

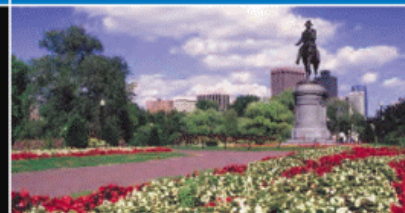
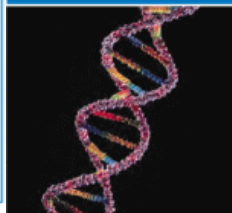


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## Boston Area Chapter

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## NEWSLETTER

November 2014, Volume XXIV, No. 6

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### President's Message: Exciting Events Highlight Chapter's Fall Calendar



Dear Boston Area Chapter Members,

What an exciting few months the Chapter has had since I last wrote to you. We awarded ten very deserving students scholarships; our annual Product Show at Gillette Stadium was a huge success; a very successful educational meeting was held in Cambridge and simulcast to the Providence GO hub; the ISPE Annual Meeting was held in Las Vegas; and we welcomed new leadership at the national level of ISPE. Here is a summary of some of these key events:

#### Joel Goldenberg Memorial Scholarship Program

The Boston Area Chapter awarded ten deserving students a combined scholarship amount of \$12,500 this semester towards their continued education in pharmaceutical-related fields of study. The award recipients and their schools are:

Anatoliy Tereshchuk, UMass Amherst

Chelsea Fox, University of Rhode Island

Daniel Ahlstedt, Northeastern University

Lauren Morse, Worcester Polytechnic Institute

Valmik Parag Doshi, Massachusetts College of Pharmacy & Health Sciences University

Raymond Lawton, UMass Dartmouth

Bo Yang, Massachusetts College of Pharmacy & Health Sciences University

Connor Brown, Assumption College

Steven Alves, UMass Lowell

Jahzmin Walker, University of Maine, Orono

Congratulations to all of them! This brings the total scholarships awarded by the Chapter to \$55,000. The Chapter will be awarding up to \$12,500 in additional scholarships later this year. Visit the Chapter website for application information but don't delay - the next application deadline is November 15.

#### 23rd Annual Product Show

On October 1 the Chapter held its 23rd annual Product Show at Gillette Stadium. Attendance increased by over 150 this year with just shy of 2,500 people attending. These ISPE Members and industry leaders saw over 385 companies either displaying in our vendor area or taking part in our Career Fair. This is the second year that the exhibit area extended to the west side of the stadium and the Product Show Committee did an incredible job of driving traffic to that side. The four educational seminars also enjoyed a high turnout this year, with between 80 and 100 participants each.

During the morning Plenary Session attendees heard from two leaders in the pharmaceutical industry.

Guest Speaker Dr. Susan Windham-Bannister, President & CEO of the Massachusetts Life Sciences Center, presented "The Massachusetts Life Sciences Initiative: Building The World's Leading Ecosystem for Life Sciences Innovation and Growth." Dr. Michael Arnold, Business Process Owner for Investigational Products and Senior Director of Strategic Partnerships for Pfizer's Global Clinical Supply Chain and Member of the ISPE International Board of Directors, presented his views on the future of the pharmaceutical industry and the role played by ISPE.

Following a new tradition begun last year, the Chapter recognized several exceptional volunteers for their outstanding service to the organization. Please refer to the article below for additional details and photos of this year's deserving winners:

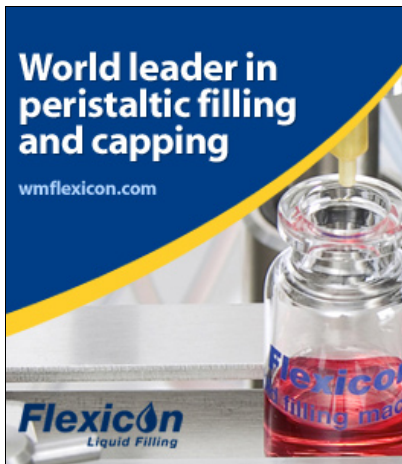
- Volunteer of the Year Awards: Michael Levesque and Mark Levanites
- Outstanding Achievement Award: Geographic Outreach (GO) Committee
- Student Chapter of the Year Award: UMass Lowell

#### New ISPE President and CEO

The Boston Area Chapter would like to welcome John Bournas as President and CEO of ISPE, succeeding Nancy Berg. Mr. Bournas takes the helm at ISPE with extensive competencies in the healthcare association

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Jamie Miller | 617.475.3050  
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industry as well as significant international experience. He brings to the Society a clear vision for the expansion of its global initiatives and business operations including leveraging technology to extend ISPE's Membership and educational programs.

