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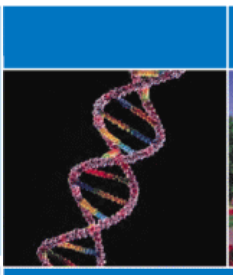


NEWSLETTER

July 2014, Volume XXIV, No. 4

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President's Message: Thank You for the Opportunity to Serve as Your President...

Dear Boston Area Chapter Members,

The Boston Area Chapter (BAC) has had a busy and yet another great year. I say "year" because as we roll into summer, I am sorry to say that this will be my last message as president of the Boston Area Chapter of ISPE.

We have continued the multi-year trend as the leading ISPE Chapter globally. As summarized below, our Chapter Members have a lot of achievements to be proud of.

First, we have successfully begun the integration of our former New England Chapter Members into the BAC through our GO (Geographic Outreach) initiative. The accomplishments related to this effort include:

formation of the GO Committee in order to develop educational and social programs outside the Boston Area; and

- first-ever simulcast broadcast of a BAC educational program.

The June educational program was broadcast live to a second location in Warwick, RI where attendees enjoyed the traditional networking reception prior to the program. They were even able to ask questions of the speaker and panelists electronically and have them answered live during the program.

This initiative has been recognized by other Chapters and we have received requests to provide our service to other areas around the country. As always, the devil is in the details but we intend to continue moving forward with this process and one day be able to provide our world-class educational programs to industry in other areas of the U.S.

As this is my last opportunity to boast of the Chapter's accomplishments, I'd like to first thank you for giving me the opportunity to serve as your president. This has been a very rewarding experience and I can't say enough positive things about our Chapter Members and our many volunteers, committee and board members, and the admin staff at CAMI that manages the Chapter's day-to-day activities for us. Our Chapter's accomplishments are the direct result of these motivated, innovative and high-energy people who continue to form and drive our Chapter.

As I have in previous messages, I am proud to provide the updates below to our major goals and initiatives from the past 12 months.

Membership We have maintained a membership retention rate greater than 93 percent for the year thus keeping our spot as the largest Chapter in the world with over 1700 Members.

Student Growth In one year we have more than doubled our student membership to over 200 Student Members spread over ten Student Chapters, three of which are new this year.

Geographic Outreach We have successfully launched the educational program simulcast effort. This will continue to expand to areas throughout New England - and beyond as we include other areas that would like to participate.

As I stated earlier, unfortunately all good things have to come to an end. This is my last President's Message as I will turn the Chapter's reins over to your new president in August, before the next newsletter issue is distributed. I am very grateful to have served as your Chapter president for the past year. It has been a pleasure to work with the dynamic and dedicated volunteers who have ensured another very successful year for the Chapter.

I am also honored to have played a role in integrating the New England and Boston Area Chapters back into a single entity. My heartfelt thanks go out to all the board members, committee chairs, committee members, the staff at CAMI and all the others who have given their time to the Chapter over the past year. Your contributions are very much appreciated by our entire membership!

Thank you again,

Dan Ramsey

President

ISPE Boston Area Chapter

Chapter Bulletin Board

Product Show Booths Selling Fast – Choose Your Booth Location Before It's Too Late

Exhibitors! Registration for the 23rd Annual Boston Chapter Product Show on October 1 is now open and booths are disappearing fast. This year's Show is shaping up to be even bigger and better than last year's, which was huge! How huge? Check out the brand-new show video at www.ispeboston.org/files/ispe_productshowvideo_youtube_master_01-13-14.mov and see why your company needs

to be at this year's Show. Then register and pick your booth location at www.ISPEBoston.org/ProductShow before it's too late. And while you're there, be sure to sign up for one (or more!) of the many new sponsorship and advertising opportunities available this year. See you at Gillette on October 1!

Boston Strongest: Congratulations to Our Newest CPIPs!

While ISPE has made the difficult decision to terminate the CPIP program, May 31 was the last day that people could take the exam and attain this valued credential. Once again, the Boston Area Chapter continues to lead the way. Please welcome and congratulate our newest CPIPs:

Kathleen Bellorado, CPIP Pfizer

John Cummins, CPIP LotusWorks USA

Jason Gale, CPIP Pfizer

Kathleen Long, CPIP, Pfizer

Howard Sneider, CPIP, CRB Consulting Engineers

Brody Stara, CPIP, Commissioning Agents

The Boston Chapter now boasts 58 CPIPs, more than 40 percent of the total CPIP population worldwide. Attaining this credential documents broad-based, extensive knowledge of the "big picture" in our industry and holders of the credential bring an unmatched level of cross disciplined knowledge that will bring value to any project or firm. With 141 CPIP's in the world, the Boston area is well poised to build on its position as (in the words of Governor Deval Patrick) "the unquestioned global leader in the life sciences industry."

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. Visit the sponsorship page on our website at www.ISPEBoston.org and open the sponsorship application. Choose the eNewsletter option that works best for you - ads are available in two sizes and run for six months or a full year - then pay by credit card online. It's that simple! Or – if you'd rather - contact the Chapter office at 781.647.4773 or office@ispeboston.org.

And while you're there, be sure to explore the full range of sponsorship options available in addition to eNewsletter ads, including educational programs, social events and website ads. 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 support the Chapter's activities. Have questions? Contact the Chapter office at 781.647.4773 or office@ispeboston.org and we'll be happy to help!

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 at www.ispeboston.org/become_a_sponsor containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Spotlight Interview: Product Show Exhibitor Patty Ascanio of Mangan Biopharm on the Product Show, the Industry and ISPE...

Longtime ISPE Member Patty Ascanio is the Director of Northeast Operations for the Biopharm Division of Mangan Inc., a specialty engineering, automation, and integration company providing a full-range of services for the refining, gas & oil, pipeline, renewable, chemicals, and life sciences industries.

Patty began her career over 25 years ago as a quality control technician and has worked her way through many levels of automation and quality management positions. Since the early nineties, she has been an active member of ISPE and is the founding Industry Advisor for the Student Chapter at the University of New Hampshire. Patty is still involved at UNH today; she serves as the current Industry Advisor for the Student Chapter.

Patty holds a B.S. in Chemical Engineering from the University of New Hampshire and a Master's degree in Business Administration (MBA) from Southern New Hampshire University. She currently lives in Hampton, NH with her husband and two daughters.

Many thanks to Patty for agreeing to answer a few questions about the Product Show, her history in the industry and her membership in ISPE.

Patty Ascanio with the Mangan Biopharm team at the 2013 Product Show.

• How long have you been exhibiting at the Product Show? Why do you continue to exhibit every year?

I have been exhibiting at the Product Show for the past five years and I attended the Show many years before that. The first time I attended, the Show was at a local hotel where the booths were wall-to-wall, there was no parking, you had to ride a shuttle back and forth to your car and there was barely room to walk around at the Show. It has come a long way since then.

• What do you like most about the Product Show as an exhibitor? As an attendee?
As an exhibitor, the thing I like the most is the number of clients and potential new clients that the Show draws. I also enjoy catching up with other vendors that I may only see once or twice a year.

As an attendee the thing I like most is the amount of information and the resources that are available at the Show. You can find information on anything and everything regarding the biotech and pharmaceutical industries at the Product Show.

• How does the Product Show compare to other shows you have attended or at which you have exhibited?

I have not attended or exhibited at another show which comes close to the ISPE Boston Area Chapter's Product Show. The Product Show draws more clients and provides more industry specific information and resources than any other show I have attended. The venue is great, the food is endless, the speakers are always relevant and spot on, and the tour of the stadium is a must see.

• Do you have a funny story concerning the Product Show? If so, please tell us…

I have always worn a company shirt when exhibiting at the Product Show. One year a buddy of mine and I decided to trade shirts. I gave him one of our company shirts and he gave me one of his. I went and changed into his shirt and then went and stood by his booth. I timed it such that my boss came by the booth while I was standing there pretending to work for this other company. It was quite funny and I've never heard the end of it.

• Describe your job. What do you like best about it?

