Connecting a World of Pharmaceutical Knowledge
Boston Area Chapter
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NEWSLETTER
May 2015, Volume XXV, No. 3

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President's Message: Spring into a New Season of Activities with the Boston Area Chapter...

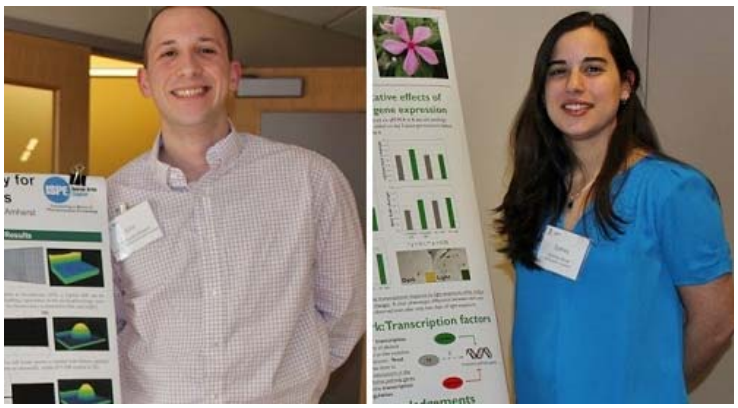
Dear Boston Area Chapter Members,

Happy spring everyone! In a few short weeks the region went from being buried under 100 inches of snow to 60° F temperatures. We went from "celebrating" breaking the all-time snow record to welcoming the boys of summer back to Fenway Park for their first home game. It's amazing how quickly things change in New England!

Here is a recap of the great events the Chapter held in the last few months. The annual ski outing was held at Waterville Valley in New Hampshire on March 6. The day started with a broken down bus but ended with a great after-ski party. Mixed in during the day were blue skies, sun, warm weather and awesome snow. Probably one of the best New England ski days in memory!

On March 19, Edmund Mrak, Drug Specialist, New England District of Food and Drug Administration and member of FDA's Pharmaceutical Inspectorate and Xach Kibbie, Senior Risk Program Manager, Quality Risk Management Department, Shire discussed how risk approaches integrate across different quality systems, in combination with a tour of Shire's state-of-the-art cell culture operations.

On April 16, the Chapter held its annual Student Poster Contest at WPI prior to the April educational program, giving competitors a chance to display their work for attendees. The winning undergrad and grad winners received 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 ISPE's Pharmaceutical Engineering magazine, as well as other Chapter/Affiliate publications. Congratulations to this year's winners:



Congratulations to Poster Competition winners undergraduate D. Ezra Aurian-Blajeni (l) from UMass Amherst and grad student Sydney Shaw (r) from Northeastern.

April's educational program was a dual-track consisting of two presentations. The intro level "Downstream Processing Techniques and Single Use Applications," was presented by Stuart Green, VP of Process Engineering for Pall Corporation's Life Science Division of North America who provided an excellent overview of the topic. The more advanced "Integrated Continuous Downstream Processing - An Enabling Approach that will Break the Bottleneck" was delivered by Dr. Kathleen Mihlbachler, Global Director of Separations Development, LEWA Process Technologies for attendees already familiar with the basics. Both presentations were well attended with a total of over 70 in attendance.

The Chapter is holding a lot of great events in the next few months and I encourage Members to take part in at least one of them. First is the annual Boston Area Chapter brainstorming session on April 29, the first step in choosing the topics for the educational programs for 2016. This is a great opportunity to help the Chapter plan programs of interest to you and your peers for the upcoming year so 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. The brainstorming session will be held at the BETC facility at WPI's Gateway Park in Worcester.

The following day, on April 30, the Young Professionals will be holding their annual Pizza, Networking and Bowling event at The Flatbread Company in Davis Square, Somerville followed by candlepin bowling at the famous Sacco's Bowl Haven. The event is planned by the YPs but is open to all "young at heart" professionals.

Next on the calendar for the busy spring season is the first of our two annual golf outings, held at the Ledgemont Country Club in Seekonk on Monday, May 11. Join other industry professionals for a casual round of golf at this great course south of Boston near the Rhode Island border. Foursomes and sponsorships are still available for this event. Don't have a foursome? Individual Members wishing to play are encouraged to register and join the fun.

The May 21 educational program will be held at Biogen's corporate headquarters in Weston where a panel of five industry professionals will conduct a series of round table discussions on better ways to deliver fast-track projects. Panelists will share their experiences and offer solid insights and recommendations for producing successful fast-track projects. Due to technical limitations at the meeting site, this event will not be simulcast. Instead, the Chapter will re-broadcast the event in its entirety at the Crowne Plaza Providence in Warwick, RI and the WPI BETC at Gateway Park in Worcester on May 28. Both locations will feature networking receptions including appetizers prior to the videotaped presentations. So plan to join us in Weston on May 21, or in Warwick or Worcester a week later, for this unique event.

So while you're enjoying this pleasant spring with its great weather, plan to add one or two of these important Chapter events to your agenda. I promise, you won't be disappointed!

Sincerely,

Christopher Opolski
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Chapter Bulletin Board

Need Help with the High Cost of Education? Apply Today for a Chapter Scholarship!

The Boston Area Chapter is once again proud to offer a merit-based scholarship program for the benefit of Chapter Members and their families. Individual awards of up to $2,000 are available for qualified applicants continuing their formal education in the life sciences, with preference given to applicants planning careers in the biotech, pharmaceutical or related industries and endeavors. To date, the Chapter has awarded 50 scholarships totaling almost $70,000!

And for the first time, beginning with the June 1 deadline, applications are completely electronic - no more paper forms to fill out! To be eligible for an award, scholarship applicants must complete the online application providing information about their academic program, extra-curricular activities, volunteer involvement with ISPE (their own or that of a parent in the case of entering freshmen) and future career plans. In addition, one written reference is required, also submitted electronically.

Who is eligible? Members in good standing of the ISPE Boston Area Chapter are eligible to apply (as are incoming freshman who are not Chapter Members, as described in the first bullet below). Eligible applicants must be enrolled in an associate's, bachelor's or master's degree program at an accredited college or university; and/or be registered in a course at an accredited college or university. Three categories of awards are available:

- **Incoming freshmen** - children of Members in good standing of the Boston Area Chapter pursuing a career in the life sciences.
- **Undergrad and grad students** - students entering their sophomore through senior years of undergraduate study or those students entering or continuing with post-graduate study; these candidates shall be Members in good standing of the Boston Area Chapter pursuing an advanced degree in a life sciences field.
- **Continuing education** - Members in good standing of the Boston Area Chapter seeking continuing education as part of their career development.

The Scholarship Program honors Joel Goldenberg, a Past President of the Boston Area Chapter, whose wish was to support the educational pursuits of ISPE Members and their families. The program is funded by proceeds from numerous Chapter fundraising activities and is designed to supplement and/or defray tuition expenses.

