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NEWSLETTER

November 2013, Volume XXIII, No. 6

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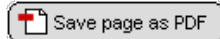


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President's Message: Thanks to All Who Made the Product Show a Huge Success!



Dear Boston Area Chapter Members,

So the Boston Area Chapter has done it again, kicking off the year by setting new trends and records. For those who didn't participate in the Annual Product Show at Gillette Stadium on October 2, you missed a world class event. Every year the event continues to break its own records. The all-day event featured educational sessions, product showcases, almost 2400 attendees including 120 students, over 350 exhibitors and a keynote address from Bob Coughlin, President and CEO of the Massachusetts Biotechnology Council.

I'd like to give special recognition to the Product Show Committee which works the entire year to support and organize this outstanding event. The committee is chaired by H. Steven Kennedy with co-chair Laurie Masiello. For its success, this

event relies on close coordination between the Product Show, Educational Program, Social, Young Professional and Student Development Committees. The Chapter is indebted to Steve, Laurie and the hardworking volunteers on all of these committees - the Product Show couldn't succeed without them! And let's not forget our many exhibitors, presenters and last - but by no means least - our attendees. Thank you for participating in record numbers!

In an effort to recognize the contributions of our volunteers and Members, the Boston Area Chapter has implemented a new awards program. The program was introduced at the Product Show where I had the privilege of recognizing some of our key Members and volunteers. I'd like to thank the award recipients for their contributions and for their dedication to helping the Chapter achieve its success:

Student Chapter of the Year – Worcester Polytechnic Institute

Volunteer of the Year – Andrea Massa, Bürkert Fluid Controls Systems

Volunteer of the Year – Sean Burgess, Integrated Builders

Outstanding Achievement – Brian Hagopian, CPIP, Clear Water Consulting

In keeping with its record breaking trends, the Chapter continues its growth and now boasts 1750 Members, making it far and away the largest Chapter in the world. This is a credit to all the Boston Area Chapter volunteers who continue to work to provide services to our Members year round.

As announced at the Product Show, the Chapter has formed a new Geographic Outreach Committee (GO) to integrate and coordinate the services that we provide throughout the newly expanded Boston Area Chapter. For the first time we will be providing educational and social events to regions outside of the greater Boston area. The first piloted event will be held in November and the GO Committee is anticipating a full launch of the program in early 2014. The Member Survey completed in October will help the GO Committee with their plans. To those who completed the survey – thank you for your input!

I look forward to being able to continue to bring great news about the Chapter as we close out 2013 and roll into 2014. Again, thank you to everyone who has been volunteering, participating and providing input. It is your involvement that continues to make the Boston Area Chapter a globally recognized leader within ISPE.

Thank you,

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Dan Ramsey
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Beloved Chapter Member Tillus Beverly Passed Away on November 6

ISPE Boston Area Chapter Member Tillus Beverly passed away in the early morning hours of Wednesday, November 6 at his home in Salem. He was 37 years old and it is suspected that he died from a heart attack.

Tillus was born in the Philadelphia area and graduated with bachelors and masters degrees in chemical engineering from Lehigh University, the latter while working for Sanofi Pasteur in Swiftwater, PA. After moving to Massachusetts, he jumped into Chapter events immediately, and soon found employment as a validation engineer at Innovative Process Solutions with a long term assignment at Amgen.

In the words of co-worker Keith Gibbs, "...knowing Tillus was to like him and admire him. He was full of vitality - he bounced when he walked, spoke with energy and enthusiasm about nearly everything, and always wore a broad smile."

Congratulations to Our Newest Certified Pharmaceutical Industry Professionals

The Chapter continues to lead the way with the CPIP program, with the fall study group well underway at Pfizer. And this month, we are pleased to congratulate another four Boston Area Chapter Members on attaining their CPIP credential.

- Michele Cheslek, CPIP – Genzyme
- Daniel Haun, CPIP – Commissioning Agents
- Robert Mitchell, CPIP – Robert Mitchell Engineering
- Rusty Morrison, CPIP – Commissioning Agents

Look for the fall study group to start adding to the Chapter's CPIP ranks soon!

As you may already know, ISPE has decided to convert the CPIP program to a recertification only program. The Chapter will be working closely with ISPE while the program's future course is developed. We will keep Members updated on results of this process as they become available. For more information on the CPIP program, please visit <http://www.ispe-pcc.org> or contact the Chapter office at (781) 647-4773 or office@ISPEboston.org and we'll be happy to help.

Scholarship Application Deadline November 15 – Don't Be Late!

The ISPE Boston Area Chapter offers a scholarship program for the benefit of Members and their families who are pursuing formal education in the life sciences with preference given to those students planning careers in the biopharm industry or related fields. (For the purposes of this program, life sciences is defined as any branch of science or engineering that deals with or can be applied to living organisms and life processes.) Scholarship awards of up to \$2000 are available for qualified applicants. Congratulations to our most recent scholarship winners, announced in September. This outstanding group includes entering freshmen, undergraduates and students working toward advanced degrees:

- Anatoly Tereschuk, UMass Amherst

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- Callie King, Worcester Polytechnic Institute
- Noreen Rizvi, Northeastern University
- Catherine Gikas, Boston University
- Lorraine Mathis, Tufts University
- Samuel Musiak, UMass Lowell
- John Busanovich, Boston College

Who is eligible? Eligible recipients must be enrolled in an accredited college or university's associates, bachelors or masters program and/or registered in a course at an accredited college or university. Three categories of individuals may apply:

- Incoming freshmen - Incoming freshmen who are the children of a Boston Area Chapter Member in good standing and are pursuing formal education in the life sciences. Preference will be given to candidates planning a career in the biopharm industry or related fields.
- Undergrad and grad students - Students entering their sophomore through senior years of undergraduate study or students entering or continuing post graduate study. These candidates shall be Members in good standing of the Boston Area Chapter pursuing a degree in the life sciences. Preference will be given to candidates planning a career in the biopharm industry or related fields.
- Continuing education - Individuals seeking continuing education as part of their career development. These individuals shall be Boston Area Chapter Members in good standing.

The next deadline is November 15th so apply today!

[Click here](#) for more information and an application. If you have any additional questions call the Chapter office at (781) 647-4773 or email office@ispeboston.org.

eNewsletter Advertising Space Now Available

Now that the Boston Area Chapter has grown to include over 1600 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!

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!

Student Members Now Attend Chapter Educational Programs at No Charge

The Chapter's Board of Directors has gone "all in" when it comes to providing pathways for students and young professionals to become actively involved with ISPE. In its latest effort to encourage a high level of participation by these industry leaders of the future, the Board has voted to allow Student Members to attend Chapter educational and related events for free. An earlier vote enabled Young Professional Members to attend at a discounted rate: \$20 for early registration and \$30 after that date. Membership in the Boston Area Chapter truly does have its privileges!

Upcoming Chapter Events - Mark Your Calendar

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Thursday, November 14, 2013

The Massachusetts Biotech Super Cluster. A Panel Discussion on Trends in Real Estate Development

Genzyme Center, 500 Kendall Street, Cambridge, MA

It has been an eventful few years watching the economic engine that is BioTech lead the Massachusetts economy in our region and some would argue, globally. Join us for an interactive and informative evening with industry leaders representing many of the best and brightest firms in our area. Interact with individuals with wide and varied backgrounds in Real Estate Development, Government Affairs, Design, Real Estate Brokerage and the Owner as we take a look back at what drives our development which supports our innovation economy. Learn about the combined efforts of professionals within these fields that help define and shape the future of our tech cluster and provide innovative work spaces for the next wave of discovery and support the path to the clinic and ultimately commercial launch. Consider the latest industry metrics for job growth and development in our cluster as it relates to other global clusters of innovation. Our panel will consider the impact of individual projects within the major regions of our cluster including Cambridge, South Boston, 128 and 495 West while discussing the impact of economic incentives, lease rates, design requirements and the influx of investments and M&A activity.

This program is designed with audience participation in mind so please bring your questions and observations.