I am the Director of Northeast Operations for Mangan Biopharm which is a Specialty Engineering, Automation, and Integration company, providing a full-range of services for the Refining, Gas & Oil, Pipeline, Renewable, Chemicals, and Life Sciences Industries. I am responsible for improving and expanding the Northeast region's service base to the biotech, pharmaceutical, and medical device industries.
The thing I like best is knowing that the work we do contributes to providing treatments for patients which can greatly improve their quality of life. It is personal for me because I have a sister and a niece who were diagnosed with multiple sclerosis 9 and 10 years ago and they both benefit greatly from medications which are manufactured by companies in this industry.

• How did you get to where you are today?

I am number six of seven children. My Dad was a blue collar worker, my Mom was a stay-at-home Mom, and we were raised Southern Presbyterian in the mountains of Virginia. I was the third child in my family to graduate from college. I commuted to school 35 miles each way while working full time at a non-woven fabric manufacturer. Half way through my sophomore year when I was pulling a GPA of about a 2.03 my Dad said to me, "It's the difference between choosing a job and having to take a job." That stayed with me ever since. I graduated with a BS in Chemical Engineering and went back a few years later to get my MBA. Hard work, supportive family, and the grace of God is how I've gotten to where I am today.

• What is your biggest challenge in your current position?

The biggest challenge I face in my current position is finding talented resources that are ready to hit the ground running in this industry. This is the reason I chose to volunteer to help with the Student Chapters of ISPE and I believe that ISPE is making a difference in the preparedness of students entering the industry.

• What changes have occurred in your field during the course of your career?

Previous Issues

Newsletter Archive

Being in the automation industry it is the technology that has changed significantly over the years and continues to change. When I first started in this industry the personal computer or PC (the IBM XT to be exact) was a brand new invention. Today there are "PCs" which will sit in the palm of your hand. My first "laptop" was a contraption which weighed about 35 pounds and was barely portable. Today my laptop is about the size of a 70 sheet spiral notebook and weighs less than 2 lbs.

• Why did you decide to join ISPE?

I originally decided to join ISPE to learn more about GAMP3 – Good Automated Manufacturing Practice. I continued to renew my membership because of the information and resources that became available to me through ISPE.

• Outside of the Product Show, what are some of the other Chapter activities you enjoy & why?

I enjoy the social activities (New Year's Social, Summer Social, etc.) because they are truly a time to relax, network, and have some fun. I enjoy attending the educational sessions which are relevant to me because the information is always fresh and provides a different perspective for me to assess and learn from. I enjoy the tours because it's fascinating to see different facilities and the work that goes into them.

Upcoming Chapter Events - Mark Your Calendar

Wednesday, July 16, 2014

ISPE Educational Planning Meeting
Waltham Woods Conference Center, Waltham, MA

This summer, the Boston Area Chapter will receive valuable input on educational programs of interest to our Members through a survey which was launched in June. The Educational Program Committee would like YOUR help to finalize the educational program content for the upcoming Chapter year using the survey results. Please join us on Wednesday, July 16, 2014 as the 2015 educational season is developed.

Register Today:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=458

Wednesday, July 23, 2014

"Nantucket Breeze" Summer Social
Pier 6, Charlestown, MA

Register today and come join the ISPE Boston Area Chapter for our "Nantucket Breeze" Summer Social at Pier 6 in Charlestown! We will hold a 50/50 Raffle with proceeds benefitting Heading Home.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=461

August, 18, 2014

Summer Golf Outing
Kernwood Country Club, Salem, MA

This event is sold out. Please contact the office to be put on a wait list. 781-647-4773

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=438

Sneak Preview of Upcoming Events

Thursday, September 4, 2014
Boat Cruise

Thursday, September 18, 2014
Good Engineering Practices

Wednesday, October 1, 2014
Annual Product Show

UMass Crown Jewel Shines at April Educational Program

by Joyce Chiu, Honeywell Safety Products; Paul Doherty, CRB Builders; Doyle Johnson, Hargrove Life Sciences; Mike Severino, Festo; with photos by Joyce Chiu and Mark J. Jodoin, Symbotic

With the coming signs of spring it was fitting that the April Educational program entitled "Facility Optimization and Process Improvement" was combined with a facility tour of the brand new Massachusetts Accelerator For Bio-Manufacturing (MAB) at UMass Dartmouth (UMD). This program enabled the university to unveil its latest life sciences asset with facility tours and a follow-on presentation from the design, engineering, construction, university and industry team that had the vision, concept and experience of building this life sciences gem.

The UMass Dartmouth Massachusetts Accelerator for Bio-Manufacturing (MAB) was both venue and topic for the April program.

The uniqueness of this program and venue attracted a near-capacity crowd to the MAB. In addition to those lucky enough to attend the program in person, a second group of attendees participated via video simulcast at the Emerging Technologies and Innovation Center at UMass Lowell. The Chapter is piloting this use of technology as part of its Geographic Outreach (GO) initiative designed to bring educational programs to Chapter Members throughout New England.

First on the evening's agenda was an information-packed facility tour. Tour guides brought their own perspective on the facility and its construction challenges, while location-critical experts presented details and interacted with attendees at each stop. During the tour, attendees in Lowell were treated to a previously-recorded video tour of the facility. Following the tour, attendees at both locations were welcomed by a full hot/cold buffet and drinks and were free to mingle and network with their peers prior to the presentations.

Tour guides brought their own unique perspective on the MAB and its construction challenges.

The MAB

The Massachusetts Accelerator for Bio-Manufacturing (MAB) is a 27,745 sqft facility located at the SouthCoast Life Sciences and Technology Park, in Fall River, MA. According to a press release issued by the governor's office following the groundbreaking in 2012, the MAB is "the only facility in the U.S. where startups will be able to test their biomanufacturing methods and bioproducts at every stage of development and access full-service support from business and marketing to pure science support – all under one roof."

The heart of the facility is designed around four flexible suites complete with the necessary support services required for production, pre-production and research activities. The facility will serve client companies with traditional biologic therapeutic products, new types of products using stem cells and tissue engineering, as well as biomaterials, biofuels and green chemistry products. The "GMP like" manufacturing area includes:

• mammalian cell culture and purification capability up to 300L scale;
• microbial fermentation and purification capability up to 300L scale;
• stainless steel and single use cell culture fermenters;
• flexible services including QA/environmental monitoring, full utilities (RO/DI water, clean steam & gases), waste stream management, data collection, media and column prep and secure access; and quarantine and release storage areas.

In addition to the complete production services, the facility has a QA/QC, R&D and training labs, lecture halls and office suites.

The Program

The Program As the sun set so did the networking session and at approximately 6:30pm everyone was asked to take a seat in the lecture hall for the program portion of the evening. An energized Michael Levesque of the Chapter's

Educational Program Committee provided opening remarks and introduced Mark Trusheim, President of Co-Bio Consulting and Bio-manufacturing Executive in Residence at UMass Dartmouth.

Behind-the-scenes facility tours are one of the Chapter's most popular member benefits.

Mark led off the program from the perspective of someone who had been involved in the development of the MAB since it was merely a gleam in legislators' eyes. Mark's first slide showed that New England has more liters of biomanufacturing volume than California, New Jersey, South Korea or any other country in the world. The MAB is then a logical extension of that biotech pre-eminence and New England should just get bigger and better!

Chris Brigham of UMass Dartmouth described the opportunities for learning that the MAB will provide to UMD undergraduate and graduate students. Instead of merely discussing and reading about fermentation, downstream purification and QC, students will have the chance to experience these concepts in a hands-on, real-world environment with some of the experts in the industry.

Sharon Jozokos of Suffolk Construction explained her role in project budgeting, planning and value engineering. There were many changes as this project was built and Sharon and her team had to analyze each for effects on cost and schedule. What made this especially challenging was the need to follow state procurement rules such as 149A, which applies when bids exceed the budgeted amount. Suffolk also made good use of the BIM model to construct the interstitial space, which became extremely crowded when a late design change required production spaces to operate more independently, something that was apparent on the tour earlier in the evening.

The evening's speakers with UMass Dartmouth Student Chapter Members.