The scholarship application must be completed online. Visit the Chapter website at www.ISPEBoston.org/Scholarship to view detailed information and complete your online application. If you have any additional questions call the Chapter office at (781) 647-4773 or email office@ispeboston.org.

ISPE and PDA Plan a Joint Educational Program - Another First for the Chapter!

by Brian Hagopian, Clear Water Consulting, Inc.

Well, your Boston Area Chapter is involved in yet another first! The Chapter has been trying (for a couple of years now) to collaborate on an event with the New England Chapter of the Parenteral Drug Association (NEPDA). We thought it made sense because we have a lot of overlap in membership as well as technical focus. Originally, we thought that a social event would be the best starting point but once we started talking, things got serious, and we decided it made more sense to collaborate on a technical educational program. So, the Chapter is pleased and proud to

announce that we will be collaborating with NEPDA on an educational program this coming September.

Mark your calendars for September 16 and be sure to attend this landmark collaborative educational program co-sponsored, co-managed, and co-produced by the Boston Chapter of ISPE and the New England Chapter of PDA with a focus on life cycle approaches to process validation. Both groups are already working diligently, sharing best practices and blending the best each society has to offer into a one-of-a-kind event that is not to be missed. We'll keep you posted as details fall into place but, in the meantime, plan to join us on September 16 for a blockbuster event!

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 has created a new website resource containing all the information you need to know to become a Chapter Sponsor.

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

So don't delay, visit www.ISPEBoston.org/sponsorship 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, May 21, 2015

ISPE: A Better Way to Deliver Fast Track Projects

Biogen, Weston, MA

PROGRAM SUMMARY

In today's competitive marketplace, speed to market is more critical than ever for ensuring the successful launch of new drug products. In response, fast-tracking the development of retrofit or greenfield facilities —from concept through commissioning—has increasingly become the norm. These projects require particularly close collaboration between all project contributors, relentless adherence to schedule, and constant communication. So what is the best way to deliver a fast track project? We held a series of round table discussions with industry experts each representing key stakeholders in the process. They will share their experiences and offer solid insight and recommendations for producing a successful fast-track project. Come and hear our panel members reveal their formula for success…the results might surprise you.

STAKEHOLDER PANELISTS
Owner: Richard Quinby, LEED AP, Associate Director, Global Project Engineering, Biogen
Procurement: Tony Mejido, North America Capex Procurement Director, Sanofi
Construction Manager: S. James Busam, Vice President, National Client Team, Gilbane Building Company
Designer: Cory Siddons, Senior Project Manager, DPS
C&Q: Eric Felz, Associate Director of Validation, Shire

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=474

Thursday, May 28, 2015

ISPE RE-SHOWING: A Better Way to Deliver Fast Track Projects

Crowne Plaza Hotel Providence - Warwick, RI

EVENT INFORMATION

Attend a re-showing at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs will both feature a networking reception including appetizers.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=559

Previous Issues

Sneak Preview of Upcoming Events

Thursday, June 18, 2015
ISPE Tech Transfer: How to Manage Your Relationship with a CMO
Genzyme Center, Cambridge, MA

Monday, August 17, 2015
ISPE Summer Golf Tournament
Kernwood Country Club, Salem MA

Product Show Preview

Exhibitors – Don't Delay! Register Today for This Year's Product Show!

by Mark Levanites, Chair, Product Show Committee

Exhibitor registration is now open for the 24th edition of the ISPE Boston Area Chapter Product Show to be held at Gillette Stadium on October 7. To register and select your booth or table, go to http://www.ispeboston.org/ProductShow and click on Registration. Vendor booths and tables are selling at a record setting pace so don't miss out on this incredible event and the ability to select the best location for your booth.

Along with registration, now is the time to lock up one of our many advertising and sponsorship opportunities. No matter what your budget there is an advertising or sponsorship opportunity for your company, from sponsoring the exciting after-party to being a trend setter and advertising your company logo on our mobile app. These are also selling fast so don't delay. For a full list of remaining advertising and sponsorship opportunities, go towww.ISPEboston.org/ProductShow/FAQ .

Planning by the Product Show Committee is on schedule and this year's Show is shaping up to be our best ever. We can share with you news on some of the latest developments:

Educational Sessions…
We are very excited to release our educational sessions for 2015. This year's sessions will include:

- "Facility Optimization & Process Improvement,"
- "Oral Solid Dosage Forms – ISPE Baseline Guide,"
- "Future Trends" panel discussion, and
- "Biotech 201: Intro to Single Use Technologies."

You spoke and we listened. This year you won't have to choose between two compelling sessions held concurrently. And you won't have to try and squeeze into a standing- room-only space. The educational sessions will be held sequentially in the same spacious area as the plenary session, so you can attend them all and there will be plenty of room for everyone!

Keynote Speaker…
Speaking of the plenary session, we are excited to announce that John Bournas, ISPE President and CEO, has graciously accepted our invitation to be one of our keynote speakers. We are looking forward to hearing his insights on where our industry and ISPE are headed in the future. This will be a great opportunity for those not attending the ISPE Annual Meeting the following month to hear John's plans for the future of our organization. John will be accompanied by members of his leadership team to see for themselves why our Product Show is the best.

Career Fair…
This year, as a benefit to our membership, we are offering tables in the Career Fair area free to companies that are hiring. We are hoping to have all the operating companies that have manufacturing operations in the region present as well as the larger service providers. If your firm is interested in participating in the Career Fair this year, please contact Alex McKinnon at alex.mckinnon@rcmt.com for details. We already have eight companies signed up, so hurry before all the spots are taken!

Product Show Mobile App…
Be sure to download the free app to your phone from the Google Play Store or the Apple App Store. There no longer will be a hard copy Show Guide as we have moved to a completely electronic format. With everything going on at the Show, you'll need it - if only to find out where and when you can get those sliders or ice cream bars!

Exhibitor Enhancements…
You asked and this year we will be offering a lead retrieval system. We are working through the details, so check this space in the next newsletter for details. We are also going Hollywood on our exhibitor training program. We are in pre-production, but the film will be ready this summer to help you get the most out of the Show!

Next newsletter we should have more information on some special guests and a charity event as well as our plans for the after party. We're also working on a special program for our Student Members and a pre-registration raffle that every Patriots fan will want to participate in.

The ISPE Boston Area Chapter is pleased that this event continues to be offered free-of-charge, supported in full by our generous exhibitors. This includes free parking, free admission, free food, free soft drinks, free educational seminars and free networking.

If your company hasn't exhibited in the past, please let us welcome you this year! To those loyal ISPE Members who have exhibited year after year, thank you. You're the backbone of this organization. You built the foundation for this event's success over the past twenty-four years and we thank you for your contribution!

