding what the contaminants are and how they can be removed is the first step in understanding how the downstream process should be designed. This discussion will provide insight as to how virus inactivation and removal, chromatography and UF/DF are achieved and best arranged in a process. In addition, the opportunities and merits of single use options for downstream processing will be discussed.

SPEAKER:

Stuart Green, VP of Process Engineering for Pall Corporation's Life Science Division of North America

TRACK 2:

Integrated Continuous Downstream Processing - an Enabling Approach that will Break the Bottleneck

This presentation is for seasoned professionals who are familiar with the purification process and want to learn about the newest technologies. Over the last decade, the expression levels



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have tremendously increased for the upstream fermentations; thus, the downstream processes (DSP) became the "bottleneck" in manufacturing process of bio-pharmaceutical, especially for monoclonal antibodies. Additionally, biosimilars/biobetters are introduced to the market which demands new downstream approaches that are cost and time effective by retaining the properties of the biomolecules. Consequently, different integrated DSP and/or multi-column continuous chromatographic technologies are investigated that showed promising results in reducing manufacturing costs. However, up to today there has not been a reported case at the production scale. What are the remaining barriers when implementing the approaches into the downstream processing? This presentation will outline the integrated continuous downstream process by focusing on the continuous chromatography and highlight major barriers and how to overcome them in the GMP environment.

SPEAKER:

Dr. Kathleen Mhlbachler, Global Director of Separations Development, LEWA Process Technologies, Devens, MA.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=550

Wednesday, April 29, 2015

2016 Educational Programs BRAINSTORMING SESSION

WPI Biomufacturing Education and Training Center (BETC) at Gateway Park, Worcester, MA

EVENT INFORMATION:

The Boston Area Chapter of ISPE is holding a Brainstorming Session to plan educational content for the 2016 programming season. This is an ideal opportunity to share your ideas and help us plan programs of interest to you for the upcoming year. If you have ideas for programs, speakers, or locations, please join us to share your thoughts. A pre-session networking reception, with light dinner, will let you unwind with fellow industry professionals. Then we will focus on your ideas and suggestions. All ideas will be collated and presented to the membership via electronic survey before being finalized for the next programming season. The Committee is meeting in July to coordinate volunteers to help develop these programs. Please consider volunteering for the Educational Programs Committee to make these programs come to life!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=554

Monday, May 11, 2015

Spring Golf Tournament

Ledgemont Country Club, Seekonk, MA

EVENT INFORMATION:

Join fellow golfers for a day out on the course! Lunch, dinner and golf are included for each player.

SCHEDULE:

11:30 AM - 12:45 PM Registration and Buffet Lunch
 1:00 PM - Shotgun Start - Scramble Format
 5:30 PM - Reception/Cocktails/Buffer Dinner

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=552

Sneak Preview of Upcoming Events

Thursday, May 21, 2015

Educational Program

Friday, June 18, 2015

Educational Program

Continuous Manufacturing Educational Program Breaks Attendance Records

by Brian Hagopian, Clear Water Consulting, with photos by Joyce Chiu, Honeywell Safety Products

The January educational program at Biogen Idec gave us a glimpse into the future of manufacturing with a focus on advances in continuous manufacturing. With the local biotech industry primarily locked into batch processes, three speakers presented information on how some products are being made continuously RIGHT NOW! And Chapter Members turned out in

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droves to learn how and why. After hearing from all three speakers, it became abundantly clear that adapting a process to continuous manufacturing is highly beneficial because continuous manufacturing reduces capital requirements, minimizes footprint and allows for the continuous production of products.



Chapter Past President Dave Novak greeted attendees during the networking reception.

Salvatore Mascia, Ph.D. of Continuous Pharmaceuticals discussed the use of an integrated continuous manufacturing (ICM) process developed through collaboration between MIT and the Novartis Center for Continuous Manufacturing for the production of small molecules. Adapting a process to continuous manufacturing poses some challenges and may require “outside the box” thinking. Dr. Mascia described how several batch processes were analyzed for capacity and throughput and then how each step was synchronized to allow for a clean flow from one step to the next. This allowed each modular process to be linked to others. The net result is that an identical quantity of material can be produced continuously with less capital while requiring a smaller footprint.



The evening's cutting edge topic drew a large crowd to Biogen Idec for the Chapter's January educational program.

Maurizio Cattaneo, Ph.D, CPIP of BioVolutions described how Quality by Design (QbD) and Risk Assessment tools were used to determine critical process parameters (CPP's), which then allowed the application of continuous manufacturing principles to the production of monoclonal antibodies (mAbs). In the case of mAbs, a batch cell culture process was adapted to a perfusion process, which allows for continuous harvesting at a much earlier stage in the game. He then described how a continuous harvest was synchronized with a chromatographic purification process where “mini-batches” of mAbs were applied to a column, eluted, and more material was applied multiple times within the same column. After purification, the “mini-batches” were tested, pooled, and sent to the fill/finish step. Dr. Cattaneo described this process as producing higher quality product on a continuous basis using fewer steps, requiring less capital and significantly less space, and producing product in about two-thirds the time of conventional batch processes.

Kathleen Muhlbachler, Ph.D. of LEWA Process Technologies described recent advances in Multi-Column Continuous (MCC) Chromatography and Simulated Moving Bed (SMB) Chromatography for the separation of products from their impurities as well as separating mirror image compounds (chiral molecules) from each other. Dr. Muhlbachler described a continuous

separation process for small molecules where several columns were used simultaneously in a defined sequence to separate product from impurities. While this technology has been used to separate small molecule chemicals and low molecular weight food products, she showed an example of how chromatography could be adapted to continuously separate biomolecules. Dr. Mihlbachler closed with a brief discussion of the regulatory challenges of transitioning from batch to continuous manufacturing. Dr. Mihlbachler will be speaking on a related topic at the Chapter's April 16 educational program being held at the Worcester Polytechnic Institute Biomanufacturing Education and Training Center at Gateway Park in Worcester.



Presenters (l to r) Salvatore Mascia, Maurizio Cattaneo & Kathleen Mihlbachler joined forces to explain the hows & whys of continuous manufacturing.

There was a lively question and answer period after each presentation had been completed followed by many one-on-one discussions after the session ended, a clear indication of the high interest level in continuous manufacturing. Many thanks to Biogen Idec for providing the venue for this thought-provoking program.

ISPE and I²SL Join Forces for Networking and Fund Raising at Flat Top Johnny's

by Aarash Navabi, CPIP Genzyme, a Sanofi Company, with photos by Joyce Chiu, CPIP Honeywell Safety Products

On January 21 the Chapter held its first networking event of 2015 - our traditional Holiday Social at Flat Top Johnny's in Kendall Square. Adding a new twist to this annual event, this year we partnered with I²SL (International Institute for Sustainable Laboratories) and were more than pleased with the outcome. With almost 130 people in attendance and a variety of mouthwatering appetizers, unlimited pool tables and an array of local brews to sip on with friends, old or new, the event was one of ISPE's most rewarding social events ever.



This year I²SL joined the Boston Area Chapter at the Holiday Social and helped raise funds for the ALS Foundation.

In addition to the food, drink and networking, the event was also a benefit for the ALS Foundation. ALS, also known as Lou Gehrig's disease, is a progressive and ultimately fatal neurodegenerative disease, one that deserves attention and support year-round. Not long ago the Foundation was the center of attention as people raised awareness by participating in the ALS Ice Bucket Challenge. Due to the excellent turnout and the generosity of our guests, we did our part by raising over \$1000 for this worthy cause in just one night.



The pool tables are always a big attraction at Flat Top Johnny's.