Nate Hafer of UMass Medical spoke next as a last-minute substitute for MAB President Paul Vigeant of UMass Dartmouth. The mission of the MAB is to provide training (at both the advanced graduate level and entry level for undergraduates), university-industry partnerships in applied research and building a statewide network linking the UMass system and private colleges and universities. The MAB board of directors, with representatives from the university system and industry, hopes to eventually have 15-20 clients per year for engineering scale-up, proof of production concept and product demonstrations.

Steve Fitzpatrick of DPS Biometics wrapped up the evening with a presentation on the design of the MAB. Architecturally the building was intended to mimic the shape of an enzyme-substrate complex. The facility is capable of up to 300L stainless steel microbial fermentation and up to 250L single use mammalian cell culture, with dedicated HVAC for each. Each production suite is "equipment agnostic," designed as plug-and-play so that almost any brand or type of equipment can be used in any configuration. This was an essential feature in the MAB's role as a demonstration facility for a wide variety of current and future process technologies.

Thank You

On behalf of the Boston Area Chapter, the Program Managers would like to thank UMass Dartmouth and the entire state university system for opening their doors and unveiling the next life sciences training and collaboration facility for the New England region. The MAB will help ensure that Massachusetts maintains its unique position as one of the most influential life sciences clusters in the world.

We would also like to thank the many volunteers at the MAB for making the tours fun, engaging and memorable; and each of the presenters for their insight, knowledge and life sciences expertise and for making this a benchmark evening for the new crown jewel of the UMass life sciences facility portfolio.

And lastly we would like to thank our programs sponsor, CRB and Festo, whose support enables the Boston Area Chapter to provide high-quality educational programs such as this.

Saying Goodbye to Winter at the Spring Golf Outing

by Dan Kenny, Northeast Engineering

The ISPE Boston Area Chapter hosted the First Annual Spring Golf Tournament on April 28 and Mother Nature was happy to cooperate. With the snow finally gone and the sun shining bright, ISPE Members and guests from all over New England put their busy schedules aside to join in a fun-filled day of golf and networking at Ledgemont Country Club in Seekonk, MA. The course was in excellent condition and the staff could not have been more accommodating.

Chapter Members and guests enjoyed gorgeous April weather at the Spring Golf Outing at the Ledgemont Country Club in Seekonk, MA

Charged with scheduling the first golf tournament of the year, the Social Committee did not disappoint. The day started with a hearty lunch buffet, with a spread that had something for everyone, and no one went out on the course hungry. Once everyone was out on the course, the laughs and cheers were heard between Hole 1 and Hole 18 all day long. Once groups started funneling back to the clubhouse, the stories got funnier and the shots got better over a beverage at the fire pit, which was set up just outside the clubhouse. After some more stories, the last groups made it to the clubhouse and a dinner buffet got underway with a full carving station and all the trimmings, followed by an awards ceremony. Awards were handed out for first, second and third longest drive and closest-to-the-pin.

Congratulations go to our winning foursomes and our six individual winners:

First Place (67*)	Second Place (67*)	Third Place (67*)
Hart Design Group	**BOND**	**Margulies Perruzi Architects**
David Destefano	Shawn Donovan	Dan Madra
Andre Gill	Wayne Arruda	Rick Fisher
Steve Anderson	Bill Angelosanto	Dan Wall
Ed Sheridan	Lenny McAlister	Bill Mack

	Women	Men
Straightest Drive	---	Jacob Hillman
Closest to Pin (tie)	---	Andrew Feibelman Jason Fantini
Longest Drive	Antonella Cordella	Andrew Feibelman

* Broke tie by back nine total

In addition there was a 50/50 raffle to raise money for Heading Home, a non-profit providing emergency, transitional and permanent housing and support services to low-income families in the Boston area (www.headinghomeinc.org). All in all, a great day was had by all!

The Social Committee would like to thank everyone who attended the Spring Golf Tournament with a special thank you to the sponsors who played such a vital role in making this great day possible: Crosspoint Engineering, Northeast Engineering, RW Sullivan Engineering, Superior Controls and Thompson Consultants. We couldn't have done it without you!

Hope to see everyone at the Chapter's upcoming social and recreational events including the Summer Social on July 23 at Pier 6 in Charlestown and the Summer Golf Tournament on August 18 at Kernwood Country Club in Salem.

May Educational Program Heads West to Worcester

by Dan Mardirosian, Worcester Polytechnic Institute with photos by Joyce Chiu, Honeywell Safety Products

The ISPE Boston Area Chapter educational program entitled "Upstream Processing: Development and Optimization – Join Us and See Where It All Begins" was held on Thursday, May 17 at Worcester Polytechnic Institute at Gateway Park in Worcester. This was a dual-track program featuring introductory and advanced lectures related to upstream

bioprocessing. There were approximately 55 attendees, both Chapter Members and non-members, with about half in each session.

The introductory track was beamed live to the Crowne Plaza Hotel in Warwick, RI for the benefit of a small group of GO (Geographic Outreach) Committee members and their guests. This was one of the final test runs for the GO Committee as they work towards their goal of simulcasting all education events to make them more accessible to Chapter Members throughout the New England region.

Speaker Kamal Rashid, Director of the Biomanufacturing & Training Center at WPI, talks with a student following the advanced track presentation.

The networking reception in Worcester featured a delicious pasta and salad bar and was well attended. During the networking reception, attendees at the live event were able to tour the new Biomanufacturing Education and Training Center (the BETC) which opened in 2013. The BETC is a 10,000 sq. ft. facility outfitted with bench to pilot scale biomanufacturing equipment dedicated to providing corporate and professional educational programs to respond to the needs of the biomanufacturing industry's workforce development efforts.

The evening began with opening remarks by Boston Area Chapter Past President Brian Hagopian, ISPE Board Member Jack Campion and Program Manager Dan Mardirosian. The introductory session was held at WPI's Life Science and Bioengineering center and was presented by Norman Garceau, PhD, Chief Scientific Officer, Blue Sky BioServices; William Hermans, Head of Cell Culture and Scale Up, Blue Sky BioServices; and Scott Gridley, PhD, Vice President of Business Development, Blue Sky BioServices.

Dr. Garceau began with an overview of microbial expression systems focusing on E.coli, E. coli expression vectors and an overview of the microbial fermentation process. William Hermans then presented an introduction to insect cell culture and the baculovirus expression system and its applications. The introductory track was completed by Scott Gridley who presented an introduction to mammalian cell culture systems and processing. The various cell types and expression systems were discussed, compared and contrasted, providing the applications and benefits of each.

Meanwhile, at the BETC, Kamal Rashid, Ph.D, Director of the BETC presented the advanced track on upstream manufacturing which covered cell line development, media optimization and scale-up strategies.

In summary, a great deal of information was shared during the evening by four highly knowledgeable presenters. 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 Boston Area Chapter and Program Manager Dan Mardirosian would like to thank the presenters, organizers and audience members for their valuable contributions to this program and WPI for providing the venue for the event.

Panelists from Baxter, Genzyme & Shire Wow Audience at June C&Q Program

by Rob Beane, Barry-Wehmiller Design Group, with photos by Mark J. Jodoin, Symbotic LLC and Joyce Chiu, Honeywell Safety Products

The Boston Area Chapter conducted an educational program on June 19 at Tufts Gordon Institute in Medford consisting of a presentation and associated Q&A panel focusing on the various ways different life sciences companies employ risk- and science-based tools and techniques for Commissioning and Qualification.

Program Manager Rob Beane (r) with (l to r) panelists Stephen Kuzil, Michelle Whipple and Eric Felz and speaker Geoffrey Von Holten.

With the industry driven to ensure that the focus of compliance activities is on those elements that have the most impact on the quality, safety and integrity of their products, the speaker and panel members were selected from a variety of life science leaders to provide different perspectives on the topic and a broad spectrum of real world examples of the programs they employ.

In addition to the live program at Tufts, the event was also simulcast remotely to the Crowne Plaza Hotel in Warwick, RI for the benefit of the Chapter's GO (Geographic Outreach) Committee members and their guests. This was one of the final test runs by the GO Committee as they work toward their goal of making all educational programs accessible to Chapter Members throughout New England via simulcast.

In a final test run, the Chapter's GO Committee attended the June program in Warwick, RI via simulcast.