If you want to be part of this great team, let us know. We are always looking for enthusiastic people to join our Product Show Committee to deliver what is undeniably the best show of its kind. Remember, register today and we'll see you on October 7!

Newsletter Archive

Ski Outing Succeeds Despite Rocky Start

by Jim Grunwald, Commissioning Agents Inc, and Peter Fox, T&M Associates

The Boston Area Chapter celebrated its 15th Annual Ski Outing on March 6 with a trip to Waterville Valley where the skiing, riding and banquet were enjoyed by 65 attendees. The conditions were perfect for a great day on the mountain and the banquet was a fantastic networking event as well.

The group proved their resilience upon learning at the last minute that the bus had broken down and would not be available for the trip to Waterville! Within short order we made contingency plans and a number of people volunteered to drive to the mountain. The Chapter would like to thank all of the individuals who offered rides - you all really saved the day!

We look forward to the continued success of the Ski Outing and all of the Chapter's social events, which we could not execute without the support of our many great sponsoring companies. We would like to acknowledge and thank our many sponsors for their support of the Ski Outing:

- A/Z Corporation
- Bard, Rao + Athanas Consulting Engineers
- Commissioning Agents
- GxP Automation
- Perkins + Will
- Superior Controls
- T&M Associates
- Ultrafiltronics

We hope you can join us for our next event, the Spring Golf Outing on May 11 at Ledgemont Country Club in Seekonk, MA. We look forward to seeing you there!

FDA and Industry Speakers Discuss Risk Assessment at March Educational Program

by Eric Felz, Shire, with photos by Joyce Chiu, Honeywell Safety Products

The Boston Area Chapter educational program entitled "Risky Business: How Quality Systems and Risk Blend" was held on Thursday, March 19 at Shire's 200 Shire Way facility in Lexington. The event started with tour guides shepherding small groups through the chilly winter weather to the 400 Shire Way facility. Once at their destination, attendees were guided through Shire's state-of-the-art facility where disposable bioreactors are used for cell culture operations. The tours took the better part of an hour and gave attendees a chance to ask questions about the facility and the processes taking place there. The tour guides proved to be great ambassadors for the facility, describing the operations and the disposable technology housed there with knowledge and enthusiasm.

The topic of risk assessment and top-quality speakers combined to create a packed house for the March educational program.

While one group toured, the other group mingled and met at the networking reception held at 200 Shire Way adjacent to Fortis Hall where the program would be held. This was an opportunity for attendees to talk with the speaker outside of the confines of a regulatory inspection. Following the reception, the evening began with opening remarks by Chapter President Chris Opolski and Program Manager Eric Felz who introduced the evening's first speaker, Edmund Mrak, Drug Specialist, New England District of Food and Drug Administration and member of FDA's Pharmaceutical Inspectorate.

Ed built an enlightening talk around risk assessments and how they fit into the overall quality structure. He was able to keep a heavy subject light and a large and diverse audience fully engaged. His ability to weave together his own stories about his inspections and some of his own touch points with quotations from regulations allowed the audience to better understand how risk fits into the overall quality systems. There was a strong back and forth interaction between Ed and the audience. He seemed as interested in hearing questions from industry as we were in hearing what he had to say on the subject.

FDA Inspector Edmund Mrak (center) chatted with attendees prior to his presentation.

At the conclusion of Ed's presentation, Shire's Xach Kibbie, Senior Risk Program Manager, Quality Risk Management Department, joined Ed on stage to give the industry's perspective on the use of risk assessments and risk tools. This point and counterpoint created a strong perspective on when and how to use these assessments to maintain compliance and allowed the audience to walk away with a strong understanding of risk management concepts. Overall audience feedback was positive with many saying the event hit the correct tone and was both informative and interactive.

As always, food, drink and conversation were a perfect match at the networking reception.

The Boston Area Chapter and Program Managers Eric Felz, Mike Foshey, and Nagmeh Salimi would like to thank panelists Edmund Mrak and Xach Kibbie for their uniquely valuable insights, the tour guides for their knowledge and enthusiasm and Shire for providing a comfortable venue for the event and inviting us into their manufacturing facility. And last but not least, RCM Technologies for their generous sponsorship of this event.

April Educational Program Features Student Poster Competition

by Dan Mardirosian, Worcester Polytechnic Institute, and Christopher Ciampa, Thermo Fisher Scientific, with photos by Joyce Chiu, Honeywell Safety Products, and Karima Erriahi, UMass Lowell

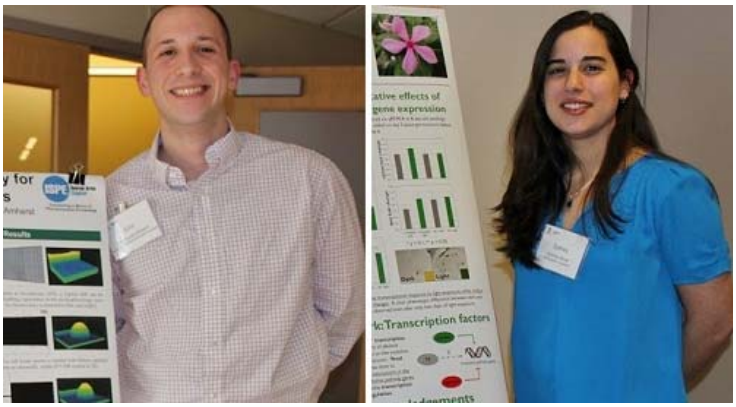
"Downstream Processing, How It's Done and How To Do It Faster & Better" was held on Thursday, April 16 at Worcester Polytechnic Institute's Gateway Park in Worcester. This was a dual-track program featuring both introductory and advanced presentations on the topic of downstream processing. In addition, the 2015 Student Poster Competition was held during the networking reception with the winners announced prior to the presentations.

Dual track educational programs offer something for everyone: students, young professionals and industry veterans.

The turnout was a healthy 70-plus, with two-thirds of the attendees choosing the introductory track at the Biomanufacturing Education & training Center (BETC) and the rest visiting the Life Science and Bioengineering Center (LSBC) next door for the advanced track. The advanced track was recorded by the Chapter for future presentation at the Crowne Plaza Hotel in Warwick, RI for Members from areas to the south, while the introductory track was recorded by WPI using their Echo system. If the latter recording can be edited and uploaded, this track will also be available for future use by the Chapter.

The networking reception, featuring a delicious pasta and salad bar, was well attended and provided an opportunity for viewing the posters and discussing them with the students who also made individual presentations before a panel of judges tasked with determining the winners. Tours of the BETC were also available. Opened in 2013, the BETC is a 10,000 sq.ft. facility outfitted with bench to pilot scale biomanufacturing equipment. It is dedicated to providing corporate and professional educational programs that respond to the needs of the biomanufacturing industry's workforce development efforts.