A very special thank you to all who bought raffle tickets and to the generous organizations that made our success possible by donating an array of fantastic prizes:

- Commissioning Agents - \$125 Gift Card to Catalyst
- Digital Dynamics - Chromecast
- GxP Automation - Glenlivet 15-Year Single Malt Scotch
- L.J. Star - Digital camera
- Perkins + Will - Two Red Sox tickets
- RW Sullivan - Round of golf at Kernwood Country Club
- Sentrol - \$100 Gift Card to Row 34
- The Richmond Group - \$100 Gift Card to Legal Seafoods

Following the Holiday Social the Chapter has an outstanding schedule of social and recreational events planned for 2015, with the Annual Ski Trip next up on March 6 and the Spring Golf Outing not far behind on May 11. If you've never attended one of these events, make this your year to join in the fun. And if you've been before we know we'll see you this year, too!

Career Workshop Draws 50 Student Members to Northeastern

by Jen Duffy, Shire, with photos by Brian Hagopian, Clear Water Consulting

Another highly successful Student Career Workshop took place on February 7 in the Alumni Center at Northeastern University. Despite the weather, over 50 students attended the event from places as far away as Maryland and Missouri, making this the largest Career Workshop yet. Last year students left the workshop with great advice and returned this year with friends and classmates eager for the opportunity to learn from industry professionals. With the interactive and encompassing agenda, it is easy to understand why this event keeps growing.

The daylong workshop covered everything a student needs to know to increase their chances of getting the internship, co-op or full time position they are looking for in the life sciences industry. The workshop kicked off with a presentation on the value of networking. Presenters next took students out of their "comfort zone" with an interactive exercise during which students practiced their networking skills to prepare them for their first introductions to professionals they are sure to meet.

Next, starting at the beginning of the career path, an approach to self-analysis was discussed, enabling students to recognize the strengths they have to offer and explaining how to incorporate these positives into effective resumes and cover letters. Students began working their way through a series of carefully created worksheets to help guide them through each topic of the day from first impressions and interviewing tips, to creating goals using the SMART planning tool (specific, measurable, attainable, relevant and time bound) for long term career path planning.



Students listened intently as Chapter Member Katie Shannon described how she landed her dream job at Biogen Idec.

Other sessions provided students with abundant insight on what employers are looking for and why networking is important. Students also had the opportunity to network with professionals and ask the questions important to them in a one-on-one setting. With questions ranging from the general "What are the roles and responsibilities of different groups in the life sciences industry?" to specific questions on the most practical path to reach particular goals, there was something for every student to learn from the speakers and from the other students as well.

A particularly engaging portion of the workshop for both students and professionals was the chance to hear how successful professionals got to where they are today. These stories shared an individual's life experiences, how they made career decisions and the lessons they learned along the way. Attendees were also able to choose from three outstanding books specifically written for graduates seeking jobs to take home with them, providing further help with the job search and interview process.

This annual event is a fantastic opportunity for students to "learn from the best" and for professionals to give back and help shape the future of the life sciences industry. It's a great feeling to be able to remember what it's like to be entering the "real world" for the first time and all the questions that go along with that, and to be able to make a positive difference in the lives of students who are looking ahead to graduation and becoming part of the life science industry.

These Fun and Educational Young Professional Events Are Sure to Cheer You Up!

by Chris Ciampa, Thermo Fisher Scientific, and Lucas Wafer, Pfizer, with photo by Dave Gallagher, GxP Automation

What was shaping up to be a snowless winter has turned into a nightmare for the New England area. How quickly things can change, as December was a very mild, dry month! The total accumulation of snow this winter is 78.5 inches. It is doubtful that spring is only a few weeks away. An arrest warrant is currently being issued to Punxsutawney Phil, who believes that he saw his shadow! Have no fear - even as the weather worsens, we have some great YP events for you to look forward to!

On Wednesday, February 25 the YPs were back at Medieval Manor. If you are looking to experience life as it was in the dark ages, we hope you were there! Where else would you have the opportunity to enjoy food from medieval times "hands on" style without using a fork, knife, or spoon? Back by popular demand, this event also allowed YP members to network and mingle with the Chapter's seasoned industry experts.



Medieval fun not your thing? Perhaps you are more interested in bowling and pizza. In April, the YPs are heading to Davis Square to Flatbread/Sacco's. There is no date set but we are looking at the week of April 27. This will be a fun night of networking, all-you-can-eat pizza and salad, and local craft beers. Not only that, but Sacco's also offers its famous candlepin bowling and Flatbread makes delicious, organic, wood-fired pizza. As a combined company, Flatbread and Sacco's Bowling has been a staple in the Somerville community for over 60 years.

With the success of Night Shift Brewery in December, a plan is in place to host another brewery tour at Aeronaut Brewery in Somerville in the near future. This presents another opportunity for the Chapter Members to learn more about the beer-making process.

Switching gears to the educational perspective, there are a couple of events designed to familiarize YP engineers with current issues and trends. On Thursday, April 16 a dual-track educational program will take place at WPI. The YP portion of the event will cover "Downstream Processing Techniques and Single Use Applications" at the introductory level and will focus on purifying cell culture and ensuring that a downstream process is contaminant free. The speaker is Stuart Green, VP of Process Engineering for Pall Corporation's Life Science Division in North America. Plan to arrive early for the Chapter's Annual Student Poster Competition being held in conjunction with the dual-track program and lend your support to the students (and future YPs) displaying their research. Winners receive \$500 and a chance to attend the ISPE Annual Meeting and compete at the international level. Keep an eye out for a Chapter email with all the details.

Other future educational events are currently in the planning stage. One of the prospective events involves automation, which is a common theme for many engineers across our industry. Nothing has been set in stone yet but we could do a lecture on automation and/or a seminar on improving automation. We are also looking into the possibility of having education events in the near future on two pertinent industry topics: relevant industry standards (USP, CFR, ISO, ASTM, etc) and the impact of commercial operation on regulatory filings.

As always the YPs would love to hear from you. If you have ideas for social or educational events or wish to attend a committee meeting, please feel free to contact Jared Marshall at jared_marshall@genzyme.com or Christopher Ciampa at christopher_ciampa@gmail.com. Also, if you are new to the industry and looking to get some exposure on an international level, there is an opportunity to get your name out on the ISPEAK blog. Please feel free to reach out to Jared if you would like more information on this.

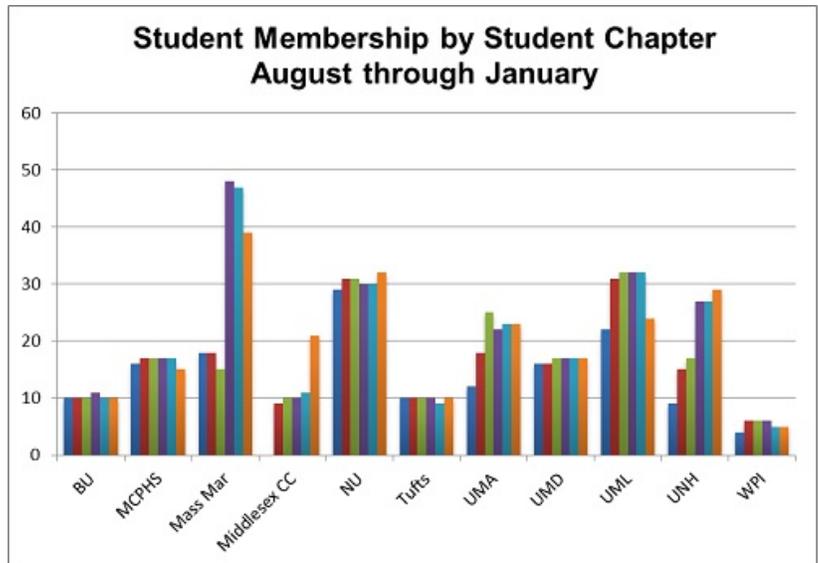
Thank you for tuning in and stay warm, safe, and healthy as the winter season progresses!

Student Chapters, Scholarship Winners, Annual Poster Contest & More

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

Student Chapters Hit a New Membership High - AGAIN!