Following the traditional networking reception, the evening began with opening remarks by Boston Area Chapter Past President Brian Hagopian, Tufts Gordon Institute Associate Director Nancy Buczko and Program Manager Rob Beane. Geoffrey von Holten, Principal at GvH Consulting, followed with a presentation entitled "Risk Based C&Q: What's Everyone Else Doing?" during which he provided an overview of the relevant risk assessment guidance documents:

- ISPE Baseline Guide 5,
- ICH Q8 – Pharmaceutical Development,
- ICH Q9 – Quality Risk Management,
- ICH Q10 – Pharmaceutical Quality System,
- ASTM E2500 - Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment and
- ISPE Guidance Document - Science and Risk-Based Approach to Delivery of Facilities, Systems and Equipment.

Geoff also presented his experiences using three case-studies from projects executed using three very different compliance approaches.

Following Geoff's presentation, the program switched gears and welcomed panelists Eric Felz, Associate Director of Validation, Shire; Steve Kuzil, Associate Director Commissioning and Qualification, Genzyme; and Michelle Whipple, Senior Manager, Validation, Baxter who fielded questions posed by audience members at both locations. The many insightful questions included definition and assignment of SMEs, transition of quality systems during commercial operations and management of vendors to get the most out of FAT/SAT efforts.

The Boston Area Chapter and Program Manager Rob Beane would like to thank Geoffrey von Holten for his very informative presentation, the panel members for their insightful responses to the audience questions and to Tufts Gordon Institute for hosting the Chapter at their Medford facility.

When it Comes to Student Members, the Sky's the Limit!

by Brian Hagopian, Clear Water Consulting

Student Membership Continues To Grow. Student membership and participation at Boston Area Chapter events has reached an all-time high and continues to skyrocket! In fact, since January, 2013 student membership has increased by over 400 percent to a total of 200 student members. If you've attended an educational program recently, you've probably noticed more young faces than ever before. It's all part of the Chapter's plan to involve students in the local life sciences industry - and it's working! Next time you attend an ISPE event, please seek out students in attendance and make them feel welcome. You would be absolutely amazed at what a small gesture will do!

Job, Coop, and Internship Postings a Huge Success. One of the major reasons students join ISPE is to find jobs. This year, the Chapter began to post entry-level positions, internships and co-op positions in the Student Chapter section of the Chapter website to help our Student Members find positions in the industry. This year, our goal was to find and post at least 50 positions and we're proud to report that we've exceeded that goal. And, this free service is working! Our Student Members have landed positions at Biogen Idec, Masy Systems, Genzyme, Vertex, Takeda/Millennium, Phosphorex, Dicerna and Process Design Solutions. Stay tuned and watch this program mushroom as more companies and students learn about this valuable service.

Scholarship Program Reaches New High. The Chapter's Joel Goldenberg Scholarship Program has been building momentum for the past three years, granting scholarship monies to a mind boggling 50 percent of applicants! The program has been so successful that it has prompted the Chapter Board of Directors to re-evaluate ways to continue to support and fund the program in the future. With student memberships at an all time high, so are scholarship applications, with 22 applicants submitting requests for the upcoming fall semester. This is one of the many ways the Chapter is "giving back" to the local life sciences industry - helping to usher in the next generation of movers and shakers.

ISPE's Message is Spreading. Word is really starting to spread across local campuses. Student membership is at

an all-time high at our existing Student Chapters but the best news is that we've formed three new Student Chapters this year alone – Mass College of Pharmacy & Health Sciences, Boston University and UMass Dartmouth - and have more in the pipeline. All this activity takes a concerted effort and lots of energy. If you're interested in helping out, just shoot us an email. Whether you have an hour a year or an hour a month, we could sure use the help. Trust me, this is a decision I guarantee you won't regret! And as our efforts continue to gear up, the Chapter will be producing targeted informational videos to help spread the word.

Students Attend ISPE Educational Events for Free. Remember, once you join ISPE as a Student Member (www.ispe.org/join-or-renew), you will be able to 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.

Study Says Massachusetts Leads Nation in Per Capita Life Sciences Jobs

Northeastern University's Dukakis Center for Urban and Regional Policy has released new data showing that the Bay State leads the nation in life sciences on a population basis.
The data presented at an event at UMass Boston's Venture Development Center showed that Massachusetts now has nearly 180,000 jobs in the life sciences sectors and supplying industries, including 113,000 direct jobs in the life sciences sectors and an additional 66,000 jobs in industries that supply the life sciences sectors. When taking population into account, this puts the Massachusetts at the head of the list, with the commonwealth employing 1.8 times more people per capita than California and 2.3 times the number in New York.

The industry sectors targeted for investment by the Massachusetts Life Sciences Center (MLSC), the agency charged with implementing Massachusetts' ten-year, $1 billion initiative have been growing rapidly, enjoying 17.5 percent growth since 2006. That's compared with 1.4 percent job growth over that time in the overall state economy, the researchers said.

"As of 2014, all ten of the top 10 major drug companies in the world have set up shop in Massachusetts," said Barry Bluestone, Dukakis Center Director in a statement. "Why? Because they wanted a front row seat to acquire small life science firms and their discoveries. And what helped make this possible? Small life sciences firms received support from the MLSC in the form of accelerator loans, research and development funds, and interns that help them translate their ideas into commercially viable products."(Source: John Agoglia, Worcester Business Journal, 19 June, 2014)

Novartis and Glaxo Smith Kline Strike Deal to Transform both Businesses

In April, Novartis and Glaxo Smith Kline (GSK) agreed to a deal that will transform both companies and create a new joint venture. As part of the deal, Novartis acquires GSK's marketed oncology portfolio, related R&D activities and rights to its AKT inhibitor. Under the terms of the transaction, Novartis would also have opt-in rights to GSK's current and future oncology R&D pipeline. Novartis will pay $14.5 billion for this acquisition, along with up to $1.5 billion contingent on a development milestone. In return, GSK will acquire Novartis' global vaccines business (excluding influenza vaccines) for an initial cash consideration of $5.25 billion with subsequent potential milestone payments of up to $1.8 billion and ongoing royalties.

Finally, Novartis and GSK have agreed to create a world-leading consumer healthcare business through a joint venture between Novartis OTC and GSK Consumer Healthcare. Upon completion, Novartis will own a 36.5 percent share of the joint venture and will have four of eleven seats on the joint venture's Board.

The Transaction is expected to complete during the first half of 2015 subject to approvals. (Source: GSK and Novartis Websites, 22 April, 2014

Eli Lilly to Acquire Novartis Animal Health

Eli Lilly has announced an agreement to acquire Novartis Animal Health for approximately $5.4 billion in an all-cash transaction to strengthen and diversify Lilly's own animal health business, Elanco. Upon completion of the acquisition, Elanco will be the second-largest animal health company in terms of global revenue. Lilly will acquire Novartis Animal Health's nine manufacturing sites, six research and development facilities, global commercial infrastructure, pipeline with more than 40 projects in development, and more than 3,000 employees.

Lilly plans to fund this acquisition with approximately $3.4 billion of cash-on-hand and $2.0 billion in debt to be issued. No other financial terms of the transaction have been disclosed. The transaction is expected to close by the end of the first quarter of 2015, subject to approvals. (Source: Eli Lilly Website, 22 April, 2014)

BrainStorm Therapeutics to Begin ALS Clinical Trial at MGH and UMass Memorial

The FDA has approved commencement of BrainStorm's Phase II clinical trial of its stem cell therapy (NurOwn) in patients with Amyotrophic Lateral Sclerosis (ALS). The trial will be launched initially at MGH in Boston and the UMass Memorial Hospital in Worcester following Institutional Review Board (IRB) approvals. Dana-Farber Cancer Institute's Connell O'Reilly Cell Manipulation Core Facility will manufacture the cells for these two clinical sites. The trial will also be conducted at the Mayo Clinic in Rochester, Minnesota.

NurOwn is an autologous, adult stem cell therapy technology that differentiates bone marrow-derived mesenchymal stem cells (MSC) into "MSC-NTF" cells. These neuron-supporting cells secrete elevated levels of neurotrophic, or nerve-growth, factors for protection of existing motor neurons, promotion of motor neuron growth, and re-establishment of nerve-muscle interaction.