Register by 5:00pm today or Walk-ins will be accepted

onsite: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=298

Thursday, December 12, 2013

Engineering Project Management

Biogen Idec, 14 Cambridge Center, Cambridge, MA

In the biopharmaceutical industry, almost every project requires a Project Manager (PM) and an Engineering Professional. Although both work towards a common goal they don't necessarily see "eye to eye" using the same success criteria. Many such differences stem from each person's experience, perspective and responsibilities.

Engineers honor their professional rigor and best practices. Project Managers balance the best interests of stakeholders and functional areas, while meeting the triple constraints of scope, cost, and schedule to deliver a high quality product, service or result.

This program will address ways for the PM and the Engineer to work better to meet the overall objectives of a successful project. The use of various tools, techniques and enhanced overall project knowledge will be the focus.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=379

Sneak Preview of Upcoming Events

Thursday, January 16, 2014

Educational Program focusing on Soft Skills

Thursday, February 20, 2014

Educational Program focusing on Standards, Practices, and Guides

22nd Annual ISPE Boston Area Chapter Product Show Breaks All Records

by H. Steven Kennedy, Co-Chair Product Show Committee, photos by Alastair Battson Photography

The 22nd edition of the ISPE Boston Area Chapter Product Show held at Gillette Stadium on October 2 was a rousing success. 2305 industry professionals and students – over 300 more than the previous record – came out on a gorgeous Fall day to participate in the event's many and varied activities. The student turnout of 150 was a special achievement, facilitated by six buses that made round trips between Gillette and our Student Chapter locations, courtesy of ISPE.

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A perfect October day welcomed Product Show attendees to Gillette.

The Show sold out even though we dramatically expanded the number of exhibitors to 355 this year. With the increase, we expanded the exhibit space and activities to clubhouses on both the east and west sides of the stadium. A show within a show, the annual Career Fair had many of the area's leading firms meeting with potential new employees throughout the day in an area redesigned for increased privacy. By all accounts, both exhibitors and attendees were excited and enthusiastic about all the changes. One exhibitor summed it up perfectly using a football metaphor when he enthused, "Let's face it – this is the Super Bowl of product shows!"



This year vendor exhibits filled clubhouses on both the east & west sides of the stadium.

A highlight of the Show was the annual Plenary Session. Chapter President Dan Ramsey gave the State of the Chapter address, reporting that the Chapter is financially sound, growing at a record rate and is now the largest ISPE Chapter in the world. He laid out his vision for the coming year, focusing on initiatives to facilitate the expansion of the Boston Area Chapter's region to all of New England. He wrapped up his presentation with awards recognizing volunteers who have made exceptional contributions to the Chapter in the last year:

- Outstanding Achievement: Brian Hagopian, CPIP, Clear Water Consulting
- Volunteer of the Year: Andrea Massa, Bürkert Fluid Control Systems
- Volunteer of the Year: Sean Burgess, Integrated Builders
- Student Chapter of the Year: Worcester Polytechnic Institute

...And congratulations to the latest winners of the Chapter's Joel Goldenberg Memorial Scholarship Program. This outstanding group includes entering freshmen, undergraduates and students working toward advanced degrees.

- Anatoly Tereschuk, UMass Amherst
- Callie King, Worcester Polytechnic Institute
- Noreen Rizvi, Northeastern University
- Catherine Gikas, Boston University

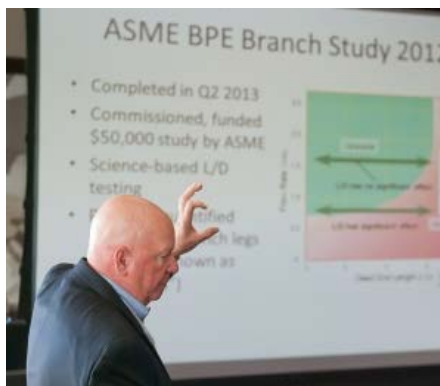
- Lorraine Mathis, Tufts University
- Samuel Musiak, UMass Lowell
- John Busanovich, Boston College



The plenary session featured an outstanding keynote address by Robert Coughlin of MassBio.

Following Dan's presentation, Keynote Speaker Robert Coughlin, President & CEO of the Massachusetts Biotechnology Council (MassBio), regaled us with a keynote address – equal parts informative and entertaining - about the state of the biopharm industry and its future and his personal connections to ensuring its success. Bob is very familiar with all areas of the Massachusetts life sciences super cluster and is a passionate advocate for research and the biotechnology community. He took the opportunity to applaud the important role played by the Boston Area Chapter locally and backed up his comments by joining ISPE on the spot! All agreed he was one of the best keynote speakers we have ever had at the Show.

If 355 exhibitors weren't enough to keep attendees busy, a full slate of education and training events were offered throughout the day. The 10:30am and noon educational sessions featuring This Old Plant, How Leaders are Harmonizing Our Industry Standards, Single Use Technologies: Real Life Experiences, and Biotech 101 were all very well attended, with standing room only crowds. A career development panel on the topic What you should know about the Life Sciences Marketplace attracted an equally large crowd during the afternoon. Rounding out the day, the Massachusetts Life Sciences Center laid out their Internship Challenge Program designed to create hundreds of new internship opportunities each year by enabling small businesses to hire paid interns. Product demonstrations by ATMI Life Sciences, Commissioning Agents, M+W Group, E+E Elektronik, FIKE, UFP Technologies, OnCode and SPS Cleantech were held in the Vendor Showcase area on alternating stages throughout the day and the winners of the 2013 Student Poster Competition were on hand to answer questions about their research.



Hot-button topics drew standing-room-only crowds to the morning & afternoon educational programs.

Of course, it wouldn't be a Boston Area Chapter Product Show without our fun networking activities. This year we had live music provided by three bands at Pharma-palooza. Attendees had opportunities to have their picture digitally taken "on the field" at Fenway or Gillette, interact with a roving magician or get a digital caricature. And when the exhibitor floor closed at 7:30pm, 680 people joined us at the nearby Bar Louis for

drinks, appetizers and a chance to meet New England Patriots #22 - Stevan Ridley.



Meeting with friends & colleagues is a big reason many attend the Show every year.

The Chapter is proud to be able to offer this world class event free of charge for attendees, supported in full by our generous exhibitors. This includes free parking, free admission, free food and soft drinks, free educational seminars, and free Pats player autographs. The Product Show is our Chapter's flagship event and the revenue it generates funds the Chapter and enables us to do many worthwhile things for our Members. So, on behalf of the Chapter, thanks to all our exhibitors for your continued support. We look forward to your participation next year and encourage you to pre-register and send in your deposit as soon as possible. Doing so will allow you to pick your booth early, as soon as registration opens early next year.



Live music was an added attraction this year.

An event like this does not happen without a lot of help from a lot of people. Our volunteers are the backbone of the Chapter. The Product Show Committee has already started work on next year's Show. If you would like to join the committee and help plan for next year, please contact the Chapter office at (781)647-4773 or office@ispeboston.org. We are always looking for new people to help make the Show bigger and better every year.



The after-party drew 680 to Bar Louis including Product Show Committee Co-Chair

Laurie Masiello, shown here with Pats running back Stevan Ridley.

If you weren't able to attend this year's Product Show, you missed the event of the season but don't despair – there's always next year! To all those who did attend, thank you. We look forward to seeing everyone on October 1, 2014 at Gillette Stadium for the 23rd edition of the Boston Area Chapter Product Show. Be there!

Standing Room Only for Product Show Educational Programs

by Sean Brown, Barry-Wehmiller Design Group, and Mike Levesque, Commissioning Agents, with photos by Alastair Battson Photography

The Product Show always provides a great chance to get the latest information on a variety of topics of interest to our industry and this year's event was no exception. In concert with expanded vendor participation, this year's educational offerings enjoyed great attendance and lots of interactive dialogue between the participants and speakers, demonstrating that, once again, the Chapter's Educational Program Committee (EPC) had chosen topics that were both popular and thought-provoking.



"This Old Plant..." drew a crowd during the morning educational session at Gillette.