Following the networking reception, the evening began with opening remarks by Chapter President Chris Opolski and Program Manager Dan Mardirosian. Chapter Past President Brian Hagopian then announced the winners of the Student Poster Competition. Congratulations to graduate winner Sydney Shaw from Northeastern University and undergraduate winner D. Ezra Aurian-Blajeni from UMass Amherst. Both winners received $500 awards and will be travelling to the ISPE Annual Meeting in November at the Chapter's expense to compete at the international level.



Congratulations to Poster Competition winners undergraduate D. Ezra Aurian-Blajeni (l) from UMass Amherst and grad student Sydney Shaw (r) from Northeastern.

Following the announcements, the group separated and attended their session of choice. The advanced session was presented by Dr. Kathleen Mihlbachler, Global Director of Separations Development, LEWA Process Technologies. The downstream process (DSP) has become the "bottleneck" in the manufacturing of bio-pharmaceuticals, especially monoclonal antibodies. Dr. Mihlbachler's talk, "Integrated Continuous Downstream Processing - An Enabling Approach that will Break the Bottleneck," was designed for seasoned professionals interested in the newest DSP technologies with which to address the ever-increasing production and efficiency of the upstream process.

Different integrated downstream processes and/or multi-column continuous chromatographic technologies have been investigated that showed promising results in reducing manufacturing costs. However, until today there has not been a reported case at the production scale. Dr. Milbachler discussed the utility of continuous chromatography and discussed in detail simulated moving bed (SMB) technology and multi-column continuous purification (MCC). She also

discussed the remaining barriers to implementation and how to overcome them in the GMP environment. The presentation was very interesting and sparked a number of questions.

WPI's Dan Mardirosian introduced Dr. Kathleen Mihlbachler whose presentation was designed for seasoned professionals interested in the latest DSP technologies.

Meanwhile, Kamal Rashid, Ph.D, Director of the BETC, introduced Stuart Green, VP of Process Engineering for Pall Corporation's Life Science Division of North America. Stuart's presentation, "Downstream Processing Techniques and Single Use Applications," introduced the unit operations typically carried out to purify a cell culture product. Participants gained an understanding of what the contaminants are and how they can be removed - the first step in understanding how the downstream process should be designed – and how virus inactivation and removal, chromatography and UF/DF are achieved and best arranged in a process.

He also described the evolution of the technology: in the 1990s, plants were running the process using stainless steel and the process took about a week from start to completion. Today, the technology has changed to disposable single use and the process time is half a week! In addition, the merits of single use options for downstream processing were discussed. The questions were numerous with the best one regarding pain points in the downstream process. According to the presenter, proper cleaning is the biggest concern. If there are contaminants in the process, it could cost the plant millions in lost product!

Attendees at the introductory presentation were treated to a surprise tour of the Biomanufacturing Education & Training Center led by BETC Director Dr. Kamal Rashid.

In summary, a great deal of information was shared dfuring the evening by two highly knowledgeable presenters with many years of industry experience. A number of questions and comments from the audience followed to fill in the few gaps that remained. The evening's program, as a whole, was a success, delivering quality information on a topic of significant interest and relevance to Chapter members. The Student Poster Competition was the icing on the cake! Congratulations again to the winners!

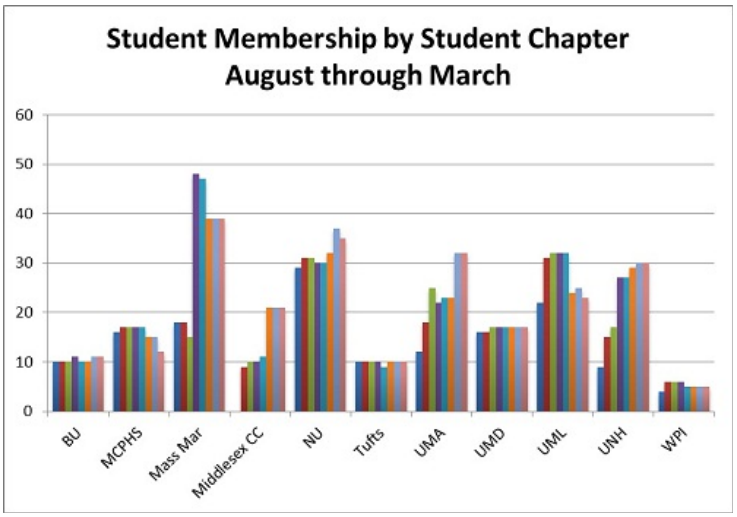
The Boston Area Chapter and Program Managers Dan Mardirosian and Chris Ciampa would like to thank the presenters, organizers and audience members for their valuable contributions to this program and to WPI for providing the venue and support staff for the event. Great Job!

Student Development Update

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

Student Chapters Just Keep Growing!

The Boston Area Chapter continues its blitz on university campuses again this year, reaching a new high of 11 Student Chapters with a few more in the process of forming. We've also reached new highs in student membership with over 270 Student Members, the most student members of any ISPE Chapter! The graph below provides a breakdown of student membership by Student Chapter from August 2014 through March 2015.



There was a major increase in student membership at Mass Maritime Academy immediately following the October Product Show. Student membership has increased consistently at Northeastern, University of New Hampshire, UMass Amherst, and Middlesex Community College throughout the school year, which is a testament to the strong efforts of students and faculty on these campuses.

Student Poster Competition a Huge Success!

This year's Student Poster Competition was held on April 16 at WPI's BETC concurrently with the Chapter's April dual-track educational program. We had a record number of entries this year in the undergraduate and graduate categories. Coupling the Poster Competition with the educational program gave students the opportunity to interact with the many industry professionals who attended the program – a definite plus for both contestants and attendees. The competition was stiff and the graduate category was a "dogfight" but the Chapter is proud to announce the following winners:

- D. Ezra Aurian-Blajeni, UMass Amherst: "Droplet-Interface Bilayers: An Emerging Technology for Screening Human Ion Channel-Drug Interactions" (undergraduate category)
- Graduate: Sydney Shaw, Northeastern: "The Effect of Light, Jasmonate and Tissue Organization on the Expression of Vindoline Greens in *Catharanthus Roseus*" (graduate category)

Each winner receives a $500 cash prize and an expense-paid trip to compete in the International Poster Contest at ISPE's Annual Meeting in Philadelphia in November. Congratulations Sydney and Ezra!

Scholarship Application Deadline June 1

The Boston Area Chapter awards up to $25,000 in scholarships annually to qualifying ISPE Members. The Chapter has a track record of awarding scholarships to about 50 percent of applicants - where else can you find such a high chance for success? Beginning with this round, applications and written references are completed online – no more paper! So be sure to visit the Chapter website at www.ISPEBoston.org/scholarships/ and complete your application by June 1.