#### ISPE Annual Meeting

This year the ISPE Annual Meeting was held October 12-14 at Caesar's Palace in Las Vegas. Over 90 Boston Area Chapter Members made the trip west, taking part in educational seminars and meeting over 180 vendors in the exhibit hall. On Sunday night the Chapter held a reception at the Fix in the Bellagio Casino with over 100 guests including our friends from the Japanese Affiliate and other North American ISPE Chapters.

#### Student Chapters

The Boston Area Chapter now has eleven Student Chapters, adding Mass Maritime Academy, Mass College of Pharmacy and Health Sciences University, Boston University, UMass Dartmouth and Middlesex Community College in the past year. Student involvement has greatly increased and the Chapter now boasts over 210 Student Members.

#### Remembering Hank Moes

It is with great sadness that I announce the death of Boston Area Chapter founder Hank Moes on September 15, 2014 at the age of ninety. An ISPE Member since 1987, Hank saw the need for support for the new biotech industry that was emerging in the greater Boston area and helped to establish the Boston Area Chapter in 1992. Hank is survived by his wife Joan, and two sons Timothy and Christopher.

Hank's lifelong accomplishments in the industry led the Chapter to create the Hank Moes Award in 2005. It is presented to a Boston Area Chapter Member in recognition of a comprehensive body of work and specific accomplishments that are widely recognized as truly extraordinary and of positive and lasting impact on ISPE, the Boston Area Chapter and the life sciences/biopharmaceutical industry.

Finally, as we approach the holiday season I want to wish everyone happiness and good cheer. The Patriots are playing well, the Celtics and Bruins have just started their seasons and the Chapter has a variety of activities brewing to keep Members busy throughout the upcoming months.

Sincerely,

Christopher Opolski

President

ISPE Boston Area Chapter

#### Chapter Bulletin Board

##### **New Online Community (CoP) Tool Offers New Features**

ISPE has created a new user interface (or "Online Community Tool") for the Communities of Practice to help CoP members gain access to more information and network with colleagues more easily. The new features allow CoP members to:

- Receive email notifications on your favorite content topics posted in the community using Google-alert style emails.
- Share content from third party public social media sites like LinkedIn, YouTube, Twitter, Facebook and others on your own personal MyPage profile.
- Network with fellow ISPE members by connecting and following ISPE colleagues.
- To utilize the new features, current CoP members simply log in as usual. Not a CoP member? It's easy to join. For more information and tips for success, consult the community FAQs at <http://www.ispe.org/ispecommunitysoftwarefaq>.

##### **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 support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at 781.647.4773 or [office@ispeboston.org](mailto:office@ispeboston.org).

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

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource that contains all of the information you need to know to become a Chapter Sponsor.

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

So don't delay, visit [www.ISPEBoston.org/sponsorship](http://www.ISPEBoston.org/sponsorship) and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or – if you'd rather - contact the Chapter office at 781.647.4773 or [office@ispeboston.org](mailto:office@ispeboston.org) and we'll be happy to help!

#### Upcoming Chapter Events - Mark Your Calendar



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**Thursday, November 13, 2014**

**Cloud Computing: New Challenges in Data Integrity and Security**  
Cubist Pharmaceuticals, Lexington, MA

OR

**Simulcast to the Crowne Plaza Hotel, Warwick, RI**

**EVENT INFORMATION:** Attend the live program at Genzyme Center in Cambridge, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers.

**PROGRAM SUMMARY:** Traditional IT Infrastructure has evolved as a result of improved data storage technology using virtual, cloud and hosted models. This round table discussion will cover how life sciences companies have been cautiously adapting to cloud and hosted IT Infrastructure models including data integrity and security concerns associated with this new paradigm.