The educational program created a competitive environment in the spirit of the Gillette Stadium venue, with the morning and early afternoon sessions each providing two presentations at the same time. During the morning time slot, the always popular "This Old Plant - Performing Projects and Manufacturing Operations Concurrently" vied with "How Leaders are Harmonizing Biopharm Industry Standards." During the afternoon, "Single Use Technologies - Real Life Experiences" competed with "Biotech 101: A Bird's Eye View of the Basics." The good news? All the presentations drew a record number of attendees!

Led by Integrated Process Technologies Senior Process Engineer Rick Kotosky, P.E. and Educational Program Committee Member and Hargrove Life Sciences New England Operations Senior Project Manager John Spohn, CPIP, the always popular topic of "This Old Plant" had an engaged group of industry experts discussing the topic most companies are facing as expansions and renovations create opportunities to repurpose existing space to support expansion.

The competing topic during the morning slot was "How Leaders are Harmonizing our Biopharm Industry Standards" which focused on several industry guidances required to design, install and maintain bioprocess systems. Included was a review of the ASME Bioprocess Equipment (BPE) Standard and several communities of practice that harmonize existing standards to address emerging issues that present challenges to manufacturing companies. The topic was presented by Sean Brown, Director Life Sciences, Barry-Wehmiller Design Group, with speakers Jay Ankers, Director of Technology at M+W Group and Frank J. "Chip" Manning, Director of Sales, Biopharmaceutical Products at VNE Corporation.

The afternoon session featured "Single Use Technologies - Real Life Experiences" which included information about choosing disposable processing equipment for biotech plants and a one-of-a-kind panel discussion by top experts who shared their experiences introducing single-use technology into their biotech manufacturing processes. This session was presented by EMD Millipore Single-Use Systems Engineer Pietro Perrone, P.E. and the panel which included Mauricio Barraza, Senior Manager of Facilities at Acceleron Pharma, Mark McElligott, Partner/Principal Process Engineer at Process Design Solutions, and Patrick Mullin, Validation Engineer at Genzyme.

Competing for attention during the afternoon session was "Biotech 101: A Bird's Eye View of the Basics." Always a popular topic, Biotech 101 attracts all experience levels so it was no surprise that Lou Traglia of Commissioning Agents presented to a standing room only crowd at noon. Lou provided an exemplary bird's eye overview of the processes required for the biotech industry. Through real world examples, equipment pictures, tangible sample products and helpful visuals Lou simplified a very complex topic. Questions from the audience were sprinkled throughout his presentation and at the end attendees requested copies of his slides for future reference.

This year's Product Show offerings reflect the Educational Program Committee's efforts to present topics aligned with the ISPE CPIP (Certified Pharmaceutical Industry Professional) focus areas. As the EPC looks forward to future educational programs we are always looking for new volunteers to bring a fresh perspective and new ideas to our planning efforts. If you would like to contribute, please contact the Chapter office at (781)647-4773 for an invitation to an upcoming EPC meeting.

Chapter's New Annual Awards Presented at Product Show

by Janet Tice, GMP Piping with photos by Alastair Battson Photography

In an effort to bring added recognition to the exceptional contributions of its volunteers, the Boston Area Chapter has introduced a new annual awards program. And the Annual Product Show – the Chapter's flagship event – provided a perfect opportunity to present the first awards.

The Volunteer of the Year Award recognizes Chapter Members who have demonstrated a high level of dedication to the Chapter's goals and who, through their dedicated effort and involvement over the past year, have enabled the Chapter to accomplish those goals. This year's winners are Andrea Massa, Bürkert Fluid Control Systems, for her efforts on behalf of the Chapter's Young Professionals; and Sean Burgess, Integrated Builders, for his contributions to the Product Show and Student Development Committees.



Chapter President Dan Ramsey with Annual Award recipients (counter clockwise from above, left) Brian Hagopian (Outstanding Achievement), Andrea Massa & Sean Burgess (Volunteer of the Year) and Bielinsky Brea on behalf of WPI (Student Chapter of the Year).

The Outstanding Achievement Award is awarded to a Chapter Member, group of Members or committee that has accomplished a specific task or completed a discrete project during the past year that has significantly contributed to the Chapter's success. This year's winner is Brian Hagopian, CPIP, Clear Water Consulting, who is being recognized for his contributions to the CPIP study groups and student development.

The Student Chapter of the Year Award is presented to a Student Chapter that has distinguished itself during the previous year by bringing significant value to its Student Members and has participated in Boston Area Chapter student-related activities to the greatest extent possible. This year's winner is the Worcester Polytechnic Institute Student Chapter.

September Program on SIP/CIP Draws a Crowd to Genzyme

by Eric Felz, Genzyme Corp

The topics of steam-in-place (SIP) and clean-in-place (CIP) are always of keen interest to Chapter Members

and the recent dual-track program was no exception, drawing over 80 Members and guests to Genzyme in Framingham on September 19. Attendees could choose between a back-to-basics introduction to the topic with "Going Back to School on Cleaning and Sterilization Processes" or a roundtable discussion designed for experienced practitioners in the field.



Students and young professionals turned out in force for the dual-track program which featured a back-to-basics intro to CIP/SIP designed for those new to the industry.

Following the traditional networking reception, the evening began with opening remarks by Boston Area Chapter President Dan Ramsey and Program Manager Eric Felz who introduced the presenters, Dawn Tavalisky of Genzyme for the introductory session; and roundtable leaders Phil Boncer from Shire Pharmaceuticals and Steven Wiles from Hyde Engineering & Consulting.

Dawn brought her energy, knowledge and experience to a packed house for the "Going Back to School..." introduction. Based on her experience at Merck, Stryker, Sanofi and Genzyme she was able to use stories from the "real world" to make the basics come alive. Although the night was late, her excitement kept the audience on their toes and her well-chosen examples added a unique dimension to her presentation and made the fundamentals easier to understand and relate to.

While Dawn brought those relatively new to the topic up to speed, Phil and Steve led a lively roundtable discussion designed for those already in the know, with as much to contribute as to learn. The round table format was chosen to allow attendees to interact with the panel and with one another while addressing current industry issues, not just scraping the surface but digging deeper using the collective knowledge of everyone in the room. As expected, a wide range of topics was touched upon, from rouge to autoclave qualification methodologies and more, and the dynamic, interactive format allowed all participants – including those with the most knowledge and experience – to gain new insights.

In summary, the dual-track program provided an opportunity to come up to speed on the basics or explore the details through in-depth conversations with experienced practitioners. In this way, it was able to serve the needs of two distinctly different groups of Members equally, industry newbies still learning the basics and experienced veterans honing their knowledge to keep up to date with the latest developments in the field.

The Boston Area Chapter and Program Manager Eric Felz would like to thank the panelists, speaker and audience members for their valuable contributions to this program and Genzyme for providing the venue for this event.

Fall Social Celebrates an Early Halloween in True Fashion

by Fasha Onorato, R.W. Sullivan Engineering, with photo by the ISPE Boston Office

On a cool October night, the Boston Area Chapter celebrated its Fall Social with the fitting theme of "Halloween" at Flat Top Johnny's in Kendall Square. The restaurant was spookily clad with ghosts, skeletons, cob webs and bones as attendees enjoyed creative costumes donned by their fellow ISPE dwellers. Delicious food was consumed as Members and non-members played pool and danced the night away to a deadly mix crafted by DJ Supakent. With over 50 people in attendance, Kendall Square was buzzing with great people, great conversation and innovative attire (including a peacock)! It was a wonderful way to celebrate the holiday and acknowledge everyone's hard work and commitment to our great Chapter.



Costumes added to the fun at the Chapter's fall social in Kendall Square.

A special thank you to Social Committee members Mark Levanites (Sequence Inc), Fasha Onorato (R.W. Sullivan Engineering), and Paul Sullivan (R.W. Sullivan Engineering) for their tireless efforts at putting together a spine-chilling event for the Chapter. And thanks to everyone who took one eye off the Red Sox game to join in the fun. For additional photos, please visit the Chapter website at www.ispeboston.org.