The Chapter has been very active on university campuses again this year, with 11 Student Chapters reaching a new high in student membership since the beginning of the semester! The Boston Area Chapter now has over 250 Student Members, more than any other ISPE Chapter nationwide! The graph below provides a breakdown of student membership by Student Chapter from August 2014 through January 2015.



While we had a large bump at **Mass Maritime Academy** immediately following the product show, student membership has increased steadily and deliberately at **Northeastern, University of New Hampshire, UMass Amherst and Middlesex Community College**, a testament to the strong efforts of students and faculty on these campuses.

Register Now for the Student Poster Competition!

This year's Student Poster Competition will be held on April 16 at WPI's BETC concurrently with the Chapter's April educational program. Students will compete in graduate and undergraduate

categories and have the opportunity to meet and network with industry professionals and attend an educational program. Winners receive a **\$500 cash prize** plus an expense-paid trip to compete in the International Student Poster Competition at the ISPE Annual Meeting in November. For specifics and to register, click [here](#).

Scholarship Program Announces Winners!

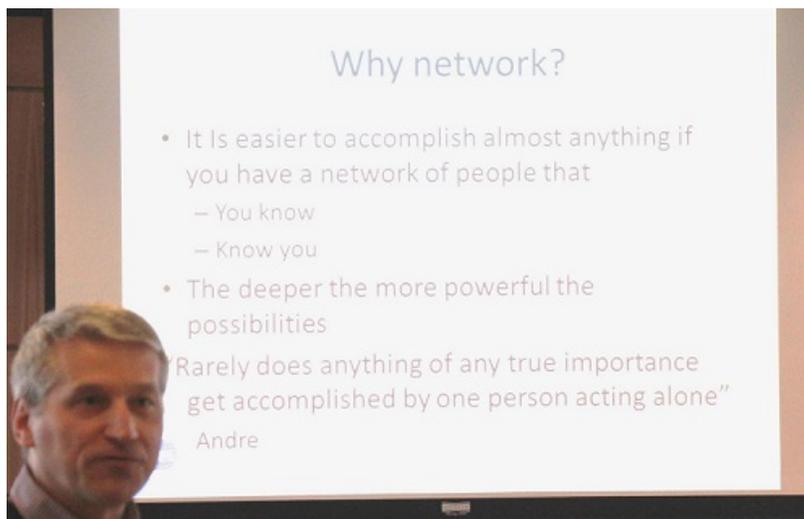
The Chapter's Joel Goldenberg Memorial Scholarship Program has awarded scholarships to the following Chapter Student Members:

D. Ezra Aurian-Blajeni	UMass Amherst
Valmik Doshi	MCPHS University
Michael Foshey	UMass Dartmouth
Megan Harless	Northeastern University
Luiza Korobkova	UMass Amherst
Paige Kane	Dublin Institute of Technology (DIT)
Raymond Lawton	UMass Dartmouth
Aislinn Mulligan	MCPHS University
Sydney Shaw	Northeastern University

Congratulations to all of our winners! And remember, you can't win if you don't apply! Visit the Chapter's website for all the details at www.ISPEBoston.org/scholarship.

Annual Student Career Workshop a Huge Success!

The Chapter held its third Annual Student Career Workshop on Saturday, February 7 on the top floor of the Alumni Center at Northeastern and was greeted with its biggest turnout ever. This event continues to grow as student attendees from prior years spread the word among their peers. See related article for all the details.



Andre Walker of Biogen Idec explained the benefits of effective networking at this year's Career Workshop.

Life Sciences Panel Discussion Hosted by ISPE At UMass Amherst!

The UMass Amherst Student Chapter organized a Life Sciences Panel Discussion, which was held on campus on February 11. Panelists included Dr. Michael Sarli from the UMass Amherst Chemical Engineering Department and Chapter Members Joyce Chiu, CPIP from Honeywell, Paige Kane, CPIP from Pfizer and Andre Walker, CPIP from Biogen Idec, with Brian Hagopian, CPIP from Clear Water Consulting acting as moderator. Over 50 students participated and got valuable advice on resume preparation, networking, translatable skills, job search techniques and career pathways from the expert panel. A special thank you to our panelists for taking time from their busy schedules to participate in a session that was truly appreciated by all the students who attended.



Panelists (l to r) Joyce Chiu, Michael Sarli, Andre Walker and Paige Kane provided valuable advice on networking skills, job search techniques and career pathways.

Remember, Student Members Attend ISPE Educational Events for Free

Remember, once you join ISPE as a Student Member (www.ispe.org/join-or-renew), you can attend all Chapter educational and related events for free! Membership in the Boston Area Chapter truly does have its privileges!

Industry News In Brief

by Jillian Willard, Genzyme, a Sanofi Company

Voyager Therapeutics & Genzyme to Collaborate in Gene Therapy Development

Voyager Therapeutics, a gene therapy company developing treatments for fatal and debilitating diseases of the central nervous system (CNS), and Genzyme, a Sanofi company, announced a collaboration to discover, develop and commercialize novel gene therapies for severe CNS disorders. The collaboration will leverage Genzyme's experience in adeno-associated virus (AAV) gene therapy and Voyager's AAV product engine to develop therapies for patients suffering from severe CNS disorders. The alliance will encompass multiple gene therapy programs, including programs for Parkinson's disease, Friedreich's ataxia and Huntington's disease, as well as other CNS disorders. The collaboration portfolio created will combine programs and intellectual property from both companies.

Voyager will drive research and development activities for all programs, working with Genzyme. Genzyme will have the option to license several programs following completion of an initial proof-of-concept human clinical trial. However, Voyager will retain all U.S. rights to its lead product programs in Parkinson's disease (VY-AADC01) and Friedreich's ataxia (VY-FXN01). Voyager will split U.S. profits with Genzyme for the Huntington's disease program (VY-HTT01). In addition, Voyager's lead amyotrophic lateral sclerosis (ALS) program (VY-SOD101) is not part of the collaboration and Voyager retains worldwide rights to this program.

Genzyme will make an upfront commitment of \$100 million to Voyager, including \$65 million in cash, a \$30 million equity investment in Voyager and additional in-kind contributions. Voyager is eligible to receive future potential development and sales milestone payments of up to \$745 million, as well as tiered royalties on product sales.

Voyager was founded by scientific and clinical leaders in the fields of AAV gene therapy, expressed RNA interference and neuroscience. The company was launched in 2014 with funding from life sciences investor Third Rock Ventures and is headquartered in Cambridge, Massachusetts. (Source: news.genzyme.com, 11 February, 2015)

Blend Therapeutics of Watertown Secures \$21 Million Financing

Blend Therapeutics, a biopharmaceutical company discovering new classes of medicines to treat cancer, announced it has secured \$21 million in new funding. The new financing includes additional equity investment from a new investor and all of Blend's existing venture investors in an expansion of the Series B round, as well as debt financing from an institutional investment firm. Including the \$21 million, Blend has obtained a total of \$39.8 million in funding to date. Blend is backed by venture investors including New Enterprise Associates, Flagship Ventures, NanoDimension and Eminent Venture Capital.

The proceeds of the financing will enable Blend to advance its proprietary Pentarin™ platform, which creates miniaturized biologic drug conjugates encapsulated in nanoparticles, representing a new class of cancer therapeutics. Blend also announced it has secured a technology license from a private biotechnology company for novel bi-podal biologic targeting ligands that is an exclusive license in the field of oncology. The in-licensing of this ligand technology will allow Blend to develop new Pentarins. These mini drug conjugates in nanoparticles enable high therapeutic concentration at the tumor site, their small size allows for effective penetration and distribution into the tumor tissue and the ligand's targeting ability allows for specific binding to tumor cells. (Source: blendtx.com, 07 January, 2015)

New Antibiotic Circumvents Development of Resistance Among Pathogens

For years, pathogens' resistance to antibiotics has put them one step ahead of researchers, which is causing a public health crisis, according to University Distinguished Professor Kim Lewis. A group from Northeastern has discovered an antibiotic that eliminates pathogens without encountering any detectable resistance. This finding challenges long-held scientific beliefs and holds great promise for treating chronic infections like tuberculosis and those caused by MRSA. The research, which was performed by Professor Kim Lewis and colleagues was published in the journal Nature.