The panel, composed of IT representatives from small and large Life Science organizations, will discuss their concerns, challenges, risk mitigation techniques and future of IT data and integrity including:

- Current Paradigm
- Cloud Based Solutions
- Hosted Solutions
- Data Integrity
- Regulatory concerns?
- Challenges
- Concerns
- Future?

**Register Today:**

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=404](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=404)

**Thursday, December 11, 2014**

**Lean Six Sigma: Theory, Applications and Lessons Learned in the Biopharma Industry**  
Lantheus Medical Imaging, Billerica, MA

OR

**Simulcast to the Crowne Plaza Hotel, Warwick, RI**

**EVENT INFORMATION:** Attend the live program at Lantheus Medical Imaging in Billerica, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers

**PROGRAM SUMMARY:** Every industry has their glory days defined by a time of rapid growth and unprecedented profitability leading to personal and professional advancement. And then everything changes. Work becomes, well work. Customers are more demanding. Competitors are better than ever. Management expects more work in less time and with fewer resources. Processes that seemed to work smoothly before are now surprisingly broken. Problems are everywhere and there's no time to solve them. Everyone and everything needs to move faster. You conclude you need more resources or a different approach to leading, managing and working. You envision an environment with more problem solvers, more creativity and more participation from everyone. Enter Lean & Six Sigma, to eliminate waste, create efficiencies, reduce variation, control costs and ensure a reliable drug supply.

Invited speakers will share several examples of how Lean - Six Sigma tools and techniques have been successfully implemented in Biopharma operations. They will also explain the rationale for impending Lean in BioPharm; and showcase a few real implementation examples. The audience will see the efficiency gains by introducing flow and problem solving tools in streamlining the process.

**Register Today:**

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=405](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=405)

## Sneak Preview of Upcoming Events

**Thursday, January 15, 2015**

Future Trends

**Thursday, January 22, 2015**

New Year's Social

## 23rd Annual Product Show Breaks All Records

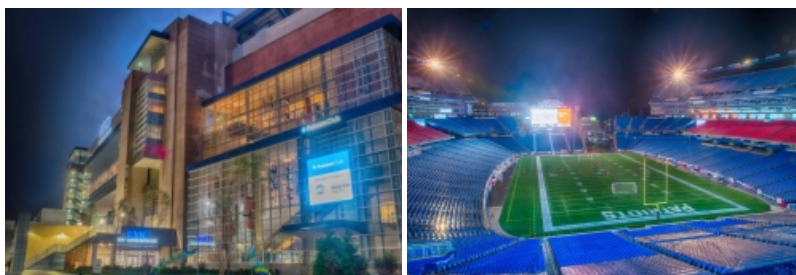
*by H. Steven Kennedy, Chair, Product Show Committee, with photos by Alastair Battson Photography*

Despite a rainy day, the 23rd edition of the ISPE Boston Area Chapter Product Show held at Gillette Stadium on October 1 was the place to be. Nearly 2500 people – over 200 more than the previous record – braved the inclement weather to participate in the event's many and varied activities and made the Show a rousing success. (And if by chance you weren't there, this short video will give you an idea of what you missed and whet your appetite for next year.)



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## Newsletter Archive



The wet weather produced a glittering evening scene at Gillette.

Changes to the Show's format - many of them suggested by last year's attendees and exhibitors – were a big success by all accounts. The major change was moving the Plenary Session to the morning. Chapter President Chris Opolski gave the State of the Chapter address reporting that the Chapter is financially sound and continues to be the largest Chapter in the world. He reviewed our activities from the past year and highlighted ongoing initiatives: simulcast of educational programs to remote hubs throughout New England and beyond, expanded scholarship program, and continued growth of Student Chapters. Chris concluded by presenting three awards recognizing excellence within the Chapter:

- Volunteer of the Year Awards: Michael Levesque and Mark Levanites
- Outstanding Achievement Award: Geographic Outreach (GO) Committee
- Student Chapter of the Year Award: UMass Lowell



Chapter President Chris Opolski opened the Plenary Session with the State of the Chapter address and this year's Chapter Awards.

Our special guest speaker, Dr. Susan Windham-Bannister, President and CEO of the Massachusetts Life Sciences Center, described the MLSC's progress implementing a 10-year, \$1-billion, state-funded life sciences investment initiative to create jobs and support advances to improve health and well-being. She noted how ISPE has helped the MLSC attract life science companies to the area by providing the training and skills to our Members that these companies are looking for in the workforce.