Clear Sailing for Young Professionals Annual Harbor Cruise



by John Hickey, Biogen Idec

Expectations were high for the 2013 Young Professionals Annual Harbor Cruise after the event was overbooked in advance of the event. With pleasant weather and beautiful views of Boston's waterfront and skyline from aboard the Boston Belle, the event lived up to the hype. Professionals of all ages enjoyed a great night on the water aided by Captain Mike's specialty cocktails and bottled beverages.

After reaping the rewards of some compulsory networking upon arrival, Chapter Members settled in for an enjoyable evening on the water. New Members on their first boat cruise loved the easygoing networking atmosphere and really enjoyed how approachable everyone was. Meanwhile, our more experienced professionals said that they really enjoyed the energy that the new Members brought to the night.

Chapter President Dan Ramsey thought the evening was a phenomenal success as well. "Andrea and the Young Professionals Committee really came through and put on a great event tonight. And it's great to have the Young Professionals getting so involved in the organization. They represent the future of the Chapter and their active involvement showcases how bright that future really is." We will certainly be looking forward to that, as well as next year's boat cruise Dan!

Students Turn Out in Force for the Annual Product Show

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

The Chapter started off the fall semester with lots of activities for students. Membership drives and student meetings were held at WPI, UMass Lowell, UMass Amherst, and University of Rhode Island to introduce students, faculty, and administrators, deans and career center staff to the benefits of ISPE.

Product Show This year, the Chapter sent buses to six of our Student Chapters (one provided their own transportation) and brought over 150 students to Gillette Stadium for the 22nd Annual Product Show on October 2. Thanks to Sean Burgess for coordinating this very successful effort and congratulations to UMass Amherst, UMass Lowell and University of New Hampshire for the highest participation!



Over 120 students attended this year's Product Show on October 2.

The Show was a great learning experience for the students who attended. They got the chance to see first-hand some of the career paths they could follow as well as being exposed to current state-of-the-art products and services. Many attended the Career Fair, where they had a chance to meet with operating companies looking for high-quality candidates to fill job openings. Another big draw was the presentation on the Internship Challenge Program by Ryan Mudawar of the Mass Life Sciences Center. The MLSC program subsidizes summer internships at small companies (less than 100 employees) and is one of the many ways Massachusetts is investing in the local life sciences industry. And Student Chapter leaders met together in one of Gillette's luxury boxes to share ideas and learn more about the Chapter's planned activities for the upcoming year.

Toward the end of the Show, students had the opportunity to meet and mingle at the Young Professionals Social where they were able to learn about opportunities and experiences in the local life sciences marketplace from recent graduates. Everyone walked away excited about having attended the Product Show and with a new appreciation for all the benefits offered to students by ISPE and the Boston Area Chapter.

Scholarship Update And speaking of benefits, the next round of scholarship applications is due on or before November 15. The Chapter has \$10,000 in scholarship funding to award during this period, so don't miss out. Be sure to visit the Chapter website [here](#) for eligibility requirements and to download an application.

Lots of Student Events This Year The Chapter has a full slate of student activities on tap for the fall and spring semesters:

- A mid-November student-centered educational program and plant tour at Genzyme in Framingham. [Click here](#) to check the Chapter's event calendar for the exact date and details about the program.
- February 8 Career Fair at Northeastern designed to prepare students to interview and make the right first impression in order to land internships, co-ops and jobs.
- March plant tour – keep an eye on the online event calendar for further information.
- April 17 Annual Student Poster Contest and dual track educational program at WPI's new Biomanufacturing Education and Training Center in Worcester.

Calling All Poster Contestants Do you have research or a project you want to share? Start planning now and participate in the Chapter's Annual Poster Contest which will be held at WPI on April 17 in conjunction with one of our monthly educational programs. Display your work and meet industry movers and shakers. Winners will receive an expense-paid trip to the ISPE Annual Meeting to compete for cash and other prizes at the International Student Poster competition where graduate and undergraduate category winners will be selected. This past year, students from Northeastern swept the local competition, making it two years running! Congratulations to Northeastern - but now it's time for the rest of our Student Chapters to step up! See the Chapter website or contact our office at office@ispeboston.org for details.

Students Attend ISPE Educational Events For Free And remember, once you join ISPE as a Student Member (<http://www.ispe.org/membership>), 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.

Roche to Invest \$880 Million Swiss Francs to Increase Biologics Output

Roche has announced plans to invest 800 million Swiss francs within its global manufacturing network to increase production capabilities for its biologic medicines over the next five years. The investment will be spread across sites in Penzberg (Germany), Basel (Switzerland), as well as Vacaville and Oceanside (USA). Approximately 500 new jobs are expected to be created in conjunction with the facility expansions. The investment will support increasing demand for licensed biologic medicines, such as RoACTEMRA (tocilizumab), Kadcyla (trastuzumab emtansine) and Perjeta (pertuzumab).

Biologic manufacturing capacity will be increased at sites in Vacaville and Oceanside, California with a planned investment of approximately 260 million Swiss francs creating around 250 new jobs. In Penzberg, Germany, Roche will invest approximately 350 million Swiss francs toward increased manufacturing capacity and equipment refurbishment, creating around 200 positions.

In addition, construction of an antibody-drug conjugate (ADC) production facility will begin in Basel, Switzerland through an investment of over 190 million Swiss francs, which is expected to create 50 jobs. This investment will provide additional capacity and flexibility to support Roche's first approved ADC, Kadcyla, and a further eight ADCs in clinical development. (Source: Roche Website)

Coronado Biosciences Announces Failure of Clinical Trial for Crohn's Treatment

Coronado Biosciences, Inc., a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer, has announced top-line results from TRUST-I, its Phase 2 clinical trial evaluating TSO (*Trichuris suis* ova or CNDO-201) in 250 patients with moderate-to-severe Crohn's disease.

The TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI < 150 points. The lack of overall response was driven by higher-than-expected placebo response rate in patients with CDAI < 290.

Coronado's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, is conducting TRUST-II, a phase 2, double-blind, randomized, placebo-controlled, multi-center study in Europe to evaluate the efficacy and safety of three different dosages of TSO in active Crohn's disease. The results from a second interim analysis are expected in the fourth quarter of 2013. (Source: Coronado Biosciences Website)

Alkermes Depression Drug Granted Fast Track Status by FDA

Alkermes plc announced that the FDA has granted Fast Track status for ALKS 5461 for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard therapies. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and with the potential to address an unmet medical need.

ALKS 5461 is a proprietary investigational medicine with a novel mechanism for the treatment of major depressive disorder (MDD). The mechanism of action for ALKS 5461 in the treatment of depressive symptoms is based on modulation of the opioid system in the brain, employing a balanced combination of agonism and antagonism of opioid receptors. ALKS 5461 consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist, and is designed to be a once-daily, non-addictive medicine. Early clinical development of ALKS 5461 was funded through a grant from the National Institute on Drug Abuse. (Source: Alkermes Website)

Genzyme MS Treatments Approved In Europe

Genzyme, a Sanofi company, announced that the European Commission has granted marketing authorization for Lemtrada™. This follows the August 30 approval of Aubagio®. The company intends to begin launching both products in the EU soon. Both products treat relapsing remitting multiple sclerosis (RRMS). Multiple sclerosis is estimated to affect more than 2.1 million people globally. There are approximately 630,000 people affected by MS in Europe.

Lemtrada 12 mg has a novel dosing and administration schedule of two annual treatment courses. The first treatment course of Lemtrada is administered via intravenous infusion on five consecutive days, and the second course is administered on three consecutive days, 12 months later. Lemtrada is a monoclonal antibody that selectively targets CD52, a protein abundant on T and B cells. Treatment with alemtuzumab results in the depletion of circulating T and B cells thought to be responsible for the damaging inflammatory process in MS. FDA action on Genzyme's supplemental Biologics License Application seeking U.S. approval of Lemtrada™ (alemtuzumab) for the treatment of relapsing MS is expected in late 2013.