The antibiotic, called teixobactin, is the first in which there are no known pathogen mutations that allow the pathogen to resist the antibiotic. Therefore, the antibiotic could potentially treat chronic infections that are highly resistant to antibiotics, as well as tuberculosis, which involves a combination of therapies with negative side effects.

Lewis and Northeastern biology professor Slava Epstein co-authored the paper with colleagues from the University of Bonn in Germany, NovoBiotic Pharmaceuticals in Cambridge, Massachusetts, and Selcia Limited in the United Kingdom. (Source: northeastern.edu/news, 07 January, 2015)

RXi Pharmaceuticals Licenses Hapten Pharmaceuticals Phase 2 Clinical Compound

RXi Pharmaceuticals announced it has entered into an assignment and exclusive global license agreement with Hapten Pharmaceuticals for the therapeutic use of Samcyprone™. Under the terms of the agreement, Hapten will sell and assign to RXi certain patent rights and related assets and rights to Samcyprone™. Once the agreement is effective, Hapten will receive an upfront payment payable in cash and common stock, will be entitled to receive future milestone payments tied to the achievement of certain clinical and commercial objectives and will receive royalties based on product sales.

Hapten Pharmaceuticals is an early stage dermatology product development company based in New York, NY. Samcyprone™ is a proprietary gel formulation of diphenylcyclopropanone (DPCP), an immunomodulating agent that works by initiating a T-cell response. Although DPCP is not a registered drug, it is used successfully by dermatologists as a topical immunomodulator to treat dermatological diseases. Samcyprone™ is expected to demonstrate an improved safety and use profile over DPCP as currently applied.

A Phase 2a trial to evaluate the efficacy and safety of Samcyprone™ for the treatment of viral warts has been completed and Phase 2a trials for the treatment of cutaneous metastases of various cancers including melanoma and for the treatment of alopecia areata are underway.

In addition, RXi announced that it has entered into a new purchase agreement with Lincoln Park Capital Fund, a Chicago-based institutional investor, whereby LPC is committed to purchase an aggregate of up to \$10.8 million in shares of RXi common stock over a 28-month term. Prior to entering this new agreement, RXi and LPC mutually agreed to terminate the prior purchase agreement that was in place, with respect to the \$18 million unsold balance. RXi plans to use the proceeds from this new agreement with LPC to support the development of Samcyprone™, as well as the advancement of the Company's ophthalmology and dermatology franchises and for other general corporate purposes.

RXi Pharmaceuticals is a biotechnology company focused on discovering, developing and commercializing innovative therapies based on its proprietary, self-delivering RNAi (sd-rxRNA®) platform. Therapeutics that use RNA interference, or RNAi, have great promise because of their ability to down-regulate the expression of specific genes that may be over-expressed in disease conditions. RXi's first RNAi product candidate, RXI 109, a self-delivering RNAi compound (sd-rxRNA), entered into human clinical trials in June 2012 and is currently being evaluated in Phase 2 clinical trials to reduce the formation of dermal fibrosis. (Source: rxipharma.com, 19 December, 2014)

Moderna Closes \$450 Million Financing, Will Add 100 Jobs

Moderna Therapeutics, a pioneer in the development of messenger RNA (mRNA) Therapeutics™, announced it has raised \$450 million in new funding to support the further expansion of its mRNA Therapeutics™ platform. Since the company's founding in 2011 by Flagship VentureLabs™, Moderna has secured more than \$950 million in funding through financing activities and commercial partnerships.

This funding round, Moderna's largest to date, will be used to further accelerate drug discovery and development across a series of drug modalities and therapeutic areas, each powered by Moderna's proprietary approach for utilizing modified mRNA to instruct native cellular machinery to make therapeutic proteins in vivo. To continue to drive these programs forward, Moderna plans immediate growth and expansion, including the addition of more than 100 employees to its current team of 145 during the coming months.

Participating in the financing round were new investors Viking Global Investors LP, Invus, RA Capital Management, and Wellington Management Company, LLP, as well as existing investors AstraZeneca and Alexion Pharmaceuticals. Additional existing investors participated in the financing.

Together with partners AstraZeneca, Alexion and DARPA (The Defense Advanced Research Projects Agency), Moderna is developing 45 preclinical programs in oncology, cardiovascular disease, rare diseases, and infectious diseases. These include programs underway at Onkaido, a Moderna venture focused exclusively on oncology, and at other therapeutically-focused ventures in development. In addition, Moderna is investing in early-stage drug discovery and development through its collaboration with Karolinska Institutet and Karolinska University Hospital, announced in October 2014. (Source: modernatx.com, 05 January, 2015)

Synageva BioPharma Proposes 2.5 Million Share Public Offering

Synageva BioPharma, a Lexington, Massachusetts biopharmaceutical company developing therapeutic products for rare disorders, announced it intends to offer 2.5 million shares of its common stock for sale in an underwritten public offering. In connection with this offering, Synageva expects to grant to the underwriters a 30-day option to purchase up to an additional 375,000 shares of its common stock. If the underwriters exercise this option, Synageva will have offered approximately 2.88 million shares of its common stock. Goldman, Sachs and J.P. Morgan Securities are serving as book-running managers for the offering.

Synageva is a biopharmaceutical company focused on the discovery, development, and commercialization of therapeutic products for patients with rare diseases. The company's pipeline programs consist of protein therapeutics for rare diseases with unmet medical need at various stages of development including the lead program, Kanuma™ (sebelipase alfa) for lysosomal acid lipase deficiency, SBC-103 for mucopolysaccharidosis IIIB (also known as Sanfilippo B syndrome), and SBC-105 for generalized calcification of infancy and other rare calcification diseases. (Source: ir.synageva.com, 05 January, 2015)

Shire to Acquire NPS Pharma in \$5.2 billion Transaction

Shire and NPS Pharmaceuticals announced that the companies have entered into a merger agreement in which Shire will acquire all the outstanding shares of NPS Pharma for \$46 per share in cash, for a total consideration of approximately \$5.2 billion. The \$46 per share price in the transaction represents a 51 percent premium to NPS Pharma's unaffected share price of \$30.47 on December 16, 2014. The transaction has been approved unanimously by the Boards of Directors of both Shire and NPS Pharma.

NPS Pharma is a rare disease-focused biopharmaceutical company and its first product, Gattex®/Revestive®, is approved in the United States and Europe to treat adults with short bowel syndrome who are dependent on parenteral support. NPS Pharma also has a product, Natpara®/Natpar® (rhPTH -83) for the treatment of hypoparathyroidism (HPT) which recently won FDA approval.

The acquisition is structured as an all-cash tender offer for all of the outstanding shares of NPS Pharma at a price of \$46 per share followed by a merger in which each remaining untendered share of NPS Pharma common stock would be converted into the same \$46 cash per share consideration as in the tender offer. (Source: shire.com, 11 January, 2015)

Biogen Idec Acquires Convergence Pharmaceuticals

Biogen Idec announced it has agreed to acquire U.K.-based Convergence Pharmaceuticals, a clinical-stage biopharmaceutical company with a portfolio of ion channel-modulating product candidates for neuropathic pain. Biogen Idec plans to leverage Convergence's experience in chronic pain research and clinical development to accelerate the growth of its own pain portfolio.

Under the terms of the deal, Biogen Idec will pay Convergence shareholders an upfront payment of \$200 million. Convergence shareholders are eligible to receive additional payments of up to \$475 million contingent on future milestones. Convergence will continue to operate out of Cambridge, U.K., under the leadership of its Chief Scientific Officer, Simon Tate, Ph.D.