Life Sciences Panel Discussion at UMass Lowell

This exciting program attracted over 50 students interested in the life sciences industry. Panelists spoke of the importance of networks and Chapter Members had the chance to share information about ISPE with a number of interested students. Northeastern's Graduate Women in Science and Engineering held a resume review session attended by Suzanne Stuhler and Brian Hagopian, who advised students on building a strong resume as they prepare to enter the job market.

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

Industry News In Brief, a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to our readers.

Rxi Drug Secures Orphan Status from FDA

A drug being developed by RXi Pharmaceuticals of Marlborough to treat patients with malignant melanoma has secured orphan drug status from the FDA, allowing RXi to seek more incentives to bring it to market, the company has announced. The drug, Samcyprone, is being developed to help prevent the skin-level spread of melanoma.

The designation qualified RXi for several incentives, including seven years of market exclusivity after the drug's approval, tax credits for clinical research costs and reductions in application fees, RXi said in a statement. The orphan designation is reserved for drugs that are used to treat rare diseases or conditions, and whose development costs might not be adequately recovered through sales. (Source: Worcester Business Journal, 17 April, 2015)

Padlock Therapeutics Initiates Collaborations with NIH, UMass Medical and Scripps

Padlock Therapeutics, a private Cambridge-based biotech, announced that the company has entered into agreements with three research partners. The company will collaborate with experts in the field of protein-arginine deiminase (PAD) enzymes and their role in disease biology at the National Institutes of Health (NIH), University of Massachusetts Medical School, and The Scripps Research Institute (TSRI). Padlock will work with investigators at these institutions to determine the role of individual PAD enzymes in certain animal disease models and to evaluate the activity of its proprietary PAD inhibitors in enzymatic assays, animal models, and human cellular systems. Padlock is developing treatments for autoimmune disease, building on its knowledge of inhibition of PAD enzymes and their role in initiating and perpetuating autoimmune diseases. These collaborations will assist Padlock in building its biology infrastructure to support the company's existing work in chemistry. Padlock was founded by scientists at The Scripps Research Institute in conjunction with Atlas Venture.

Padlock's founding hypothesis is that autoantigens drive the initiation and development of autoimmunity by perpetuating, maturing, and intensifying a destructive autoimmune attack on healthy tissue. Autoantigens also drive the formation and deposition of immune complexes, which account for much of the morbidity and mortality in patients with autoimmune disease. In patients where the source of autoantigen is known, extinguishing autoantigen production offers the potential to impact disease progression and intensity without affecting systemic immunity.

The protein-arginine deiminases (PADs) are a family of enzymes that modify side chains on proteins and, in some patients, produce the autoantigens that drive disease. Inhibiting PADs in these patients may provide an approach to treating patients who suffer from rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, and other destructive autoimmune diseases. (Source: Padlock Therapeutics Website, 08 April, 2015)

CRISPR Therapeutics to Establish R&D Operations in Cambridge

CRISPR Therapeutics, a biopharmaceutical company focused on translating CRISPR-Cas9 gene-editing technology into transformative medicines for serious human diseases, announced the appointment of Bill Lundberg, M.D., to Chief Scientific Officer to lead the company's development programs and to spearhead the creation of its R&D operations in Cambridge. The Cambridge facility will house R&D operations and business development.

CRISPR Therapeutics was launched out of the Basel-based Versant Ventures offices in 2013 and has undertaken translational development programs in multiple disease areas with collaborators in Europe and the U.S. (Source: CRISPR Therapeutics Website, 07 April, 2015)

Vertex, Biogen and Alnylam on the Move

Vertex Pharmaceuticals has terminated leases on three properties in Cambridge, effective 28 February, 2015. The properties include two laboratory and office properties at 200 Sydney and 40 Erie covering 293,000 square feet, both leased by Vertex through December 2015, and an additional 21,000 square feet at 21 Erie leased by Vertex through May 2017. The space should be available beginning in September 2015 after BioMed Realty updates the properties.

Biogen has agreed to a new ten-year lease for approximately 80,000 square feet of Class A laboratory and office space on the fifth floor of BioMed Realty's 301 Binney Street property in Cambridge. Biogen joins Ironwood Pharmaceuticals and Living Proof, which are also located in the building.

Alnylam has signed a lease for 295,000 square feet of Class A laboratory and office space at 675 West Kendall. Alnylam Pharmaceuticals focuses on RNAi therapeutics toward genetically defined targets for the treatment of diseases with limited treatment options. Alnylam will occupy all the rentable space available on the six floors of 675 West Kendall when the lease with the current tenant, Vertex Pharmaceuticals, ends in May 2018. (Source: BioMed Realty Website, 02 March, 25 March, 02 April and 06 April, 2015)

Blueprint Medicines and Alexion to Collaborate

Blueprint Medicines has announced a collaboration with Alexion to discover, develop and commercialize drug candidates for an undisclosed activated kinase target which is the cause of a rare genetic disease. Blueprint Medicines will apply its kinase-focused drug discovery platform to identify and optimize drug candidates and will conduct all research activities prior to the filing of an Investigational New Drug (IND) application with the FDA. Alexion will be responsible for the development and commercialization of these drug candidates under the collaboration.

Under the terms of the agreement, Blueprint Medicines will receive an upfront payment of $15 million and will be reimbursed for all research expenses. Blueprint Medicines is eligible to receive over $250 million in payments upon the successful achievement of pre-specified preclinical, clinical, regulatory and commercial milestones. In addition, Blueprint Medicines will be eligible to receive royalty payments following commercialization. (Source: Blueprint Medicines Website, 03 March, 2015)

FDA Approves First Biosimilar in U.S.

The FDA has approved Sandoz's Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States. Zarxio is biosimilar to Amgen's Neupogen (filgrastim), which was originally licensed in 1991. Sandoz is the first company to receive approval of a biosimilar in the U.S. through the new FDA biosimilars pathway established under the Biologics Price Competition and Innovation (BPCI) Act.

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

The FDA's approval of Zarxio was based on review of evidence that included structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates Zarxio is biosimilar to Neupogen.

Zarxio has been approved as biosimilar, not as an interchangeable product. Under the BPCI Act, a biological product that that has been approved as an "interchangeable" may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Filgrastim is a naturally occurring protein, produced commercially by recombinant DNA technology, which stimulates production of white blood cells. Marketed as Zarzio outside of the U.S., the Sandoz biosimilar filgrastim is available in more than 60 countries worldwide, has generated over 7.5 million patient-days of exposure and is the most widely used filgrastim in Europe.

Neutropenia is a condition characterized by a low amount of neutrophils in the blood - one of the most common types of white blood cells - whose role is to protect the body from infections. Neutropenia occurs often following cancer treatments, as well as advanced HIV infections.