Aubagio 14 mg is a once-daily, oral therapy indicated for treatment of adult patients with RRMS. Aubagio is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for Aubagio is not fully understood, it may involve a reduction in the number of activated lymphocytes in the central nervous system (CNS). Aubagio is approved to treat relapsing MS in the United States, Australia, Argentina, Chile, and South Korea, and is under review by additional regulatory agencies. (Source: Genzyme Website)

Ariad Pharmaceuticals Alters Clinical Trial for Leukemia Drug Iclusig

Ariad Pharmaceuticals, Inc. announced results of its review of updated clinical data from its clinical trial of Iclusig® (ponatinib) and actions that it is taking following consultations with the FDA. Clinical trials for Iclusig

indicated non-serious and serious arterial and venous adverse events combined occurred in approximately 20% of Iclusig-treated patients.

Patient enrollment in all clinical studies of Iclusig is being paused, and subject to agreement with the FDA, will be resumed with anticipated changes in dose and other modifications. In concert with this action, the FDA placed a partial clinical hold on all new patient enrollment in clinical trials of Iclusig. Patients who are currently receiving Iclusig in clinical trials will continue on therapy. Reductions in Iclusig dose will be implemented on a trial-by-trial basis for patients whose Iclusig treatment is ongoing. The eligibility criteria for Iclusig clinical trials will be modified to exclude patients who have experienced prior arterial thrombosis resulting in heart attack or stroke.

Clinical trial data demonstrate continued efficacy after dose reduction. At this time, the U.S. prescribing information for Iclusig is unchanged. Iclusig continues to be available in the U.S. to patients with resistant or intolerant chronic myeloid leukemia and Philadelphia-chromosome positive acute lymphoblastic leukemia in the commercial setting at the approved, once-daily dose of 45 mg. ARIAD has been in consultation with the FDA and other health authorities about changes in Iclusig product labeling to reflect the updated information. (Source: Ariad Pharmaceuticals Website)

Verax Biomedical of Marlborough Closes \$12M Funding Round

Verax Biomedical announced that it has completed a \$12 million financing that will position the company for aggressive growth in 2014. This financing will also accelerate the completion of and clinical studies for an improved version of its bacterial contamination test. Both products are designed to address a significant and potentially lethal bacterial contamination risk in transfused platelets.

The additional funding will position the company to meet market demand created by increased focus by regulators, blood bankers and hospitals on the risk of bacterial contamination in platelets, the anticipated release of the company's second product, an improved version of its Platelet PDG® test, and further expansion in overseas markets. It will also fuel an expansion of the company's research & development efforts already under way with the recent move of their corporate headquarters and laboratories to a larger facility in Marlborough, Mass.

Blood centers perform culture tests for bacteria in apheresis platelets 24 hours after donation, analyze results and dispose of contaminated units. But platelets have a five-day shelf life and bacteria levels just 24 hours after donation may be too low for detection by culture. Studies show that early culture testing misses an estimated three of every four bacterially contaminated units, which are then released to hospitals for transfusion. The Verax Platelet PGD® test is a rapid immunoassay that detects antigens present on the surface of bacteria. It is used at the point of care, usually a hospital transfusion service laboratory, within 24-hours of transfusion when bacteria, if present, will be at higher levels and easier to detect. (Source: Verax Biomedical Website)

Natick Startup Karyopharm Therapeutics Pursues IPO

Karyopharm Therapeutics Inc., a clinical-stage pharmaceutical company focused on developing novel first-in-class drugs directed against nuclear transport targets for the treatment of cancer and other major diseases, announced that it has filed a registration statement on Form S-1 with the Securities and Exchange Commission (SEC) relating to a proposed initial public offering of shares of its common stock. All shares of the common stock to be sold in the offering will be offered by Karyopharm. The number of shares to be offered and the price range for the offering have not yet been determined.

Karyopharm's Selective Inhibitors of Nuclear Export (SINE) compounds function by preventing the export of tumor suppressor proteins from the nucleus of a cell, thereby leading to their accumulation in the nucleus, which subsequently reinitiates and amplifies their tumor suppressor function. (Source: Karyopharm Therapeutics Website)

Lilly and Pfizer to Work with Joslin Diabetes Center on Kidney Disease

Joslin Diabetes Center's Office of Commercialization and Ventures announced it is collaborating with Eli Lilly and Company and Pfizer Inc., which will enable Joslin and both companies to accelerate research aimed at predicting kidney failure in patients with type 2 diabetes and developing potential ways to treat and prevent this complication of diabetes. This is the first time two pharmaceutical companies have joined forces with Joslin.

As part of this co-funded research effort, Joslin will analyze samples from a unique biorepository collected over a period of 15 years from Joslin type 2 diabetes patients in order to study specific biomarkers associated with the development of kidney failure, with the goal of predicting which patients are at risk of losing kidney function and eventually helping develop targeted drugs to address this condition.

Renal complications, also known as diabetic nephropathy, are one of the most life-threatening complications of diabetes. Over the course of many years, this damage frequently leads to end-stage renal disease, when the kidneys are no longer able to work at the level needed for everyday life. About a half million people in the United States have ESRD, which requires dialysis or kidney transplantation. Nearly 44 percent of these cases are due to diabetes. Currently, there is no accurate noninvasive test to identify patients at high risk of ESRD. (Source: Joslin Diabetes Center Website)

US Judge Rules that NIH be Permitted to Fund BU BioLab

A judge in the US District Court ruled that the National Institutes of Health should be permitted to fund the new National Emerging Infectious Diseases Laboratories at the Boston University Medical Center in Boston's South End and Roxbury neighborhoods. The facility will house Biosafety Level-3 and 4 laboratories designed to research extremely dangerous pathogens, such as the Ebola virus, for biodefense purposes. The plaintiff's in the case requested that the Court prevent federal funding of the BioLab on the ground that the NIH had failed to comply with the National Environmental Policy Act and strongly opposed building the BioLab in a high density urban neighborhood.

The Court found that the NIH had met its obligation under NEPA to take a hard look at the environmental consequences of its decision to build the BioLab in Boston. The Final Supplementary Risk Assessment reported that the risk of infections to the public resulting from accidents or malevolent acts "is extremely low, or beyond reasonably foreseeable," and the probability of secondary infections is so low that none is likely to occur for any of the pathogens over the proposed 50 year lifetime of the BioLab. This conclusion that the BioLab will pose low risk to the public is based, in part, on the security safeguards built into the facility, the low amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into every day practice at the BioLab.

The NIH emphasizes that the benefits of having the BioLab in Boston include opportunities for efficient medical research, collaboration and training with other institutions in Boston and Cambridge to advance critical research on biodefense and infectious diseases. (Source: Website)

Merck to Cut 8500 Positions, Reduce Costs by \$2.5 Billion and Restructure R&D

Merck announced additional workforce reductions, which combined with previously announced reductions of approximately 7,500, will result in a decrease of about 20 percent in Merck's total global workforce of 81,000 employees. The reductions are part of a global initiative to sharpen its commercial and R&D focus. The company expects to realize approximately \$2.5 billion in annual net cost savings by the end of 2015 and estimates that \$1.0 billion, or 40 percent, of the savings will be realized by the end of 2014. The company anticipates that the substantial majority of savings will come from marketing and administrative expenses and R&D.

Total pre-tax costs for the new restructuring program are estimated to range between \$2.5 billion and \$3.0 billion. The company estimates that approximately two-thirds of these costs will result in cash outlays, primarily related to separation expenses, and approximately one-third are non-cash, primarily related to accelerated depreciation of facilities to be closed or divested.