Earlier clinical trials have shown that treatment with NurOwn cells was well tolerated and safe. According to the final clinical study report for BrainStorm's Phase I trial in Israel, the study successfully met its primary and secondary endpoints. Initial observations of the company's Phase IIa trial data in Israel appear to reinforce these findings. An interim update is expected to be released later this quarter. (Source: BrainStorm Cell Therapeutics Website, 28 April, 2014)

AstraZeneca Rejects Pfizer's Merger Proposals

Over the past six months, Pfizer made multiple attempts to come to an agreement with AstraZeneca on a merger. The company submitted a preliminary, non-binding indication of interest to the board of directors of AstraZeneca in January 2014 regarding a possible merger transaction. After limited high-level discussions, AstraZeneca declined to pursue negotiations and discussions were discontinued. Pfizer again contacted AstraZeneca on 26 April 2014 seeking to renew discussions in order to develop a proposal that could be recommended by both companies to their shareholders but AstraZeneca again declined to engage. Multiple improved proposals were submitted to AstraZeneca during the month of May, but the final proposal made on May 18 was ultimately rejected.

Pfizer's initial proposal made to the board of AstraZeneca on 5 January 2014 included a combination of cash and shares in the combined entity which represented an indicative value of £46.61 ($76.62) per AstraZeneca share and a substantial premium of approximately 30 percent to AstraZeneca's closing share price of £35.86 on 3 January 2014.

On 16 May 2014, Pfizer sent a letter to the Chairman of AstraZeneca setting forth the terms and basis of an improved proposal with an indicative value of £53.50, comprising 1.845 shares in the combined entity and 2,157 pence per AstraZeneca share. In response, AstraZeneca indicated that its board believes that Pfizer's £53.50 proposal substantially undervalued the company. At that time, Pfizer confirmed that it would not make a hostile offer directly to AstraZeneca shareholders and will only proceed with an offer with the recommendation of the board of directors of AstraZeneca.

Pfizer made its Final Proposal Announcement on 18 May, announcing a possible offer comprising, for each AstraZeneca share, 1.747 shares in the combined entity and 2,476 pence in cash, representing an indicative value of £55.00. Pfizer stated that the proposal was final and could not be increased except in limited circumstances specified in the Final Proposal Announcement. Pfizer announced on May 26 that this final proposal had been rejected and that it had no intentions of further offers. (Source: Pfizer Website 28 April, 19 May and 26 May, 2014)

Bristol-Myers Squibb Acquires iPierian

Bristol-Myers Squibb has acquired iPierian, a privately held biotechnology company focused on the discovery and development of new treatments for Tauopathies, a class of neurodegenerative diseases associated with the pathological aggregation of Tau protein in the human brain.

The acquisition gives BMS full rights to iPierian's lead asset IPN007, an innovative preclinical monoclonal antibody for treatment of progressive supranuclear palsy (PSP) and other Tauopathies, and has the potential to commence Phase 1 clinical trials by early 2015. Genetically defined diseases, such as PSP, are caused by a known change in the genome. Knowledge of this genomic change is then used to design a therapeutic approach aimed precisely at that molecular defect, such as the anti-Tau antibody for PSP.

Under the terms of the agreement, BMS has acquired all of iPierian's issued and outstanding shares of capital stock and all common stock equivalents in an all cash transaction for a purchase price of $175 million, with the potential for additional development and regulatory milestone payments totaling $550 million, along with future royalties on net sales. The transaction is expected to be accounted for as an asset acquisition for BMS resulting in a $175 million charge during the second quarter of 2014.
Tau is a protein that binds the cell's internal skeleton and may help regulate the activity of brain cells. Tau forms abnormal deposits called neurofibrillary tangles which can disrupt activity of brain cells and lead to disease. Additionally, Tau is secreted and may drive disease spread and progression. By identifying targets that prevent or reverse Tau dysfunction, it may be possible to identify novel therapeutic strategies to modify the course of a disease. Initial development focus for IPN007 would be on progressive supranuclear palsy (PSP), a rare brain disease with Tau dysfunction that presents as an atypical parkinsonian disorder, with the potential for future development in other Tauopathies such as frontotemporal dementia (FTD) and Alzheimer's disease (AD) for which no disease modifying treatments exist. (Source: Bristol-Myers Squibb Website, 29 April, 2014)

Shire Acquires Lumena Pharmaceuticals

Shire and Lumena Pharmaceuticals have announced the acquisition of Lumena by Shire. Lumena brings to Shire two new oral therapeutic compounds: LUM001, in Phase 2, and LUM002, ready to enter Phase 2 later in 2014. LUM001 and LUM002 are both inhibitors of the apical sodium-dependent bile acid transporter (ASBT), which is primarily responsible for recycling bile acids from the intestine to the liver. Blocking bile acid transport with ASBT inhibitors reduces bile acid absorption and has the potential to improve liver function and relieve disease symptoms, and may slow disease progression.

LUM001 is currently in Phase 2 clinical development for four rare cholestatic liver disease indications, two pediatric and two adult, with a potential 2016 launch. These potential indications are Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC). LUM001 has received orphan drug designation for all four potential indications in both the United States and the European Union.

LUM002 is a once daily, orally-administered, highly potent and selective inhibitor of ASBT, in development for the treatment of nonalcoholic steatohepatitis (NASH), a common and often "silent" liver disease characterized by fat deposits in the liver and inflammation which can progress to significant fibrosis. While the underlying cause of liver injury in NASH is not fully known, it is strongly associated with obesity, Type 2 diabetes, high cholesterol and triglycerides, and other metabolic disorders. Approximately 6 million individuals in the US are estimated to have progressed to NASH and some 600,000 to NASH-related cirrhosis.

Shire does not expect the acquisition of Lumena to result in a change to its previously stated earnings guidance for 2014. (Source: Shire Website,12 May, 2014 and World Gastroenterology Organization Global Guidelines, June 2012).

Lysosomal Therapeutics Receives $4.8 Million in Seed Funding

Cambridge-based Lysosomal Therapeutics has announced it has raised $4.8 million in seed funding. Atlas Venture was the lead investor, with additional participation from Hatteras Venture Partners, Lilly Ventures, Sanofi-Genzyme BioVentures, Roche Venture Fund, Partners Innovation Fund and several angel investors, including Orion Equity Partners. LTI was founded by Dimitri Krainc, M.D., Ph.D., and former Genzyme executives Henri Termeer, Bob Carpenter and Peter Wirth. Kees Been is the founding president and chief executive officer of the company.

LTI's approach to discovering new drugs for neurodegenerative diseases is based on research performed in Krainc's lab at MGH. Recent genetic research suggests that GCase mutations, which cause Gaucher Disease (a lysosomal storage disorder), may also cause a predisposition to Parkinson's disease (PD). Lysosomal Therapeutics' initial research shows that restoring lysosomal function in human neurons of GD and PD patients may normalize the otherwise-elevated levels of alpha-synuclein found in PD.

In addition to its work with GD and PD, Lysosomal Therapeutics is investigating other lysosomal enzyme deficiencies and their respective genetic links to common neurodegenerative diseases. (Source: Lysosomal Therapeutics Website, 12 May 2014)

EMD Millipore Receives Grant from MLCS to Collaborate with Promethera Biosciences

EMD Millipore, headquartered in Billerica, has announced it has received a $400K grant from the Massachusetts Life Sciences Center (MLSC) to fund a partnership with Promethera Biosciences, a Belgian pharmaceutical company whose mission is to discover, develop, and commercialize cell therapy products to treat liver diseases in an innovative way. This is one of four grants given to life science companies in Massachusetts to fund international collaboration as part of MLSC's International Collaborative Industrial Program.

Through this collaboration, EMD Millipore's microfluidic technology will enable the researchers at Promethera to mimic the liver microenvironment long-term, allowing for increased consistency and scale-up potential for live cell models. Using liver stem cells provided by Promethera and EMD Millipore's microfluidic cell culture platform, both organizations strive towards improved preclinical liver toxicity testing methods. Current methods for liver toxicity testing are limited by technical challenges that the platform can address.