The Sandoz pipeline has several biosimilars across the various stages of development, including five programs in Phase III clinical trials/filing preparation. (Source: Sandoz-Biosimilars Website and FDA Website, 06 March, 2015)

Ipsen Inaugurates New Cambridge R&D Center and Begins Research Alliance with Harvard University

Ipsen announced the inauguration of its new R&D center, Ipsen Bioscience, in Cambridge. Ipsen Bioscience is developing peptide therapeutics for endocrinology and oncology. Ipsen Biopharmaceuticals, the North American operations of Ipsen, has offices located inBasking Ridge, New Jersey and Toronto, Ontario, Canada. Ipsen Biopharmaceuticals is focused on the commercialization and the medical and clinical support of its key products in the areas of oncology, neurology and endocrinology.

Ipsen has also signed a multi-year research alliance agreement with Harvard University designed to stimulate new research projects. The alliance will enable researchers at Ipsen and Harvard to identify and develop collaborative programs in the areas of neuroendocrine tumors, neuromuscular disorders, and platform technologies related to toxins and peptides.

The agreement builds upon the success of an existing, three-year program initiated in July 2013. Supported by Ipsen, the Harvard laboratory of Dr. Min Dong is engineering novel recombinant botulinum toxin molecules that may improve upon the therapeutic characteristics of existing treatments for neuromuscular tremors and spasms. (Source: Ipsen Website, 01April, 2015)

Abbvie To Acquire Pharmacyclics, Blockbuster Product

AbbVie and Pharmacyclics announced an agreement under which AbbVie will acquire Pharmacyclics, and its flagship asset Imbruvica (ibrutinib), a highly effective treatment for hematologic malignancies. The acquisition adds to AbbVie's hematological oncology portfolio, a rapidly growing market, now approaching $24 billion globally. The transaction values Pharmacyclics at approximately $21 billion and was approved by the Boards of Directors of both companies.

Imbruvica is a Bruton's tyrosine kinase (BTK) inhibitor approved for use in four indications to treat three different types of blood cancers including chronic lymphocytic leukemia, mantle cell lymphoma and Waldenstrom's macroglobulinemia. Imbruvica received initial FDA approval in 2013 and is the only therapy to have received three Breakthrough Therapy designations by the FDA. It is currently approved in more than 40 countries. (Source: Abbvie Website.com, 04 March, 2015)

GSK to Establish Global Vaccines R&D Centre in Maryland, Move Cambridge R&D Operations

GSK announced it is establishing a new global center for vaccines research and development in Rockville, Maryland. The site will become one of three global vaccines R&D centers for GSK, complementing the company's existing global R&D centers in Rixensart, Belgium and in Siena, Italy, a site which GSK recently acquired from Novartis in March 2015. It will consolidate vaccines R&D activities currently conducted at other GSK sites including in Philadelphia, PA and Cambridge, MA, into one centralized location. GSK anticipates site operations for vaccines to begin in Rockville as early as September 2015. (Source: GSK Website, 02 April, 2015)

Takeda Licenses Rights to Use ImmunoGen Antibody-Drug Conjugate Technology

Takeda and ImmunoGen have announced that Takeda has licensed exclusive rights to use ImmunoGen's Antibody-Drug Conjugate (ADC) technology - including ImmunoGen's new DNA-acting IGN payload agents - to develop and commercialize targeted anticancer therapeutics to up to two undisclosed targets. The agreement also provides Takeda with the option to take a license for a third target for an additional upfront fee.

ImmunoGen will receive $20 million upfront and - for each target - is eligible to receive milestone payments potentially totaling up to $210 million plus royalties on the commercial net sales of any resulting ADC products. Takeda is responsible for the development, manufacturing and marketing of any ADC products resulting from this agreement.

Takeda signed an agreement with ImmunoGen through its wholly owned subsidiary, Millennium Pharmaceuticals. (Source: Immunogen Website, 23 March, 2015)

Amgen's Phase 3 Study for Humira Biosimilar Shows Positive Results

Amgen has announced that a Phase 3 study evaluating the efficacy and safety of biosimilar candidate ABP 501 compared with AbbVie's Humira (adalimumab) in patients with moderate-to-severe rheumatoid arthritis met its primary and key secondary endpoints. ABP 501 is being developed as a biosimilar candidate to adalimumab, an anti-TNF-α monoclonal antibody, which is approved in many countries for the treatment of inflammatory diseases, including rheumatoid arthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and ulcerative colitis. Amgen has nine biosimilar molecules in development and expects to launch five of these biosimilars between 2017 and 2019. (Source: Amgen Website, 03 February, 2015)

Bristol-Myers Squibb Acquires Flexus Biosciences

Bristol-Myers Squibb Company announced that it has completed the acquisition of Flexus Biosciences. The transaction includes full rights to F001287, Flexus' lead preclinical, small-molecule IDO1-inhibitor targeted for IND filing in the second half of 2015 and an IDO/TDO discovery program that includes its IDO-selective, IDO/TDO dual and TDO-selective compound libraries. A newly formed entity established by the current shareholders of Flexus will retain, from and after the closing, all non-IDO/TDO assets of Flexus including those related to Flexus' Phase 1 FLT3 and CDK4/6 inhibitor, its earlier stage small-molecule Treg cancer immunotherapy programs, and its current personnel and facilities. The transaction has a potential total consideration of $1.25 billion, including $800 million upfront and development milestones that, upon achievement, could total up to $450 million. (Source: BMS Website, 23 February and 08 April, 2015)

Biogen Idec Becomes Biogen

Biogen Idec is now known simply as Biogen. The company has introduced a new corporate identity and logo that reflect both its evolution and focus on bringing forth new therapies in areas of high unmet need – while honoring Biogen's scientific heritage and legacy as a pioneer in the biotechnology industry. Biogen's common stock will continue to trade on the Nasdaq Global Select Market under the symbol "BIIB," and its CUSIP number will not change.

Biogen Idec was created in 2003 through the merger of Biogen and IDEC Pharmaceuticals, creating one of the world's leading research-based life sciences organizations. The company has since focused its research and commercial efforts in three core areas: neurology, immunology and hematology. (Source: Biogen Website, 23 March, 2015)

Lilly and Innovent Biologics Ink Biotech Drug Development Collaboration in China

Eli Lilly and Innovent Biologics have announced one of the largest biotech drug development collaborations in China to date between a multi-national and domestic company. Under terms of the agreement, Lilly and Innovent will collaborate to support the development and potential commercialization of at least three cancer treatments over the next decade. The agreement creates possible new treatment options for cancer patients, while strengthening the presence of both companies in the Chinese oncology market.

As a part of the agreement, Innovent will lead the development and manufacturing for the China market, while Lilly will be responsible for commercialization of the three potential medicines. Innovent also has co-promotion rights. Under the terms of the agreement, Innovent will receive a total upfront payment of $56 million. Lilly could also issue future payments exceeding $400 million for the pre-clinical immuno-oncology molecule if the product reaches certain development, regulatory and sales milestones. Sales royalties and other payments would occur on certain products if commercialized.