Convergence Pharmaceuticals is an independent biotechnology company focused on the development of novel analgesics. The company was formed in October 2010 following the acquisition of certain neuroscience clinical assets from GlaxoSmithKline, with funding from Apposite Capital, New Leaf Venture Partners and SV Life Sciences. The company has a pipeline of differentiated clinical-stage compounds targeting chronic pain signaling through modulation of specific ion channels.

One of Convergence Pharmaceutical's leading candidates is CNV1014802, a state-dependent small molecule sodium channel blocker that preferentially inhibits the Nav 1.7 ion channel, a therapeutic target implicated by genetics in human pain conditions. CNV1014802 is currently in development as a treatment for patients with trigeminal neuralgia (TGN), a chronic and debilitating form of excruciating episodic facial pain. Positive data from a recent Phase 2 clinical trial showed that CNV1014802 was associated with a consistent reduction of pain severity and a reduction in the number of paroxysms compared to placebo. In addition, CNV1014802 was generally well tolerated. There were no serious adverse events related to the candidate, and the adverse event profile was similar to placebo. (Source: biogenidec.com, 11 January, 2015)

Alnylam and Isis Form New Agreement, Extend Partnership

Isis Pharmaceuticals and Alnylam Pharmaceuticals, both involved in developing RNA-targeted therapeutics, announced they have formed a new agreement, extending their existing strategic partnership, which was originally formed in 2004. This new agreement includes a cross-license of intellectual property (IP) on four disease targets, providing each company with exclusive RNA therapeutic license rights for two programs. The agreement also includes a non-exclusive technology IP cross-license, providing each company rights to certain of each other's technology advances for RNA therapeutics through April 2019.

Per the terms of the new agreement, Alnylam and Isis are forming an IP cross-license with reciprocal economic terms on four therapeutic targets, where each company obtains exclusive license rights to two therapeutic programs. Alnylam is granting Isis an exclusive, royalty-bearing license to its chemistry, RNA-targeting mechanism and target-specific IP for oligonucleotide therapeutics against two targets: Factor XI and apolipoprotein (a), or Apo(a). Isis is currently

developing an investigational antisense drug toward Factor XI for the prevention of thrombosis. Isis-FXI is currently in Phase 2 clinical development. Isis is also currently developing an investigational antisense drug targeting Apo(a) to treat cardiovascular disease. Isis-Apo(a) is currently in a Phase 2 clinical trial.

In exchange, Isis is granting Alnylam an exclusive, royalty-bearing license to its chemistry, RNA-targeting mechanism and target-specific IP for oligonucleotide therapeutics against two targets: antithrombin (AT) and aminolevulinic acid synthase-1 (ALAS-1). Alnylam is currently developing an investigational RNAi therapeutic targeting AT for the treatment of hemophilia and rare bleeding disorders. ALN-AT3 is currently in a Phase 1 clinical trial enrolling hemophilia subjects. Alnylam is also currently developing an investigational RNAi therapeutic targeting ALAS-1 for the treatment of hepatic porphyrias, including acute intermittent porphyria (AIP); Alnylam has just filed a clinical trial application to begin a Phase 1 clinical trial with ALN-AS1.

The new agreement also includes an extended technology IP cross-license. Specifically, Alnylam is granting Isis a royalty-bearing, non-exclusive license to new platform technology arising from May 2014 through April 2019 for single-stranded antisense therapeutics. In turn, Isis is granting Alnylam a royalty-bearing, non-exclusive license to new platform technology arising from May 2014 through April 2019 for double-stranded RNAi therapeutics. This IP cross-license includes chemistry, motif and mechanism patents but excludes patent claims on formulations, manufacturing, and specific targets. (Source: investors.alnylam.com, 09 January, 2015)

Roche Enters Collaboration with Cambridge-Based Foundation Medicine

Roche and Foundation Medicine, Inc. (FMI) announced they are entering into a collaboration in the field of molecular information and genomic analysis with a specific focus on oncology. FMI provides molecular information to characterize tumors, which aids physicians in matching their patients with approved targeted therapy options and novel treatments under development. Understanding the comprehensive genomic profile of a cancer patient's disease will enable better personalized healthcare solutions and optimize treatment outcomes for patients.

Under the terms of the R&D collaboration agreement, Roche is committing to funding of potentially more than \$150 million for a minimum of five years and will contribute its knowledge in oncology. FMI will continue to operate independently and will contribute its experience in the development of genomic profiling tests for oncology. The initial focus of the R&D collaboration will be on developing genomic profile tests for cancer immunotherapies and for continuous blood-based monitoring.

Roche will be able to utilize FMI's proprietary molecular information platform to standardize clinical trial testing. This aspect of the relationship is designed to enable comparability of clinical trial results for R&D purposes, and ultimately in the clinic. FMI's pharmaceutical business will not be impacted.

The R&D collaboration and FMI's current and future tests are expected to deliver insights to support development of combination therapies, novel targets, more accurate patient population identification and inclusion in clinical trials, and next generation companion diagnostics.

In addition to the R&D collaboration, both parties also agreed to a commercial collaboration agreement designed to broaden FMI's position across clinical and molecular information markets. Specifically, Roche will obtain rights ex-US (under the FMI brand) to existing FMI products, as well as to future co-developed products. In the U.S., Roche will engage its U.S. medical education team in providing medical information to pathologists. The collaboration agreements will become effective upon the completion of Roche's direct investment in FMI and the tender offer, as described below.

Under the terms of the contemplated transaction, Roche will invest \$250 million in FMI at a per share issuance price of \$50 (5 million shares) to fund FMI operations and development. In addition, Roche will commence a tender offer at a per share price of \$50, which, when combined with Roche's direct investment in FMI, will result in Roche owning a minimum of 52.4 percent and a maximum of 56.3 percent of FMI on a fully diluted basis. The offer price constitutes a 109 percent premium over the closing price of 09 January, 2015.

The transaction has been unanimously approved by the FMI Board of Directors. In addition, Third Rock Ventures, Kleiner Perkins Caufield & Byers and Google Ventures, three shareholders owning a combined approximate 31 percent of FMI equity, have entered into a support agreement pursuant to which they have each committed to vote in favor of the transaction and to tender at least a majority of their shareholdings in the tender offer.

Upon the closing, FMI's board of directors will be increased to nine directors and will include three designees of Roche, including Daniel O'Day. Four existing independent directors of Foundation Medicine and Michael Pellini, MD, will continue as directors and one new independent director will be added. It is anticipated that Alexis Borisy will remain Chairman. The transaction is expected to close in the second quarter of 2015. (Source: roche.com, 12 January 2015)

Shire's Investigational Drug Receives FDA Fast Track Designation

Shire announced that the FDA has granted Fast Track designation for SHP609 (idursulfase-IT, also known as HGT-2310) for the treatment of neurocognitive decline associated with Hunter syndrome (mucopolysaccharidosis II or MPSII). This investigational formulation of idursulfase has been designed for direct administration into the cerebrospinal fluid via an intrathecal drug delivery device. This formulation is being investigated and developed for use with Shire's approved treatment for Hunter syndrome, Elaprase® (idursulfase) which is administered intravenously and does not cross the blood-brain barrier in clinically relevant amounts.

The FDA's Fast Track program is designed to facilitate the development and expedite the review

of drugs that address serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designation provides increased opportunities to interact and meet with FDA, and increases the likelihood of being eligible for priority review if supported by clinical data at the time of biologics license application.

Shire is currently enrolling patients in its Phase 2/3 pivotal trial (HGT-HIT-094 or AIM-IT), which is a controlled, randomized, open-label, multi-center, assessor-blinded study designed to determine the effect on clinical parameters of neurodevelopmental status of monthly administration of idursulfase IT in pediatric patients with Hunter syndrome and early cognitive impairment who already receive and tolerate therapy with Elaprase. An extension study is also planned to assess long-term safety and efficacy.