This effort will span many functions and sites within the EMD Millipore network, including experts (both business and technical) in cell analysis instrumentation, research content, cell culture systems, as well as a handful of external collaborations with pharmaceutical sites including sister-company EMD Serono. The partnership was conceived by and submitted to the MLSC by Tim Galitski, Head of Science and Technology at EMD Millipore and Phillip Lee, New Business Initiative Lead for microfluidic technologies. (Source: EMD Millipore Website, 10 March, 2014)

Boston Scientific to Acquire Interventional Division of Bayer AG

Boston Scientific has entered into a definitive agreement to acquire the Interventional Division of Bayer AG for $415 million in cash, including fees for transitional services. The company expects to close the transaction in the second half of 2014, subject to customary closing conditions. Upon completion of the transaction, Bayer Interventional will become part of the existing Boston Scientific Peripheral Interventions business.

Based near Minneapolis, Bayer Interventional has approximately 350 employees and offers a number of innovative technologies designed to treat coronary and peripheral vascular disease. In 2013, Bayer Interventional generated sales of approximately $120 million. The agreement calls for an up-front payment of $415 million.

Boston Scientific has also signed a definitive agreement to acquire IoGyn, a pre-commercial stage company. IoGyn has developed and received FDA clearance for the Symphion™ System, a next generation system for hysteroscopic intrauterine tissue removal including fibroids (myomas) and polyps. This acquisition enables the pairing of the Symphion System with the Boston Scientific Genesys HTA™ System for abnormal uterine bleeding, to create a compelling set of gynecologic surgery products. Boston Scientific estimates the current worldwide hysteroscopic market segment at $80 million, with projections that it will grow to more than $200 million by 2020. (Source: Boston Scientific Website, 06 and 15 May, 2014)

Sarepta Therapeutics Expands Presence in Massachusetts

Sarepta Therapeutics, a developer of innovative RNA-based therapeutics, announced an agreement to acquire a multifunctional manufacturing facility on 26 acres of land in Andover. This announcement came only weeks before the opening of the company's headquarters in Kendall Square. Sarepta intends to use the facility to manufacture investigational exon skipping therapies for Duchenne muscular dystrophy (DMD). The transaction comprises approximately $25 million in acquisition costs and planned enhancements, and is expected to close in July subject to conditions and extensions in the agreement.

The company plans to use the facility to further enhance and scale its proprietary manufacturing processes for PMO (phosphorodiamidate morpholino oligomer) chemistries. In addition, the facility will be used to manufacture drug supply to support clinical trials of Sarepta's exon skipping therapies for DMD, as well as research and development of future potential products and modified PMO chemistries. The multifunctional facility was constructed in 1996 and upgraded in 2006, and has been qualified under Current Good Manufacturing Practice (cGMP) regulations. When fully operational, the facility supports approximately 40 technicians and support staff. In addition, the acquisition includes 26 acres of land available for future potential expansion.

In addition to the new manufacturing space, the company's new Kendall square headquarters includes approximately 45,000 square feet of office and laboratory space capable of supporting early stage drug discovery and development. Since the relocation began, Sarepta has rapidly grown to approximately 160 employees, with nearly 90 based in Cambridge. (Source: Serepta Website, 22 May and 02 June, 2014)

Pfizer Opens New Research and Development Site in Cambridge

Pfizer has announced the opening of a new 280,000 square-foot R&D hub in Cambridge. The new Pfizer facilities in Kendall Square bring together 1,000 colleagues from three area locations and position Pfizer in closer proximity to leading academic institutions, hospitals and patient organizations.

Led by Pfizer Group Vice President of BioTherapeutics R&D, José-Carlos Gutiérrez-Ramos, Ph.D, the new laboratory facilities, located in the heart of Kendall Square at 610 and 700 Main Street, respectively, are leased from MIT. Pfizer scientists will work in state-of-the-art lab space on a range of clinical programs across several therapeutic areas, including inflammation, immunology, rare disease, cardiovascular and metabolic diseases, and neuroscience. (Source: Pfizer Website, 16 June, 2014)

Moderna Therapeutics Announces Expansion in Kendall Square

Moderna Therapeutics has expanded its facility to 320 Bent Street in Kendall Square, a move that adds nearly 50,000 square feet of office, laboratory and manufacturing facilities to Moderna's operations in Massachusetts. The new site at 320 Bent Street will house Moderna Venture Incubator laboratories, non-GMP production facilities and the relocated offices of Moderna's headquarters. The company's former headquarters at 200 Technology Square in Cambridge will remain occupied by Moderna and be dedicated to research and development and GMP manufacturing.

Since 2011, Moderna has received more than $1.4 million in tax incentives from the Massachusetts Life Sciences Center (MLSC) based upon commitments to create more than 70 new jobs in the Commonwealth.

The pace of Moderna's development is driven by progress with its research on the mRNA Therapeutics™ technology platform, its proprietary research programs, and the research programs of the organizations with which Moderna has

strategic agreements, AstraZeneca, Alexion Pharmaceuticals and DARPA (the Defense Advanced Research Projects Agency).

Moderna is accelerating the number of research programs using mRNA Therapeutics™, with 16 research programs currently ongoing. In addition, AstraZeneca will soon add another 15 programs to its eight programs already underway; and Alexion has initiated two programs since signing an agreement with Moderna in January and intends to add more programs soon. (Source: Moderna Therapeutics Website, 12 June, 2014)

FDA Approves Biogen Idec's Second Hemophilia Therapy

The FDA has approved Biogen Idec's Eloctate™ for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hemophilia A. Eloctate™ is the first recombinant hemophilia A therapy with prolonged circulation in the body. It is the only treatment for hemophilia A to reduce the frequency of bleeding episodes with prophylactic infusions every three to five days, offering people with hemophilia A the potential to extend the interval between prophylactic infusions.

The FDA's approval is the first regulatory approval worldwide for Eloctate™, and the therapy is currently under review by regulatory authorities in several other countries, including Canada, Australia and Japan. This FDA action follows regulatory approvals of Biogen Idec's hemophilia B therapy, Alprolix™ in the United States, Canada and Australia.

Hemophilia A is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired. This can lead to recurrent and extended bleeding episodes. Complications of bleeding episodes may range from severe swelling and pain to arthritis, joint damage, physical disability and death. According to the National Hemophilia Foundation (NHF) guidelines, traditional hemophilia A prophylactic therapy involves infusions three times per week or every other day, which equates to approximately 150 to 180 infusions per year.

Therapies for hemophilia A, the most common form of hemophilia, can be administered either on a schedule to help prevent or reduce bleeding episodes (prophylaxis), or to control bleeding when it occurs (on-demand). The NHF recommends routine prophylaxis as optimal for the treatment of people with severe hemophilia. In recent years, regimens have shifted from on-demand treatment to routine prophylaxis because of observed improvement in long-term clinical outcomes, such as joint damage. (Source: Biogen Idec Website, 06 June, 2014)

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.

Eli Lilly Wins FDA Approval for Drug for Stomach Cancer

The FDA has approved Cyramza (ramucirumab) to treat patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma, a form of cancer located in the region where the esophagus joins the stomach. Stomach cancer forms in the tissues lining the stomach and mostly affects older adults. According to the National Cancer Institute, an estimated 22,220 Americans will be diagnosed with stomach cancer and 10,990 will die from the disease, this year.

Cyramza is an angiogenesis inhibitor that blocks the blood supply to tumors. It is intended for patients whose cancer cannot be surgically removed or has spread after being treated with a fluoropyrimidine- or platinum-containing therapy.

The FDA reviewed Cyramza under its priority review program, which provides an expedited review for drugs that have the potential, at the time the application was submitted, to be a significant improvement in safety or effectiveness in the treatment of a serious condition. Cyramza was also granted orphan product designation because it is intended to treat a rare disease or condition. (Source: FDA Website, 21 April, 2014)

FDA Proposes New Program for Medical Devices that Address Unmet Needs

The FDA has proposed a new program to provide earlier access to high-risk medical devices that are intended to treat or diagnose patients with serious conditions whose medical needs are unmet by current technology.