Lilly has a robust oncology pipeline that includes both small molecules and monoclonal antibodies, which are being studied to treat a wide range of cancers including breast, colorectal, liver and non-small cell lung. Innovent Biologics is a leading biopharmaceutical company in China focused on the development and manufacturing of complex, high-end biologics for both the Asian and global markets that meet EMA and FDA/cGMP standards. (Source: Eli Lilly Website, 20 March, 2015)

Foundation Medicine and H3 Biomedicine Collaborate on Precision Therapies for Cancer

Cambridge-based Foundation Medicine and H3 Biomedicine have announced a multi-year collaboration for the discovery and development of precision medicines in oncology. The collaboration marries Foundation Medicine's comprehensive genomic knowledgebase of more than 35,000 genomic profiles with H3 Biomedicine's drug discovery engine and computational biology platform. The approach aims to identify potential drug targets based on the unique genomic dependencies of individual cancers, rapidly accelerate clinical development, and lead to the commercialization of new, safe and effective precision medicines for individuals living with cancer.

Under the terms of the agreement, H3 Biomedicine will pay Foundation Medicine a technology access fee for identification of target concepts arising from use of Foundation Medicine's knowledgebase and success milestones for selection, validation, clinical progression, and commercialization of products developed from the program. In addition, Foundation Medicine is eligible to receive royalties on sales of any products resulting from the collaboration.

Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company's clinical assays provide a fully informative genomic profile to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies and clinical trials.

H3 Biomedicine is a privately held biopharmaceutical company focused on the discovery and early development of novel, targeted anti-cancer compounds for the unmet needs of genetically defined patient populations. H3 has leveraged its integrated expertise in genomics, tumor biology, bioinformatics and innovative synthetic organic chemistry to create an integrated drug development ecosystem to deliver patient-based, genomics-driven, small molecule drugs. In less than three years, H3 has developed four discovery platforms, which have produced two drug candidates for which the company expects to file investigational new drug (IND) applications in late 2015. (Source: Foundation Medicine Website, 23 February, 2015)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

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

Novartis Wins FDA Approval for Farydak for Multiple Myeloma

The FDA has approved the Novartis drug Farydak (panobinostat) for the treatment of patients with multiple myeloma. The drug had been granted priority review and orphan product designation. Farydak is the first HDAC inhibitor approved to treat multiple myeloma. It is intended for patients who have received at least two prior standard therapies, including bortezomib and an immunomodulatory agent. Farydak is to be used in combination with bortezomib, a type of chemotherapy, and dexamethasone, an anti-inflammatory medication.

Multiple myeloma is a form of blood cancer that arises from plasma cells, a type of white blood cell, found in bone marrow. According to the National Cancer Institute, approximately 21,700 Americans are diagnosed with multiple myeloma and 10,710 die from the disease annually. Farydak works by inhibiting the activity of enzymes known as histone deacetylases (HDACs).

Farydak carries a Boxed Warning alerting patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak. Because of these risks, Farydak is being approved with a Risk Evaluation and Mitigation Strategy (REMS) consisting of a communication plan to inform health care professionals of these risks and how to minimize them.

The FDA granted Farydak priority review and orphan product designation. Farydak is marketed by East Hanover, New Jersey-based Novartis Pharmaceuticals. (Source: FDA Website, 23 February, 2015)

FDA Expands Use of BMS Drug for Treatment of Lung Cancer

The FDA has expanded the approved use of Opdivo (nivolumab) to treat patients with advanced (metastatic) squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Opdivo is marketed by Princeton, New Jersey-based Bristol-Myers Squibb.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 224,210 new diagnoses and 159,260 deaths in 2014. The most common type of lung cancer, NSCLC affects seven out of eight lung cancer patients, occurring when cancer forms in the cells of the lung. Opdivo works by inhibiting the cellular pathway known as PD-1 protein on cells that blocks the body's immune system from attacking cancerous cells.

Opdivo for squamous NSCLC was reviewed under the FDA's priority review program. The FDA previously approved Opdivo to treat patients with unresectable or metastatic melanoma who no longer respond to other drugs. (Source: FDA Website, 04 March, 2015)

FDA Approves Anthrasil for Patients with Inhalation Anthrax

The FDA has approved Anthrasil, Anthrax Immune Globulin Intravenous (Human), to treat patients with inhalational anthrax in combination with appropriate antibacterial drugs 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.

Anthrasil is manufactured from the plasma of individuals vaccinated against anthrax. The plasma contains antibodies that neutralize toxins produced by the anthrax bacteria. The product is manufactured by Cangene based in Winnipeg, Canada. It was developed with support from the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. (Source: FDA Website, 25 March, 2015)

FDA Approves New Treatment for Diabetic Retinopathy

The FDA has expanded the approved use for Regeneron Pharmaceuticals' Eylea (aflibercept) injection to treat diabetic retinopathy (DR) in patients with diabetic macular edema (DME). Eylea is administered by a physician as an injection into the eye once a month for the first five injections and then once every two months. It is intended to be used along with appropriate interventions to control blood sugar, blood pressure and cholesterol. In February, the FDA approved Genentech's Lucentis (ranibizumab injection) to treat DR in patients with DME.

The FDA granted breakthrough therapy designation to Eylea for the treatment of DR with DME. The FDA previously approved Eylea to treat wet (neovascular) age-related macular degeneration, a condition in which abnormal blood vessels grow and leak fluid into the macula. Eylea is also approved to treat DME and macular edema secondary to retinal vein occlusions, both of which cause fluid to leak into the macula resulting in blurred vision. (Source: FDA Website, 25 March, 2015)

Sanofi Receives FDA Approval of Insulin Toujeo

Sanofi has announced that the FDA approved Toujeo, a once-daily long-acting basal insulin, to improve glycemic control in adults living with type 1 and type 2 diabetes. Toujeo will be available in

the Toujeo disposable prefilled pen which contains 450 units of Toujeo and requires one third of the injection volume to deliver the same number of insulin units as compared to the Lantus disposable prefilled pen. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the U.S., who require 80 IU or less per day. Toujeo is currently pending marketing authorization with the European Medicines Agency (EMA) and other health authorities around the world. (Source: Sanofi Website, 25 March, 2015)

DBV Technologies Wins Breakthrough Therapy Designation for Treatment of Peanut Allergy in Children

French drug manufacturer DBV Technologies has announced that the FDA has granted Breakthrough Therapy Designation to Viaskin Peanut for children. Breakthrough Therapy Designation is intended to expedite the development and review of drugs/biological products for serious or life-threatening diseases or conditions, such as peanut allergy. The FDA granted this Breakthrough Therapy Designation after DBV reported positive Phase IIb results with Viaskin Peanut. DBV is preparing the launch of its Phase III trial of Viaskin Peanut in children suffering from peanut allergy.