The multi-year initiative includes:

- Investing in new licensing and business development activities to acquire external innovation and commercial opportunities to strengthen the pipeline
- Reducing its global real estate footprint, particularly in New Jersey where it is headquartered.
- Increasing its focus on the key therapeutic areas – diabetes, acute hospital care, vaccines and oncology.
- Increasing its focus in ten prioritized geographic markets, which account for the majority of revenue in its pharmaceutical and vaccine business. These markets are the United States, Japan, France, Germany, Canada, United Kingdom, China, Brazil, Russia and Korea.
- Focusing on its most promising programs such as the company's anti-PD-1 immunotherapy program in oncology, BACE for Alzheimer's disease (MK-8931), its next generation HCV program and V503, the company's 9-valent HPV vaccine.
- Out-licensing or discontinuing selected late-stage clinical development assets and reducing its focus on platform technologies.
- Making externally sourced programs a greater component of its pipeline strategy. (Source: Merck Website)

Novartis Relocates Neuroscience Division in Cambridge

After shutting down its neuroscience division in Switzerland in 2012, Novartis has revived it in Cambridge with a new Global Head of Neuroscience, Ricardo Dolmetsch, Ph.D. Novartis intends to hire 30 associates by the end of 2013 and 70 more during the next three years at the Cambridge global research headquarters to help patients with neuropsychiatric and neurodegenerative diseases. The location in Cambridge will allow the company to take advantage of academic collaborations. The division will focus on Autism, Schizophrenia and Bipolar disorder, Parkinson's disease, Alzheimer's disease and Frontotemporal Dementias. (Source: Novartis Website)

Genzyme Plans \$80M Expansion in Framingham

Genzyme, a Sanofi company, announced that it is investing \$80 million to build a new downstream processing facility for Fabrazyme® (agalsidase beta). The new plant, which will be located adjacent to the new Fabrazyme cell culture manufacturing site in Framingham will significantly expand purification capacity to support anticipated growth in global demand over the coming years.

Fabrazyme is approved for treatment of Fabry disease, a rare inherited condition, which over time can cause renal, cardiac and cerebrovascular events. The final product, which is administered as an IV infusion, is formulated and fill-finished in a separate facility in Waterford, Ireland and shipped to multiple distribution

centers for labeling, packaging and shipping around the world. (Source: Genzyme Website)

Civitas Raises \$38M for Clinical Development of Inhaled Form of L-Dopa

Civitas Therapeutics, Inc. announced the successful completion of a \$38 million Series B financing. Civitas plans to use the proceeds from this financing for late stage clinical development of the company's lead program, CVT-301, an inhaled formulation of levodopa (L-dopa) being developed for relief from debilitating motor fluctuations (OFF episodes) associated with Parkinson's disease. Civitas recently initiated a Phase 2b clinical study to evaluate the efficacy and safety of CVT-301, self-administered by patients, in treating emergent OFF episodes during one month of continued use. The company will report preliminary data from this study in the first half of 2014.

In addition, Civitas will explore additional opportunities to leverage its ARCUS® platform for other disease states. The proprietary ARCUS platform is capable of delivering a large, precise dose of a drug independent of inspiratory flow rate. Civitas believes that this platform will provide a significant clinical advantage for drug delivery of inhaled formulations. (Source: Civitas Website)

Glaxo's Melanoma Treatment Fails to Meet Endpoint, Clinical Trial to Continue

GlaxoSmithKline plc announced that an independent analysis of the DERMA study, a Phase III randomised, blinded, placebo-controlled trial of the MAGE-A3 cancer immunotherapeutic, showed that the study did not meet its first co-primary endpoint as it did not significantly extend disease-free survival (DFS) when compared to placebo.

The DERMA study evaluated the efficacy and safety of the MAGE-A3 cancer immunotherapeutic in Stage IIIB/C melanoma patients. MAGE-A3 is a tumour-specific antigen that is expressed in a variety of cancers, including melanoma with no presentation in normal cells. MAGE-A3 is expressed in about 65% of Stage III melanomas.

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the DERMA trial until the second co-primary endpoint is assessed. This endpoint, DFS in the gene signature positive sub-population, is designed to identify a subset of MAGE-A3 positive patients that may benefit from the treatment. Results from this analysis are expected in 2015. The IDMC for the DERMA study indicated that the current review of the safety information raised no concern for the continuation of the trial.

GSK is continuing to evaluate the same investigational MAGE-A3 cancer immunotherapeutic in another independent Phase III study (MAGRIT) in Non Small Cell Lung Cancer (NSCLC) following surgical removal of the primary tumor with first data anticipated in the first half of 2014. (Source: GlaxoSmithKline Website)

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.

New Test System Identifies Yeasts and Bacteria Known to Cause Illness

The FDA has approved the first mass spectrometer system for automated identification of bacteria and yeasts that are known to cause serious illness in humans. The VITEK MS, manufactured by bioMérieux in Durham, N.C., can identify 193 different microorganisms and perform up to 192 different tests in a single automated series of testing, with each test taking about one minute.

The VITEK MS can identify yeasts such as those from the *Candida*, *Cryptococcus* and *Malassezia* groups, and bacteria from the *Staphylococcaceae*, *Streptococcaceae*, *Enterobacteriaceae*, *Pseudomonadaceae*, and *Bacteroidaceae* families, which are associated with skin infections, pneumonia, meningitis, and bloodstream infections. People with immune systems that are compromised or weakened by HIV/AIDS, cancer treatment, or anti-rejection therapy following an organ transplant are particularly vulnerable to these infections.

The VITEK MS incorporates a technology called matrix-assisted laser desorption/ionization–time of flight mass spectrometry (MALDI-TOF MS). The technology uses a laser to break yeast and bacteria specimens into small particles that form a pattern unique to the microorganism. The VITEK MS automatically compares the microorganism pattern to 193 known yeasts and bacteria in the test system's database to identify the microorganism.

The VITEK MS is for clinical use for the identification of microorganisms cultured from human specimens. It is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections. (Source: FDA Website, 21 August, 2013)

FDA Approves Abraxane for Late-Stage Pancreatic Cancer

The FDA has expanded the approved uses of Abraxane (paclitaxel protein-bound particles for injectable suspension, albumin-bound) to treat patients with late-stage (metastatic) pancreatic cancer. Abraxane is a

chemotherapy drug that can slow the growth of certain tumors. Abraxane is intended to be used with gemcitabine, another chemotherapy drug, in patients with pancreatic cancer that has spread to other parts of the body.

Abraxane is also approved to treat breast cancer (2005) and non-small cell lung cancer (2012). It is marketed by Celgene, based in Summit, N.J. Gemcitabine is marketed by Indianapolis-based Eli Lilly. (Source: FDA Website, 06 September, 2013)

FDA Approves First Generic Capecitabine to Treat Colorectal and Breast Cancers

The FDA has approved the first generic version of Xeloda (capecitabine), an oral chemotherapy pill used to treat cancer of the colon or rectum (colorectal cancer) that has spread to other parts of the body (metastatic), and metastatic breast cancer. Teva Pharmaceuticals USA has gained FDA approval to market generic capecitabine in 150 and 500 milligram strengths.

It is important that the prescriber know if the patient is also taking a medicine used to thin the blood, such as warfarin. Capecitabine could increase the effect of this medicine, possibly leading to serious side effects. Capecitabine has a boxed warning to alert health care professionals and patients about this risk. (Source: FDA Website, 16 September, 2013)

FDA Finalizes New System to Identify Medical Devices

The FDA announced a final rule for the unique device identification system (UDI) that, once implemented, will provide a consistent way to identify medical devices. The UDI system has the potential to improve the quality of information in medical device adverse events reports, which will help the FDA identify product problems more quickly, better target recalls, and improve patient safety. The FDA has worked closely with industry, the clinical community and patient and consumer groups in the development of this rule.

Once fully implemented, the UDI system rule is expected to have many benefits for patients, the health care system and the device industry. It will enhance the ability to quickly and efficiently identify marketed devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems. (Source: FDA Website, 20 September, 2013)

FDA to Regulate Apps that Turn Smartphones into Medical Devices

The FDA issued final guidance for developers of mobile medical applications, or apps, which are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. The guidance outlines the FDA's tailored approach to mobile apps.

The agency intends to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Drug & Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. The FDA intends to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended.