The proposed Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions (EAP) program features earlier and more interactive engagement with FDA staff, including the involvement of senior management and a collaboratively developed plan for collecting the scientific and clinical data to support approval. These features, taken together, should provide patients with earlier access to safe and effective medical devices.

EAP is not a new pathway to market, but rather a collaborative approach to facilitate product development under the agency's existing regulatory authorities. While other existing device programs have focused on reducing the time for the premarket review, EAP also seeks to reduce the time associated with product development.

The EAP builds on the Innovation Pathway pilot, which the FDA launched in 2011, and the FDA's experience with expedited review programs for pharmaceuticals, including Accelerated Approval and Breakthrough Therapies. When utilizing the EAP program, the FDA will continue to apply the current approval standard of demonstrating a reasonable assurance of safety and efficacy. (Source: FDA Website, 22 April, 2014)

FDA Approves Drug for Rare Castleman's Disease

The FDA has approved Sylvant (siltuximab) from Janssen Biotech to treat patients with multicentric Castleman's disease (MCD), a rare disorder similar to lymphoma (cancer of the lymph nodes). MCD causes an abnormal overgrowth of immune cells in lymph nodes and related tissues in the body. The disease usually affects adults who often suffer from fever, night sweats, weight loss and weakness or fatigue because their body's immune system is weakened and cannot fight infections.

Sylvant is an injection that works by blocking a protein that stimulates abnormal growth of immune cells. It is intended for patients with MCD who do not have HIV or human herpes virus 8 (HHV-8).

The FDA reviewed Sylvant under its priority review program, which provides an expedited review for drugs that

demonstrate the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. Sylvant was also granted orphan product designation because it is intended to treat a rare disease or condition. (Source: FDA Website, 23 April, 2014)

Novartis Drug Approved by FDA for Late-Stage Lung Cancer

The FDA has granted accelerated approval to Zykadia (ceritinib) for patients with a certain type of late-stage (metastatic) non-small cell lung cancer (NSCLC). Zykadia is an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor that blocks proteins that promote the development of cancerous cells. It is intended for patients with metastatic ALK-positive NSCLC who were previously treated with crizotinib, the only other approved ALK tyrosine kinase inhibitor.

Lung cancer is the leading cause of cancer-related deaths among men and women. According to the National Cancer Institute, an estimated 224,210 Americans will be diagnosed with lung cancer, and 159,260 will die from the disease this year. About 85 percent of lung cancers are NSCLC, making it the most common type of lung cancer. However, only 2-7 percent of patients with NSCLC are ALK-positive.

The FDA is approving Zykadia under the agency'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, 08 May, 2014)

FDA Approves Entyvio for Ulcerative Colitis and Crohn's Disease

The FDA has approved Entyvio (vedolizumab) injection marketed by Takeda Pharmaceuticals America to treat adult patients with moderate to severe ulcerative colitis and adult patients with moderate to severe Crohn's disease. Entyvio is approved to treat those conditions when one or more standard therapies (corticosteroids, immunomodulators, or tumor necrosis factor blocker medications) have not resulted in an adequate response.

Ulcerative colitis is a chronic disease that affects about 620,000 Americans. It causes inflammation and ulcers in the inner lining of the large intestine and is one of two main forms of chronic inflammatory bowel disease. The inflammation can lead to abdominal discomfort, gastrointestinal bleeding, and diarrhea. (Source: FDA Website, 20 May, 2014)

FDA Approves First Gene-Based Test to Determine Red Blood Cell Types

The FDA has approved the Immucor PreciseType Human Erythrocyte Antigen (HEA) Molecular BeadChip Test, the first FDA-approved molecular assay used in transfusion medicine to assist in determining blood compatibility. The assay can be used to determine donor and patient non-ABO/non-RhD (non-ABO) red blood cell types in the United States.

The surfaces of red blood cells display minor blood group antigens in addition to the major ABO blood group antigens. Some people develop antibodies to non-ABO antigens following transfusion or pregnancy. This is especially true in people who may receive repeated blood transfusions, such as those with sickle cell disease. The development of such antibodies can cause red blood cell destruction if red blood cells with the corresponding antigens are later transfused.

The Immucor PreciseType HEA Molecular BeadChip Test is manufactured by BioArray Solutions of Warren, New Jersey. (Source: FDA Website, 21 May, 2014)

FDA Approves Dalvance to Treat Skin Infections

The FDA has approved Dalvance (dalbavancin), marketed by Chicago-based Durata Therapeutics, a new antibacterial drug used to treat adults with skin infections. Dalvance is intended to treat acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria like Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains) and Streptococcus pyogenes. The treatment is administered intravenously.

Dalvance is the first drug designated as a Qualified Infectious Disease Product (QIDP) to receive FDA approval. Under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act, Dalvance was granted QIDP designation because it is an antibacterial or antifungal human drug intended to treat serious or life-threatening infections. (Source: FDA Website, 23 May, 2014)

FDA Approves First Generic Versions of Pfizer's Celebrex

The FDA has approved the first generic versions of Celebrex (celecoxib) capsules, a treatment for rheumatoid arthritis, osteoarthritis, short-term (acute) pain, and other conditions. Teva Pharmaceutical Industries received approval to market celecoxib capsules in 50 milligram, 100 mg, 200 mg, and 400 mg strengths, and has 180-day exclusivity on the 100 mg, 200 mg, and 400 mg strength products. Mylan Pharmaceuticals, Inc. received approval to market 50 mg celecoxib capsules. (Source: FDA Website, 30 May, 2014)

FDA Launches openFDA to Provide Easy Access to Public Data

The FDA has launched openFDA, a new initiative designed to make it easier for web developers, researchers, and the public to access large, important public health datasets collected by the agency.

In alignment with the recent Presidential Executive Order on Open Data and the Department of Health and Human Services Health Data Initiative, openFDA will make the FDA's publicly available data accessible in a structured, computer readable format that will make it possible for technology specialists, such as mobile application creators, web developers, data visualization artists and researchers to quickly search, query, or pull massive amounts of public information instantaneously and directly from FDA datasets on an as needed basis.

OpenFDA utilizes a search-based Application Program Interface (API) to collect large amounts of existing publicly available data, offering developers the ability to search through text within that data, ranking results much like a search using Google would do. This method then allows them to build their own applications on top of openFDA, giving them a large amount of flexibility to determine what types of data they would like to search and how they would like to present that data to end-users. This enables a wide variety of applications to be built on one common platform.

The FDA will continually work to identify additional public datasets to make available through openFDA. More information can be found at open.FDA.gov or you can email the FDA for more information at open@fda.hhs.gov. (Source: FDA Website, 02 June, 2014)

New Members

Bruce Ackman, Spectra Automation

Mr. Janmeet Anant, *Regulatory Advocate*, EMD Millipore

Mr. Gerard R. Archambault, Jr., *Regional Sales Mgr.,* Pure H2O Technologies

Mr. Nathan Bartling, *Territory Manager*, Parker Domnick Hunter

Michael Chrin, *Process Controls Engineer*, Barry-Wehmiller Design Group

Francis L. Corden, Jr., *Director of Advanced Services*, New England Controls, Inc.

Ken Davis, *Regional Manager*, Monoflo

Mr. Roger W. Decker, *Product Manager Validation Services*, GEHC

Mr. Scott DeVinney, *Project Development Mgr.,* The Sherwin-Williams Company

Mr. John Diep, *Process Engineer*, NNE Pharmaplan

Mr. James C. Dunlap, *Student*, Cedarville University

Bryan Farley, *Directory PTS*, Shire

Mr. Randy Furmanick, *President*, Applewood Controls

Alexander J. Gikas, *Chemical Engineer*, Worcester Polytechnic Institute

Fahad S. Gilani, *Student*, University of Massachusetts Amherst

Mr. Daniel Gilsdorf, *Project Development Manager*, Sefar, Inc

Mr. Robert Hamilton, *Vice President*, Sefar, Inc

Ms. Lei He, *Student*, Massachusetts College of Pharmacy and Health Sciences

Ms. Melody J. Hebert, *Senior Director R&D Quality Systems QA*, Takeda Pharmaceuticals

Ms. Marcy Henderson, *Associate Director, Corporate Quality Assurance*, Vertex Pharmaceuticals

Mr. Robert C. Houser, *Product Manager*, SOTAX

Ms. Gabrielle Hunt, Northeastern University

Kinza Irshad, MCPHS University

Stephen R. Kelso, *Controls Engineer,* Barry-Wehmiller Design Group

Kosal Keo

Mr. Scott Leahy, *Technical Marketing Manager*, VACUUBRAND, INC.