DBV is developing the Viaskin technology platform, which delivers biologically active compounds, including allergens, via intact skin. Viaskin is an electrostatic patch, based on Epicutaneous Immunotherapy, or EPIT, which administers an allergen directly onto the superficial layers of the skin to activate the immune system by targeting antigen-presenting cells without allowing passage of the antigen into the bloodstream. (Source: DBV Technologies, 09 April, 2015)

New Members

Alagappan Annamalai, Pfizer

Patrick Armstrong, PixarBio Corporation

Hilary A. Aroke, PhD Student, URI

Tiffany A. Babbitt, Quality Risk Management, Continuous Process Improvement Analyst, Genzyme, A Sanofi Company

Christopher Beganski, Biogen

Virginia M. Bergman, Senior Validation/Project Engineer, Superior Controls, Inc.

Dr. Claudia W. Buser, Director, Cell Banking Development, Genzyme/A Sanofi Company

Joseph S. Campisi, Vice President, EHS & Compliance, AEI Consultants

Christine Carberry, SVP, Quality, Technical Ops, Program & Alliance Management, FORUM Pharmaceuticals

Joseph Cassella, Associate Director, ProPharma Group

Timothy Cava, Process Engineer, Lantheus Medical Imaging

Vanessa R. Cavallaro, Community College of Rhode Island

Taylor K. Chartier, Development Engineer, Shire

Jonathan W. Chin, Process Engineer, Shire Pharmaceuticals

Jeremey D. Condon, Controls Engineer, Shire

David E. Connolly

Amy Cazeault Crane

Michael D'Avanzo, Jr., Student, Middlesex Community College

Ryanne M. Dailey, Student, Worcester Polytechnic Institute

Thomas L. Easton, Tufts University

Christine W. Gakuya, QA Specialist, Infinity Pharmaceuticals

Jeffrey Gerstein, Director of Commissioning, Qualification, and Validation, DPS

Douglas Gigliotti, University of Massachusetts Lowell

William J. Grabowski, President & CEO, HealthStar, Inc.

Adam Green, Senior Sales Engineer, CD-adapco

Eileen Heffernan, Account Executive, Boston Analytical

Stacia Hogle, Process Equipment Engineer, Genzyme

James Michael Hughes, Senior Validation Engineer, Shire

Shashank Kadam, Shire

Robert Kenyon, Vice President, Manufacturing, Biogen

Joseph L. Kifer, Business Development Manager, RDK Engineers

Josephine Ko, Student, Boston University

Chris Ladd, AIA, Vice President

Deidre R. LaFontaine, Student, Community College of Rhode Island

Keith A. LeBlanc, Sr. Maximum Containment Specialist, Boston University

Stephen M. Lindsey, Building Commissioning Engineer, Commissioning Agents Inc.

David P. Lino, Director Quality of Regulatory, Citra Labs/Biomet Biologics

Songhua Liu, Development Engineer, EMD Millipore

Jessica L. Lucia, Rhodes Technologies

Dr. Gennady Malin, Principal Quality Engineer, Genzyme, Sanofi Company

David E. Medeiros, Student, CCRI Warwick

Parikshit Mehendale, Director of Engineering, Lantheus Medical Imaging

Arie Menachem, Consumer Safety Officer, US Food & Drug Administration

Edmund Mrak, US FDA

Aislinn Mulligan, Student, MCPHS University

Michael D. Murphy, Process Equipment Engineer, Genzyme

Scott Nelson, Associate Director, Quality, Sunovion

Brady Neyland, Student, UMass-Lowell

Michael O. O'Rourke, Business Development Manager, Dortek USA

Chirag Parikh, CSV Senior Validation Engineer II, Shire

Andrew L. Pendleton, Sales Manager, Sensitech

Thomas Peterson, Barry-Wehmiller Design Group

Jeff S. Pirro, Process Engineer, Pfizer

Anthony Puleo, Validation Consultant, ICQ

Michael T. Puntin, Engineering Manager, Berkshire Sterile Manufacturing

Apurv Puri, Engineer II, Hyde Engineering + Consulting

Elizabeth A. Richmond, Director, Global Packaging Technology, Vertex Pharmaceuticals Inc.

Denise Ritchie, Account Manager, EMD Millipore

Ricardo Rivera

Hector R. Rodriguez, Sr. Director, EHS and Sustainability, Biogen

Rick Rose, Validation Associate III, Baxter

Scott D. Rosenberry, Principal, Ops2data, LLC

Maimoona Saleem, Project Supervisor, Upstream, Biogen Idec

Thomas Susko, AIA, Senior Process Architect, DPS

Christopher Thornberry, Manager, Engineering, Shire

Emma Turton, Student, Worcester Polytechnic Institute

R Scott Warila, Associate Professor Biology, Community College of Rhode Island

Andrew Whynot, Business Development Associate, Chemic Laboratories, Inc.

Lee A. Willard, technical solutions, Technical Sales, Applied Chemical Transfer

Jason Wong, Senior Process Engineer, Biogen

Adam Yacoub, Validation Consultant, Valsource, LLC

Rozanna Yaing

Member Anniversaries

Over Twenty Years

- Greta W. Davis, Lantheus Medical Imaging (25 years)
- Russell B. Parry (23 years)
- Simon Bedigian, Olympic Systems Corp (21 years)
- John H. Evers, Lantheus Medical Imaging (25 years)
- Michael J. Fisher, Genzyme, Sanofi (21 years)
- Joshua Froimson, AbbVie Bioresearch Center (21 years)
- Stephen P. Miraglia, Sapphire Project Services LLC (22 years)
- David Monette, Novo Nordisk (21 years)
- Peter Mosgrove, Mettler-Toledo Thornton Inc (23 years)
- Stanley E. Rotkiewicz, Jr., Genzyme Corporation (23 years)
- Michael J. Sweeney, Hart Design Group (22 years)
- David A. Wilson, Abbott Bioresearch Center (23 years)

Twenty Years

- Richard M. Delorme, Emerson Process Mgmt/Rosemount
- Michael J. Denault, Denault Associates
- Christian P. Dunlap, Schneider Electric
- Doyle R. Johnson, Jr., Hargrove Life Sciences LLC
- David P. MacKay, Pfizer
- Peter J. Sbrollini, Brandt Industrial, Inc.

Fifteen Years

- Patricia W. Nugent, Shire HGT
- Richard E. Avery
- John W. Murphy, Dolphin 8 Corp
- Mark A. Sitcoske, High Purity New England

Ten Years

- Berkeley W. Cue
- Joseph P. DeWolfe, Seracare Life Science
- Michael Harris, Stantec Consulting Services Inc
- Syed Imam, Storeroom Solutions Inc.

Five Years

- Geetanjali Abbi, Genzyme Corp
- Valentin Splett, Bioengineering Inc

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