Hunter syndrome is a severely debilitating rare disease that affects 1 in 162,000 total live births, and mainly males. Hunter syndrome is an X-linked disorder caused by a deficiency or absence of the lysosomal enzyme iduronate-2-sulfatase (I2S), which leads to severe clinical complications and early mortality. (Source: shire.com, 26 January, 2015)

Alexion Partners with BioXcel in Big Data Project

Connecticut-based BioXcel, a company providing cloud-based pharma big data solutions, announced the initiation of a big data project with Alexion to characterize and prioritize sets of rare disease targets for therapeutic treatment. Alexion will use BioXcel's first-in-class Big Data Innovation Lab. This lab applies recursive mapping and big data algorithms by leveraging its proprietary PharmGPS™ Orphan Disease Suite, Integrated Center of Xcellence housing multidisciplinary teams, and its specialists with experience deciphering rare disease treatments.

BioXcel's proprietary Orphan Disease Suite encompasses more than 9,000 rare & ultra-rare diseases, 4,000-5,000 associated genes, 1,500 disease pathways, and distinct target-indication tiles for antibody, protein, RNA, small molecule and gene therapy treatment. The platform enables partners to make decisions for a rare disease indication and the associated ideal mode of pharmacotherapy with parameters that include strategic, medical, scientific and commercial aspects. The suite enables the discovery, development, and commercialization of orphan drugs based on disease severity, gene ontology, disease pathways, proteinopathy, standard of care, emerging innovation, enabling technologies, and current drug pipeline. (Source: bioxcel.com, 28 January, 2015)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

FDA Approves Anti-Clotting Drug Savaysa

The FDA has approved the anti-clotting drug Savaysa (edoxaban tablets) made by Tokyo-based Daiichi Sankyo to reduce the risk of stroke and dangerous blood clots in patients with atrial fibrillation that is not caused by a heart valve problem. Savaysa also has been approved to treat deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients who have already been treated with an anti-clotting drug administered by injection or infusion for five to ten days.

Savaysa has a Boxed Warning that provides important dosing and safety information for health care professionals about specific patient groups, including a warning that Savaysa is less effective in atrial fibrillation patients with a creatinine clearance greater than 95 milliliters per minute. Savaysa will be dispensed with a patient Medication Guide that provides instructions on its use and drug safety information. (Source: FDA Website, 08 January, 2015)

FDA Approves New Psoriasis Drug Cosentyx from Novartis

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

Cosentyx's active ingredient is secukinumab, an antibody that binds to a protein (interleukin IL-17A) which is involved in inflammation. By binding to IL-17A, secukinumab prevents it from binding to its receptor, and inhibits its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis.

Cosentyx is administered as an injection under the skin. It is intended for patients who are candidates for systemic therapy, phototherapy using ultraviolet light or a combination of both and is being approved with a Medication Guide to inform patients that, because Cosentyx is a medicine that affects the immune system, patients may have a greater risk of getting an infection. (Source: FDA Website, 21 January, 2015)

FDA Approves Natpara from NPS Pharmaceuticals for Patients with Hypoparathyroidism

The FDA has approved Natpara (parathyroid hormone) from NPS Pharmaceuticals to control hypocalcemia (low blood calcium levels) in patients with hypoparathyroidism, a rare disease that affects approximately 60,000 people in the United States.

Hypoparathyroidism occurs when the body secretes abnormally low levels of parathyroid hormone, which helps regulate calcium and phosphorus levels in the body. Hypoparathyroidism

is caused by loss of function of the parathyroid glands and occurs most commonly as a result of surgical removal of the parathyroid glands and more rarely as a result of autoimmune or congenital diseases. Patients with hypoparathyroidism can experience numbness, tingling, muscle twitching, spasms or cramps, abnormal heart rhythm, and seizures as a consequence of low blood calcium levels.

Natpara carries a boxed warning that bone cancer (osteosarcoma) has been observed in rat studies with Natpara. It is unknown whether Natpara causes osteosarcoma in humans, but because of a potential risk of osteosarcoma, Natpara is only recommended for use in patients whose hypocalcemia cannot be controlled on calcium supplementation and active forms of vitamin D, and for whom the potential benefits are considered to outweigh this potential risk. Natpara is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). (Source: FDA Website, 23 January, 2015)

FDA Approves Novartis Vaccine to Prevent Serogroup B Meningococcal Disease

The FDA has approved Bexsero, a vaccine to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age. Bexsero is manufactured by Novartis Vaccines and Diagnostics, based in Cambridge, Massachusetts.

Bexsero is the second vaccine approved by the FDA in the past three months to prevent this disease. The agency approved the first meningococcal serogroup B vaccine in October 2014. Before these approvals, existing approved meningococcal vaccines in the U.S. covered only four of the five main serogroups of *N. meningitidis* bacteria that cause meningococcal disease: A, C, Y and W.

Bexsero was granted breakthrough therapy status, which is intended to expedite the development and review of medical products that address a serious or life-threatening condition. The FDA worked closely with the company during the vaccine's development, and was able to evaluate Bexsero's safety and effectiveness and approve it two months in advance of its priority review goal date. At the time Bexsero was granted breakthrough therapy status, there were no other FDA-approved vaccines available to prevent serogroup B meningococcal disease. (Source: FDA Website, 23 January, 2015)

FDA Permits Marketing of Mobile Medical Apps for Continuous Glucose Monitoring

The FDA has allowed marketing of the first set of mobile medical apps that allow people with diabetes to automatically and securely share data from a continuous glucose monitor (CGM) with other people in real-time using an Apple mobile device such as an iPhone.

The Dexcom Share Direct Secondary Displays system's data-sharing capability allows caregivers to a person with diabetes to monitor that individual's blood sugar levels remotely through a legally marketed device that is available on mobile devices. Devices like the Dexcom Share were previously available through open source efforts, but were not in compliance with regulatory requirements. The Dexcom Share system is the first of its kind to offer a legally marketed solution for real-time remote monitoring of a patient's CGM data.

The Dexcom Share system does not replace real-time continuous glucose monitoring or standard home blood glucose monitoring. It is also not intended to be used by the patient in place of a primary display device. Additionally, CGM values alone are not approved to determine dosing of diabetes medications. CGMs must be calibrated by blood glucose meters, and treatment decisions, such as insulin dosing, should be based on readings from a blood glucose meter.

The Dexcom Share system is manufactured by San Diego based Dexcom, Inc. (Source: FDA Website, 23 January, 2015)

FDA Approves First Generic Version of Pfizer's Nexium

The FDA has approved the first generic version of Nexium (esomeprazole magnesium delayed-release capsules) to treat gastroesophageal reflux disease (GERD) in adults and children ages 1 and older. Esomeprazole is a proton pump inhibitor that reduces the amount of acid in the stomach. Ivax Pharmaceuticals, a subsidiary of Teva Pharmaceuticals USA, has gained approval to market esomeprazole in 20 and 40 milligram capsules. (Source: FDA Website, 26 January, 2015)

FDA Expands Uses of Shire's Vyvanse to Treat Binge-Eating Disorder

The FDA has expanded the approved uses of Vyvanse (lisdexamfetamine dimesylate) to treat binge-eating disorder in adults. The drug is the first FDA-approved medication to treat this condition. Vyvanse was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that are intended to treat a serious disease or condition and may provide a significant improvement over available therapy.

Vyvanse is dispensed with a Medication Guide for patients, which provides important information about the medication's use and risks. The most serious risks include psychiatric problems and heart complications, including sudden death in people who have heart problems or heart defects, and stroke and heart attack in adults. Central nervous system stimulants, like Vyvanse, may cause psychotic or manic symptoms, such as hallucinations, delusional thinking, or mania, even in individuals without a prior history of psychotic illness. Vyvanse is not approved for, or recommended for, weight loss. Its efficacy for weight loss has not been studied.