Ms. Katherine Leitch, *Director of Engineering*, Alexion

Mr. Adam Lomnicki, *Project Manager*, Commodore Builders

Mr. Eric McCracken, *Sales Executive*, CSSI

Ms. Carmen M. Medeiros, *Student*, MCPHS University

Douglas Meyer, Biogen Idec

Mr. Ryan P. OConnell, *Student,* New England Institute of Technology

Bhaumik Parekh, *Validation Engineer*

Mrs. Cristin M. Perrault, *Engineering Administrative Asst/Librarian*, Atrium Medical Corporation

Mr. David M. Peters, *General Manager*, Elliott Controls, Inc.

Thirunarayanan Puliyampatti

Mr. Martin Razo, *Manager*, Sanofi Pasteur

Mr. Michael A. Rexhouse, *Junior Process Engineer*, DPS Engineering

Mr. Periklis G. Sarakiniotis, *Student*, Boston University

Mr. Dhaval Shah, *Commissioning & Validation Engineer*, New Jersey Institue of Technology

Omar Siddiqi, *Validation Engineer*, Shire Pharmaceuticals

Ms. Michelle Vegliante, *Pharmacy Intern Technician*, University of New England College of Pharmacy

Member Anniversaries

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp

Mr. John P. Alleruzzo

Mr. Joseph M. Baumann, Genzyme Corp

Mr. Simon Bedigian, Olympic Systems Corp

Dr. James V. Blackwell, PhD, MBA, The Windshire Group, LLC

Mr. Richard F. Caires, Jr., Shire HGT

Mr. John G. Campion, P.E., The Hart Companies

Mr. Richard P. Capobianco

Mr. Ronald C. Case, Aztec Technologies, Inc.

Mr. Michael S. Cheney, Biogen Idec

Mr. Brian L. Clark, GMP Operations Consulting

Mr. Bud Clauer

Mr. Donald Cole, Hart Passivation Services, Inc.

Dr. Charles L. Cooney, Massachusetts Institute of Technology

Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation

Mr. Andrew A. Coull, JM Coull Inc

Michael B. Cronin, Alexion Pharmaceuticals

Mr. George A. Dainis, P.E., Industrial Facilities Design Inc

Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. Edward F. Dean, III, Eagle Electrical Supply Co

Mr. David Dears, Victaulic

Mr. Frederick C. DeCicco, Sharpe Mixers

Mr. William O. Downie, AstraZeneca

Mr. Brian P. Druce, Genzyme

Mr. James R. Dube, Alexion Pharmaceuticals

Mr. Daniel J. Dumont, Dynamic Systems Inc

Mr. Mostafa N. Elmorsi, Boehringer Ingelheim Pharma

Mr. John H. Evers, Lantheus Medical Imaging

Mr. Ric Feldt, Jeff Smith & Associates

Mr. Timothy J. Fields, Protein Sciences Corporation

Mr. Michael J. Fisher, Genzyme, Sanofi

Mr. Christopher J. Fournier, Mar Cor Purification

Mr. Joshua Froimson, AbbVie Bioresearch Center

Mr. Michael S. Giorgetti, Sr., Alkermes Inc

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

Mr. Andrew R. Hahn

Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz

Mr. Edwin L. Harmon, III, Genzyme Corp

Mr. David G. Harney, Microfluidics

Mr. Richard R. Harper, Flow Tech Inc

Ms. Shelly Henderson, HCA

Mr. Paul F. Herbert, Alkermes Inc

Mr. Stephen R. Higham, PE, Genzyme Corp

Mr. Johnson Hoey, Forest Laboratories, Inc.

Mr. Mitchell I. Hollander, Lantheus Medical Imaging

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

Mr. Robert W. Juffras, MS, Olympus Biotech

Ms. Pauline Jurasinski, Genzyme a Sanofi Company

Mr. Jerome E. Justin, Shire Pharmaceuticals

Mr. Frank J. Kuszpa, Jr., Jones Lang LaSalle

Mr. Stephen P. Kuzil

Mr. Thomas G. Larkin, Amgen Inc

Mr. Thomas H. Lauzon, ImmunoGen Inc

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

Mr. Richard V. Levy, PhD, PDA

Peter F. Levy, PL Consulting, LLC

Mr. Robert M. Luke, Georg Fischer Inc

Mr. William C. Lynch

Mr. Allan J. MacDonald, CPIP, BosBio

Mr. Frank J. Manning, VNE Corp

Mr. Daniel J. Mariani, M+W Group

Mr. Denis M. Mathiowetz, DM BioPharm Associates Inc.

Mr. Gary E. McKiernan, PM Group

Mr. Todd McLaren

Ms. Lynda S. Miller, Eisai, Inc.

Stephen P. Miraglia, Sapphire Project Services LLC

Mr. Hank Moes

Mr. David Monette, Olympus Biotech

Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc

Mr. Thomas W. Moss, Integra Companies

Mr. Armen J. Nahabedian, Pfizer

Mr. Russell B. Parry

Mr. Christopher R. Perley, Dyax

Mr. Peter A. Petrillo, Millennium Facilities Resources Inc

Mr. Stephen R. Potter, Baxter

Mr. Tim J. Potvin, PE, Quality Air Control

Mr. Richard D. Priester, Strategic Facility Planning LLC

Dr. John J. Prior, Genzyme Corp

Mr. Douglas A. Queen, TRG Builders LLC

Mr. Thomas A. Ramundo, New England Controls Inc

Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc

Ms. Cheri M. Redman, Amgen

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

Mr. Scott Ripatrazone, Insco Group

Mr. Stephen P. Rossmeisl

Mr. Stanley E. Rotkiewicz, Jr., Genzyme Corporation

Mr. Tom J. Routliffe, Medimmune

Mr. Paul E. Rowe, Millipore Corporation

Mr. John J. Rozembersky, Rozembersky Group

Mr. Gregory M. Ruklic, Independent

Mr. Pasquale M. Sacco, Shire HGT

Mr. William S. Seaver, TEK Stainless Piping Products

Mr. Michael J. Severino, Festo Corporation

Mr. Robert J. Sheehan

Mr. Peter K. Silverberg, Abec, Inc.

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

Mr. Michael G. Sprague, Ethide Laboratories

Mr. Michael J. Sweeney, Hart Design Group

Mr. David A. Tomsik, CRB Consulting Engineers

Dr. Donald L. Towns, Donald L Towns Professional Engineer

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. Jeffrey L. Werner, BFS Pharma Inc

Mr. James L. Whalen, Watson-Marlow Flexicon

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Jay F. Zaino, GxP Automation LLC

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

15 Year Anniversary

Mr. Gerard P. Creaner, GetReskilled, Inc.

Mr. Christopher J. Gallagher, Applied Water Solutions, Inc.

Mr. John C. Kyranos, Shire

10 Year Anniversary

Mr. Michael Calorossi, MannKind Corporation

Mr. Richard Morin, Millipore

Mr. William Pietrusiak, Cypress Color & Chemical Inc

Mr. Brian Pochini, CPIP, Genzyme, A Sanofi Company

Mr. Thomas H. Spooner, Amgen Inc

Mr. Peter Vandergraaf, Q-mation

Ms. Jillian M. Willard, Genzyme Corp

Mr. Edward I. Winnett, Validation Techologies Inc

Mr. Gary T. Woods, Crosspoint Engineering Corp

5 Year Anniversary

Ms. Nancy A. Borgeson, Pfizer Inc

Dr. Robert R. Boulanger, Jr., Protein Sciences Corp

Mr. Paul J. Doherty, CRB Builders

Mr. David M. Dube, Momenta Pharmaceuticals

Mr. Robert B. Fitts, Spraying Systems Company

Mr. John Hanly, Pfizer Inc

Mr. Erik W. Swanson

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