Mobile apps have the potential to transform health care by allowing doctors to diagnose patients with potentially life-threatening conditions outside of traditional health care settings, help consumers manage their own health and wellness, and also gain access to useful information whenever and wherever they need it. The agency has cleared about 100 mobile medical applications over the past decade; about 40 of those were cleared in the past two years. (Source: FDA Website, 23 September, 2013)

Genentech's Perjeta Wins FDA Approval for Preoperative Breast Cancer

The FDA granted accelerated approval to Genentech's Perjeta (pertuzumab) as part of a complete treatment regimen for patients with early stage breast cancer before surgery (neoadjuvant setting). Perjeta is the first FDA-approved drug for the neoadjuvant treatment of breast cancer.

Perjeta was approved in 2012 for the treatment of patients with advanced or late-stage (metastatic) HER2-positive breast cancer. HER2-positive breast cancers have increased amounts of the HER2 protein that contributes to cancer cell growth and survival. Perjeta's new use is intended for patients with HER2-positive, locally advanced, inflammatory or early stage breast cancer (tumor greater than 2 cm in diameter or with positive lymph nodes) who are at high risk of having their cancer return or spread (metastasize) or of dying from the disease.

The FDA reviewed Perjeta's use for neoadjuvant treatment under the agency's priority review program, which provides for an expedited review of drugs that may offer major advances in treatment. (Source: FDA Website, 30 September, 2013)

FDA Approves New Drug to Treat Major Depressive Disorder

The FDA has approved Brintellix (vortioxetine) to treat adults with major depressive disorder. Brintellix is co-marketed by Takeda Pharmaceuticals and Lundbeck, both based in Deerfield, Ill.

Major depressive disorder (MDD), commonly referred to as depression, is a mental disorder characterized by mood changes and other symptoms that interfere with a person's ability to work, sleep, study, eat and

enjoy once-pleasurable activities. Episodes of depression often recur throughout a person's lifetime, although some may experience a single occurrence.

Brintellix and other antidepressant drugs have a Boxed Warning and a Medication Guide alerting patients and healthcare professionals that antidepressants can increase the risk of suicidal thoughts and behavior in children, adolescents and young adults ages 18 to 24 during initial treatment. Studies show adults older than 24 years of age do not appear to have an increased risk of suicidal thoughts and behavior, while adults ages 65 and older appear to have a reduced risk. Patients starting antidepressant therapy should be closely monitored for worsening of their depression and the emergence of suicidal thoughts and behavior. (Source: FDA Website, 30 September, 2013)

FDA Approves Adempas to Treat Pulmonary Hypertension

The FDA has approved Adempas (riociguat) to treat adults with two forms of pulmonary hypertension. Adempas is marketed by Bayer HealthCare Pharmaceuticals based in Wayne, N.J.

Pulmonary hypertension is caused by abnormally high blood pressure in the arteries of the lungs. It makes the right side of the heart work harder than normal. In its various forms, pulmonary hypertension is a chronic, progressive, debilitating disease, often leading to death or need for lung transplantation.

Adempas carries a Boxed Warning alerting patients and health care professionals that the drug should not be used in pregnant women because it can harm the developing fetus. Female patients can receive the drug only through the Adempas REMS program. All female patients must be enrolled in the program, comply with pregnancy testing requirements and be counseled regarding the need for contraception. The REMS restricted distribution program requires prescribers to be certified by enrolling in the program. Also, pharmacies must be certified and can dispense Adempas only to patients who are eligible to receive it under the REMS. (Source: FDA Website, 08 October, 2013)

European Commission Approves Hospira's Biosimilar mAb Inflectra

Hospira has announced the European Commission (EC) approval of Inflectra™ (infliximab), Europe's first biosimilar monoclonal antibody (mAb) therapy. Inflectra has been approved for the treatment of inflammatory conditions including rheumatoid arthritis (RA), ankylosing spondylitis, Crohn's disease (CD), ulcerative colitis (UC), psoriatic arthritis (PsA) and psoriasis.

Inflectra is a biosimilar medicine to the reference medicinal product, Remicade® (infliximab), and is the first monoclonal antibody (mAb) to be approved through the European Medicines Agency (EMA) biosimilars regulatory pathway. A biosimilar developed in-line with EU requirements can be considered a therapeutic alternative to an existing biologic. Remicade recorded European sales of over USD 2 billion in 2012.

"Inflectra offers physicians, patients and healthcare systems a more affordable treatment option, while maintaining similar quality, efficacy and safety to its reference product. We are confident that with lower drug costs, Inflectra can provide an opportunity for European Union health systems to manage their budgets more effectively, supporting Hospira's commitment to provide patients with better access to high-quality, more affordable care," said Richard Davies, Senior Vice President and Chief Commercial Officer, Hospira.

Inflectra was approved by the EC following review of safety, efficacy and tolerability data from a comprehensive clinical trial program. In a phase III randomised, double-blind study, Inflectra met its primary endpoint of therapeutic equivalence to Remicade. Safety and tolerability data also demonstrated Inflectra's equivalence to Remicade.

In 2009, Hospira entered into an agreement with South Korean-based biopharmaceutical company, Celltrion, which is developing eight monoclonal antibody biosimilars. Under the terms of the agreement, Hospira obtained the rights to Inflectra in Europe and certain CIS (Commonwealth of Independent States) countries, the United States, Canada, Australia and New Zealand. Inflectra will be launched throughout Europe at the earliest opportunity taking into account any relevant patent protection.

Hospira is the world's leading provider of injectable drugs and infusion technologies. The company is headquartered in Lake Forest, Ill., and has approximately 16,000 employees. The head office for Hospira in Europe, Middle East and Africa is in Leamington Spa, UK. (Source: Hospira Website, 10 September, 2013)

Medtronic's Artificial Pancreas Wins FDA Approval

Medtronic has announced FDA approval of the MiniMed® 530G with Enlite®, an artificial pancreas system for people with diabetes. Medtronic's system is the first in the United States that can automatically stop insulin delivery when sensor glucose values reach a preset level and when the patient doesn't respond to the Threshold Suspend alarm. The MiniMed 530G system incorporates the new Enlite sensor, Medtronic's most accurate and comfortable continuous glucose sensor with a 31 percent improvement in overall accuracy from the previous generation.

"The diabetes community has eagerly awaited approval of this system that stops insulin delivery when sensor glucose values fall below a predetermined threshold," said Richard M. Bergenstal, M.D., executive director of the International Diabetes Center at Park Nicollet Health Services in Minneapolis and Clinical Professor for the Department of Medicine at the University of Minnesota. "We are hopeful that advances such as this and improvements in the accuracy of continuous glucose sensors will help people with diabetes strive for better control of their diabetes."

The MiniMed 530G system was approved for use by people with diabetes ages 16 and older. Medtronic will conduct a post-approval study including children ages two and older. The Enlite sensor can be worn for six days.

As a condition of approval, in addition to the post-approval study, Medtronic will engage in direct patient follow up and will make certain manufacturing accommodations. These commitments are consistent with the product approval by the FDA and an accompanying warning letter issued to Medtronic on Sept. 19, 2013.

Medtronic has already addressed many of the observations noted in the warning letter and is committed to resolving the remaining observations as quickly as possible and in accordance with the product approval requirements. Medtronic is committed to providing safe and effective products for people with diabetes.

(Source: Medtronic Website, 27 September, 2013)

New Members

Mr. Mosaab Alsaray, *Manufacturing Associate III, Cell Culture*, Biogen Idec

Mr. Jeremiah D. Alves

Mr. Martin Axelsson, *Mechanical Engineer*, Eppendorf

Mr. Mark A. Baker, *Validation Specialist*, CAI

Matthew Barrows, *Associate Director*, Genzyme Corporation

Mr. Christopher A. Bellerive, *Operations Manager*, Worcester Polytechnic Institute / BETC

Mr. Christopher J. Bouchard, *Student*, Massachusetts Maritime Academy

Jacob D. Bourgeois, *Project Manager*, Design Group

Mr. Joshua Bourke, *Student*, University of Massachusetts Dartmouth

Jeffrey Boyar, *Manager Corporate Quality Risk Management*, Alexion Pharmaceuticals

Ms. Sheila Boyce, *Sr. Systems Engineer*, Genzyme

Mr. Tom Brady, *Senior Account Manager*, Fisher Clinical Services, Inc.