Vyvanse is marketed by Shire U.S., based in Wayne, Pennsylvania. (Source: FDA Website, 30 January, 2015)

FDA Seeks \$4.9 Billion for FY 2016, a 9 Percent Increase Over FY 2015

The FDA is requesting a budget of \$4.9 billion to protect and promote the public health as part of the President's fiscal year (FY) 2016 budget – a nine percent increase over the enacted budget for FY 2015. The overall request includes \$147.7 million in budget authority for initiatives tied to several key areas, including the management of critical medical products issues.

The FY 2016 budget request reflects the FDA's commitment to fulfill the mandates of groundbreaking legislation passed in recent years, which has given the agency increased regulatory responsibilities. The FDA's scope has also expanded as it regulates an ever-increasing number of food and medical products imported from all over the world.

Highlights of the FDA FY 2016 budget include implementing a new food safety system, improving the safety and quality of medical products and building a more modern FDA. (Source: FDA Website, 02 February, 2015)

FDA Approves Pfizer's Ibrance for Postmenopausal Women with Advanced Breast Cancer

The FDA has granted Pfizer's Ibrance breakthrough therapy designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies. It also received a priority review, which provides for an expedited review of drugs intended to provide a significant improvement in safety or effectiveness in the treatment of a serious condition or meet an unmet medical need. Ibrance is being approved more than two months ahead of the prescription drug user fee goal date of April 13, 2015, the date when the agency was scheduled to complete its review of the application.

Ibrance is being approved under the FDA's accelerated approval program, which allows approval of a drug to treat a serious or life-threatening disease based on clinical data showing the drug has an effect on a surrogate endpoint reasonably likely to predict clinical benefit to patients. This program provides earlier patient access to promising new drugs while the company conducts confirmatory clinical trials. (Source: FDA Website, 03 February, 2015)

FDA Approves Genentech's Lucentis to Treat Diabetic Retinopathy

The FDA has expanded the approved use for Genentech's Lucentis to treat diabetic retinopathy (DR) in patients with diabetic macular edema (DME). Lucentis is administered by a physician as an injection into the eye once a month. It is intended to be used along with appropriate interventions to control blood sugar, blood pressure and cholesterol.

The FDA granted Lucentis for DR with DME breakthrough therapy designation. The FDA can designate a drug a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients with serious or life-threatening conditions. The FDA also reviewed the new use for Lucentis under the agency's priority review program, which provides for an expedited review of drugs that demonstrate the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. (Source: FDA Website, 06 February, 2015)

FDA Approves Esai's Lenvima for Thyroid Cancer

The FDA has granted approval to Lenvima (lenvatinib) to treat patients with progressive, differentiated thyroid cancer (DTC) whose disease progressed despite receiving radioactive iodine therapy (radioactive iodine refractory disease). Lenvima is marketed by Woodcliff Lake, New Jersey-based Eisai Inc.

Lenvima was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that, if approved, would provide significant improvement in safety or effectiveness in the treatment of a serious condition. The drug also received orphan product designation because it is intended to treat a rare disease. Lenvima is being approved approximately two months ahead of the prescription drug user fee goal date when the agency was scheduled to complete its review of the application. (Source: FDA Website, 13 February, 2015)

New Members

Chiamaka M. Aghaizu, Student, Northeastern University

Samuel Allen, Student, University of New Hampshire

Ashley A. Andrews, Student, University of Massachusetts Amherst

Jesse Arsenault, Student, University of Massachusetts -Amherst

Olivia Baffoe, Student, Middlesex Community College

Regina Benson, Senior QA Auditor, Takeda

Khushbu K. Bhatt, Student, Northeastern University

Courtney L. Boldoy, Student, Middlesex Community College

Michael G. Brown, Director of Quality Compliance, Biovia
Ying Cai, Sr. Engineer III, Biogen Idec
Sherrri Carlson, Project Engineer, DPS Engineering
Wei Ting Chang, Student, Northeastern University
Joseph Chartier, Sartorius Stedim
Daoyang Chen, Student, Northeastern University
John P. Coffey, Director of Manufacturing, ImmunoGen
Alexadra Collins, Student, Middlesex Community College
Kim Coughlin, Air Systems Technologies
Sophie Daudenarde, Global Product Manager, EMD Millipore
Pamela M. Decastro, Student, Middlesex Community College
Tiff DeGroot, Student, University of New Hampshire
Nathan Desrochers, Student, University of Massachusetts Amherst
Brooks Dolen, Student, Middlesex Community College
Schuyler Doten, Associate Bioprocess Scientist, Merrimack Pharmaceuticals
Steve Fothergill, Senior Piping Designer, DPS
Madoka Yoshiki Framzen, Student, Middlesex Community College
Kim Fucile, Recruiter, Softworld
Brian M. Glaude, Field Application Specialist, Thermo Fisher Scientific
Alex Gottlieb, Research Associate, Takeda Oncology
Diane Hewitt, Employer Relations and Career Development Specialist, UMass Lowell
Pamela Hinckley, Account Manager, E.G. Lifesciences
Chloe Hintz
Vivekanand Kalaparthi, Graduate Student, Tufts University
Jordie Kamuene, Student, University of Massachusetts
Josephine Ko, Student, Boston University
Sando K. Kollie, Student, Middlesex Community College
YuShuan Lai, MD/PhD Student, UMass Medical School
Yuqian Lang, Engineer, Hyde Engineering +Consulting
Mark Langlois, Associate Director Facilities, Neurotech Pharmaceuticals, Inc
Chanmary Lau, Student, University of Massachusetts
Steve Lavargna, President, Watson-Marlow, Inc
Jeremy Lebowitz, Director, Development, JENSEN HUGHES
John H. Leeds, III, Mechanical Engineer, DPS Engineering
Yajun Lin, Student, Northeastern University
Sharon MacDonald, Business Process Analyst, Shire
Jonathan Mack, Sales and Marketing Associate, The Wilkinson Companies
David Mackey, Student, University of Massachusetts Amherst
Kamila Magalhaes, University of Massachusetts
MaryAnne Maines
Monyrauth Mam, Student, University of Massachusetts Amherst
Sarvani Manne, Student, University of Massachusetts, Lowell
David Mason, Validation Engineer, DPS
John Maturo, Commissioning and Qualification Professional, Sanofi Pasteur Biologics, LLC
John P. McMullen, Northeastern Regional Sales Manager, Kinetic Systems Inc.
Garrett C. Miner, Student, Middlesex Community College
Farris Nabulsi, Northeastern University
Christopher Nesman, Facilities Manager, EMD Serono
Cory J. O'Brien, Student, University of Massachusetts, Lowell
Erica O'Callaghan

Carla Oliva, Associate Director, Clinical Supplies Planning and Forecasting, Shire Pharmaceuticals

Kristina Papa, Bioreactor Process Engineer, ImmunoGen, Inc

Guy Parenti

Bethany S. Parker, Student, University of New Hampshire

Juhi Patel, Student, Middlesex Community College

Chris Patterson, Principal, CPM Facilities Services

Saqib Peerzade, Student, University of Western Australia

Ryan D. Pepi, Student, University of Massachusetts Amherst

James M. Phelan, PE, Project Manager, ExxonMobil Research & Engineering

Stephen Piela, Global Product Manager, EMD Millipore

Eva M. Price, New England Lab

Jessica Proulx, Associate Product Manager, EMD Millipore

Vivek Puthzath, Principal Engineer, E-Volve Systems

Dr. Kamal A. Rashid, Ph.D., Director, Biomanufacturing Education and Training Center at WPI