Jeanne Celiberti, *Director Operations*, AVEO Oncology

Julie Chau, *Process Automation Engineer*, GxP Automation LLC

Ms. Sally Chu, *Student*, University of Massachusetts Amherst

Mr. Robert K. Coughlin, *President & CEO*, MassBio

Mrs. Norline Crossdale-Walker, *Sr. QS Engineer*, Genzyme

Mr. Justin Cullity, *Student*, University of New Hampshire

Mr. Phillip Durgin, *Lead Investigator*, Pfizer, Inc

Mr. Daniel Eltringham, *Student*, University of New Hampshire

Mr. Roger J. Filannino, *Validation Engineer*, CAI

Ms. Emily L. Fullerton, *Process Engineer*, Genzyme

Mr. Avery C. Furness, *Validation Specialist*, Commissioning Agents Inc.

Mr. Arnab Ganguly, *Student*, Purdue University

Ms. Margaret Grace, *IS Compliance Specialist*, Genzyme Corp

Ms. Ruth S. Graff, *Operations Director*, Roush Life Sciences

Peter Habura, *GMP QA Manager*, Cubist Pharmaceuticals, Inc.

Mr. Christopher R. Hango, *Student*, Worcester Polytechnic Institute

Mr. Randy L. Hernandez, Ing., *Mechanical Engineer*, Carr/Centritech

Michelle Hoshino, Pfizer Inc.

Zachary R. Houle, *Senior Process Engineer*, Shire

Ms. Kailyn E. Jacobson, *Intern*, University of Rhode Island

Michael Johnson, *Principal*, Integrated Commissioning and Qualification

Beren N. Jones, *Validation Specialist*, Commissioning Agents

Mr. Steven Jones, *President*, Validation Support LLC

Mr. Areen Kalantari, *Student*, University of Massachusetts Lowell

Mr. Jerome H. Kapferer, *Operations Manager*, GxP Automation

Mr. Jeffrey Kent, *Student*, Northeastern University

Mr. Skaison Kim, *Student*, University of Massachusetts-Amherst

Mr. Robert Kirkpatrick

Mr. Josh Koblitz, *Global Procurement*, Shire

Mr. Nicholas Thomas Koenig, University of Massachusetts at Amherst

Ms. Laura L. Krause, *Student*, Wentworth Institute Technology

Mr. Matthew LaBonty, *Student*, University of Maine

Ms. Susan M. Lacroix, *Lead Investigator*, Pfizer

Mr. Steven M. Lewis, *VP Operations*, DPS Engineering

Mr. Lexan Lhu, *Application Engineer*, Charter Medical

Mr. Mark A. Lindholm, *Project Manager*, Commissioning Agents Inc.

Mr. Mustapher Lubega, UMass Lowell

Mr. Jonathan D. Lucier, *Engineer*, Commissioning Agents Inc.

Ms. Sandra A. Lueken, *Sr. Director Quality Assurance*, MedImmune/AstraZeneca

Ms. Sade A. Luwoye, *Student*, University of Massachusetts Amherst

Eric C. McCurry, *Process Science Associate*, Regeneron Pharmaceuticals

Supriya Mehta, *Global Quality Manager*, Sensitech Inc

Mr. Premdharan Meyyan, *Student*, Boston University

Mr. Miron Mironov, *Sales Manager*, Bausch + Stroebel Machine Company, Inc.

Ms. Shannon E. Molloy, *R&D Specialist*, Pfizer

Mr. Stephen J. Montibello, PE, *Director of Business Development*, BR+A Consulting Engineers, LLC

Ms. Lauren Morse, *Student*, Worcester Polytechnic Institute

Mr. Marcel Moulaison, *Executive Director, Quality Operations*, Sunovion Pharmaceuticals Inc.

Mr. Corei Moxey, *Student*, Northeastern University

Mr. Rob Nichols, *Business Development, Science & Technology*, Suffolk Construction

Ms. Kathryn L. Ostertag, *Clinical Trial Materials Manger*, Sunovion Pharmaceuticals, Inc.

Mr. Long Bin Pan, *Process Engineer*, Genzyme Corp

Ms. Patricia Parker, *QA Director*, Pfizer

Ms. Palak H. Patel, *Student*, University of Massachusetts at Lowell

Mr. Kaushal V. Patel, *Process Engineer*, ADVENT Engineering Services Inc.

Ms. Alessa M. Peterson, University of Massachusetts Lowell

Kevin J. Porter, *Associate Director Validation*, AMRI Inc.

Kristin Prescott, *Sr. Engineer*, Shire

Mr. Gordon G. Pugh, *Sr. Vice President/COO*, Alkermes plc

Mrs. Kara L. Puopolo, *Technical Coordinator*, AVEO Oncology

Ms. Halah Rahman, *Student*, University of Massachusetts Lowell

Raquelimar Rodriguez, *Senior Process Engineer*, Astrazeneca

Mr. Michael J. Rongione, *Managing Engineer*, Pare Corporation

Mr. Robert Sampson, *Capital Program Manager*, Pfizer Inc.

Director Global Procurement,

Prakash Savarirayan, Shire
Mrs. Sokharoth T. Soun, *Cleaning Validation Co-op*, UMASS Lowell
Mr. Christopher S. Spada, *Validation Specialist*, Mangan Biopharm
Mr. Darren W. Stevens, *Associate Manager IT QA*, Regeneron Pharmaceuticals
Phani Sukhvasi, *Process Engineer*, Vertex Pharmaceuticals
Matteo Taormina, *Validation Consultant*, Valsource LLC
Mr. Thomas F. Taylor, *President*, Roush Life Sciences
Ms. Nicole E. Taylor, *Student*, Colby-Sawyer College
Ms. Mikaela A. Therrien, *Student*, University of Massachusetts Lowell
Garrett S. Thompson, *Student*, University of New Hampshire
Mr. Daniel Craig Thrasher, *Engineer, Process Development*, Bind Therapeutics
Ms. Amy Torchia, Shire HGT
Mr. Jose O. Torres, *Director, QC*, ImmunoGen Inc

Member Anniversaries

Join us in celebrating the 5, 10, 15 and 20+ year anniversaries of Boston Area Chapter Members. Congratulations to all of our long term Chapter members - your loyalty helps make us successful, year after year!

20+ Years of Membership

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Mr. Ric Feldt, Jeff Smith & Associates
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Mr. Alexander E. Smith, Jr., M+W U.S., Inc.

Mr. Jose M. Soto, Pfizer Inc.

Mr. Michael G. Sprague, Ethide Laboratories

Mr. Lester L. Starr, Jr., Cutler Associates

Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

Mr. Michael J. Sweeney, Hart Design Group

Mr. David A. Tomsik, CRB Consulting Engineers

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

Mr. Timothy C. Tyson, Aptuit, Inc.

Mr. Robert P. Vecchione, BWT/Christ Aqua Pharma & Biotech NA

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. Jeffrey L. Werner, BFS Pharma Inc

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

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Mr. Peter M. Sampson, Pure Process Technology

Mr. Jonathan P. Savona, Accuspec Inc

Mr. Brian W. Saxton

10 Year Anniversary

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Mr. David G. Brush, Integrated Process Technologies

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

Mr. Timothy J. Cotter, Cotter Brothers Corporation

Mr. Joseph M. Ferrelli, Optek-Danulat, Inc.

Mr. Christopher P. Foran, Superior Controls Inc.

Mr. James J. Hoefner, TEK Supply Inc.

Francis X. McConville, FXM Engineering & Design

Mr. Christopher N. Pacheco, Amgen Inc.

Mr. Robert A. Patrick, Superior Controls Inc.

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Mr. Robert A. Snow, CPIP, Genzyme Corp a Sanofi Company

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Ms. Suzanne L. Stuhler, Shire HGT

Mr. Stephen P. Sylvester, A/E, M+W USA

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