Jessica A. Reilly, Sales Representative, Sartorius-Stedim Biotech

Robert F. Robbins, Electrical Engineer, DPS

Jonathan Karl Romero, Associate Director Global Eng, Biogen Idec

Hannan Saeed, CCRl

Satyajeet Salvi, Hampshire College

Dr. Ashish Sarode, Post Doctoral Fellow, University of Rhode Island

Jianyu Shang, Northeastern University

Bo Shao, Student, Northeastern University

Kraig Strong, Packaging Engineer III, Biogen Idec

Juan D. Suriel-Montero, Student, UMASS Amherst

Dr. Karen Sutherland, Director, Pfizer

Hussein Syed, Validation Consultant, Valsource Inc

Yuji Takeda, Student, Tufts University

Elizabeth Townsley, Student, UMMS

David Ventola, Director Business Development - EP, B&W MEGTEC

Katherine Viveiros, Student, University of Rhode Island

Avi Vyas, Manager Development and Validation,

Ian M. Wallis, President, Ian Wallis & Associates

Bethany M. Walls, Regulatory Affairs Specialist, EMD Millipore

Michael S. Walsh, Vice President, Columbia Construction Co

Fernanda White, Student, Middlesex Community College

Andrew G. Wolek, Supply Chain Lead, Pfizer

Takahiro Yamazaki, Student, Yokohama National University

Member Anniversaries

20+ Years of Membership

Thomas W. Moss, Applied Process Solutions, Inc.

Mostafa N. Elmorsi, Boehringer Ingelheim Pharma

Abel A. Erdman, Bristol-Myers Squibb Co

Stephen R. Higham, PE, Genzyme Corp

Armen J. Nahabedian, Pfizer

Michael G. Sprague, Ethide Laboratories

Michael B. Cronin, Alexion Pharmaceuticals

Michael S. Cheney, Biogen Idec

Richard V. Levy, PhD, PDA

Donald M. Haiges, PE, WSP

Robert M. Luke, Georg Fischer Inc

Randolph A. Cotter, Sr., Cotter Brothers Corporation

Robert W. Juffras, MS, Epirus Biopharmaceuticals

Frank J. Manning, VNE Corp

Christopher R. Perley, Dyax

Jerome E. Justin, Shire Pharmaceuticals

Donald Cole, Hart Passivation Services, Inc.

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

Greta W. Davis, Lantheus Medical Imaging

John H. Evers, Lantheus Medical Imaging

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

Frederick C. DeCicco, Sharpe Mixers

Pasquale M. Sacco, Shire HGT

Pauline Jurasinski, Genzyme a Sanofi Company

Richard D. Priestler, Strategic Facility Planning LLC

Mitchell I. Hollander, Lantheus Medical Imaging

Thomas A. Ramundo, New England Controls Inc

Thomas C. Ransohoff, BioProcess Technical Consultants Inc

Brian P. Druce, Genzyme

Daniel J. Mariani, M+W Group

James L. Whalen, Watson-Marlow Flexicon

John P. Alleruzzo

Robert J. Sheehan

Saboo Aghababayan, Genzyme Corp

Richard F. Caires, Jr., Shire HGT

Dr. Charles L. Cooney, Massachusetts Institute of Technology

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

David G. Harney, Microfluidics

John J. Rozembersky, Rozembersky Group

Gregory M. Ruklic, Independent

Jack N. Wentz, Lantheus

Gary V. Zocolante, Evoqua Water Technologies LLC (formerly Siemens Water Technologies Corp)

Peter Mosgrove, Mettler-Toledo Thornton Inc

Russell B. Parry

Stanley E. Rotkiewicz, Jr., Genzyme Corporation

David A. Wilson, Abbott Bioresearch Center

Shelly Henderson, HCA

Tom J. Routliffe, Medimmune

Stephen R. Potter, Baxter

Lawrence W. Weiner, Biogen Idec

Richard P. Capobianco,

Richard R. Harper, Flow Tech Inc

Dr. John J. Prior, Genzyme Corp

David A. Rielly, CEM, LEED GA, Novartis Pharmaceuticals

Daniel J. Dumont, Dynamic Systems Inc

William C. Lynch

James D. Vogel, PE, The BioProcess Institute

Stephen P. Kuzil

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

Tim J. Potvin, PE, Quality Air Control
Stephen P. Miraglia, Sapphire Project Services LLC
Michael J. Sweeney, Hart Design Group
Stephen P. Rossmeisl, Albany Molecular Research, Inc
Fred H. Arbogast, Critical Process Filtration Inc.
Denis M. Mathiowetz, DM BioPharm Associates Inc.
William S. Seaver, TEK Stainless Piping Products
Paul E. Rowe
Jeffrey L. Werner
Ric Feldt, Jeff Smith & Associates
David A. Tomsik, CRB
Dr. Donald L. Towns, Donald L Towns Professional Engineer
James R. Dube, Alexion Pharmaceuticals
Thomas G. Larkin, Amgen Inc
John G. Campion, P.E., The Hart Companies
George A. Dainis, P.E., Industrial Facilities Design Inc
Frank J. Kuszpa, Jr., Jones Lang LaSalle
Lynda S. Miller, Lonza Biologicals
Brian L. Clark, GMP Operations Consulting
Andrew A. Coull, JM Coull Inc
Christopher J. Fournier, Mar Cor Purification
Michael S. Giorgetti, Sr., Alkermes Inc
Todd McLaren
Douglas A. Queen, TRG Builders LLC
Scott Ripatrazzone, Insco Group
Peter K. Silverberg, Abec, Inc.
Ronald C. Case, Aztec Technologies, Inc.
Edward F. Dean, III, Eagle Electrical Supply Co
David Dears, Victaulic
Andrew R. Hahn
Peter A. Petrillo, Millennium Facilities Resources Inc
Jay F. Zaino, GxP Automation LLC
Paul F. Herbert, Alkermes Inc
Thomas H. Lauzon, Synageva BioPharma
Simon Bedigian, Olympic Systems Corp
Michael J. Fisher, Genzyme, Sanofi
Joshua Froimson, AbbVie Bioresearch Center
David Monette, Novo Nordisk
Dr. James V. Blackwell, PhD, MBA, The Windshire Group, LLC
Nicholas J. Casale, Biogen Idec
Joseph M. Baumann, Genzyme Corp
Timothy J. Fields, Protein Sciences Corporation
Allan J. MacDonald, CPIP, BosBio
Johnson Hoey, Forest Laboratories, Inc.
Robert T. Clark, Perrigo Company PLC
Michael J. James, Northeast Water Services
Amy Foley, The Richmond Group Inc
William Sayles, TRG Builders LLC
Michael L. Anderson, Total Facility Solutions, Inc
Kenneth A. Bradley, Pfizer Inc

Daniel J. Pratt, Pharamlucence Inc

Glenn J. Martin, MG America

Richard D. Quinby, Biogen Idec

15 Year Anniversary

Paul J. Adams, Putney, Inc.

Matthew J. Camelio, Sanofi Pasteur Biologics Co

Michael D. Coyle, AstraZeneca

Vincent R. Kosewski, Sunovion Pharmaceuticals Inc

Carolyn W. Lee-Parsons, Northeastern University

Lila F. Li, Shire

Howard G. Sneider, CPIP, CRB

John T. Zurheide, Jr., Genzyme Corp

10 Year Anniversary

Jennifer Daquioag, SNC Lavalin

Theodore C. Donahue, Jr., Organogenesis Inc

Steven Lacerte, AstraZeneca Pharmaceuticals, LP

Andrew S. Mutz, Casella Process Solutions

James T. Rutigliano, Forest Laboratories Inc

Dr. Keith H. Wells, Biologics Consulting Group

5 Year Anniversary

Dana Alexander, Genzyme

Lee S. Donohue, Genzyme Corporation

Dr. Juergen Hahn, Levitronix Technologies LLC

Osvaldo Rentas, MannKind Corporation

Terry J. Seanard, Jr., CPIP, New England Controls, Inc.

Andrew Ye, Boehringer Ingelheim Pharma

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