Special Guest Dr. Susan Windham-Bannister of the Massachusetts Life Sciences Center described the vibrant biopharma marketplace in Massachusetts.

Dr. Michael Arnold, Sr. Director Strategic Relationships and Investigational Products Business Process Owner at Pfizer, followed Dr. Windham-Bannister with our keynote address. Dr. Arnold is also a Member and the current Secretary of the ISPE International Board of Directors and during his address he provided a unique insight into ISPE's future and the role the Society plays in the industry. He was extremely impressed with the Show and the Boston Area Chapter in general and is looking forward to learning more about our best practices and how we can help other Chapters.



Keynote Speaker Dr. Michael Arnold of Pfizer provided a unique perspective on the future of the industry and the role played by ISPE.

The Show doors opened at noon following the Plenary Session. Attendees were then able to visit the exhibit area with its 375 booths – another Product Show record. The new traffic flow path was well received. Attendees were able to visit all the exhibitors with ease and without the “dead” spots present in previous years.



Thousands of attendees moved through the exhibit areas with ease due to the improved layout and wider aisles.

As always, a full slate of educational programs was offered throughout the day. The Educational Programs Committee conducted four sessions during the afternoon timeframe, all of which were very well attended (in excess of 100 each) with standing-room-only crowds:

- “Biotechnology: The Challenge for Tomorrow” with Dr. Kamal Rashid,
- “Harder Than It Looks – Projects Executed Concurrently with Manufacturing Operations” with Rick Kotosky and John Spohn,
- “Water Based Critical Utilities-RO, WFI, Steam: The Bottom of the Iceberg that Makes a Plant Actually Run” with Brian Hagopian, and
- “Successful Project and Organizational Change through Effective Stakeholder Management” with Neeraj Shah.



Popular topics of general interest ensured overflow crowds for the four educational seminars.

In the Vendor Showcase area, product demos were held by ClorDiSys Solutions, Cambridge IT Compliance, E&S Technologies, High Purity New England and Lives International. And, as a special bonus, Nidhi Maniar, R&D Associate at UMass Medical and winner of the Student Poster Competition, was on hand to present her poster and answer questions about her research.

The Annual Career Fair, a “show within a show,” provided a venue for leading area firms to meet potential new hires. For the first time, free tables were given to operating manufacturing companies to help them find qualified employees from among the ranks of our membership. In another first this year, we partnered with Career Builder to help source that talent and the feedback was positive all around. We will be expanding

that program next year, so if you are an operating company, be sure to sign up early.

Of course it wouldn't be a Boston Area Chapter Product Show without our fun networking activities. With the help of the Patriots Cheerleaders for Charity we raised almost \$1000 for the Patriots Charitable Foundation. With the backdrop of carnival games and food, we had live music provided by two great local bands, Stoli and Wolfpack. And when the exhibitor floor closed at 7:30pm, nearly 800 joined us at nearby Bar Louis to relax and unwind with drinks, appetizers and a chance to meet Pats Defensive End Chandler Jones.



The after party drew hundreds to Bar Louis, including Product Show Committee Co-Chair Steven Kennedy, shown here with Pats Defensive End Chandler Jones.

The Boston Area Chapter is pleased that this event continues to be offered free of charge, supported in full by our generous exhibitors. This includes free parking, free admission, free food and soft drinks and free educational seminars. The Product Show is our Chapter's flagship event and the revenue generated funds the Chapter and allows us to do many worthwhile things for our Members. So on behalf of the Chapter, thank you to all our exhibitors for your continued support. We look forward to your participation in 2015 and you are encouraged to pre-register and send in your deposit as soon as possible. Doing so will allow you to pick your spot in the exhibit area as soon as registration opens.

A Product Show like this does not happen without a lot of help from many people. Volunteers are the backbone of this organization. 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 2015, please contact the Chapter office at [office@ispeboston.org](mailto:office@ispeboston.org) or 781.647.4773. We are always looking for new volunteers to help make the Product Show bigger and better.

If you weren't able to attend this year, you missed the event of the season. To those that did attend, thank you and we look forward to seeing all of you on October 7, 2015 at Gillette Stadium for the 24th edition of the Boston Area Chapter Product Show!

### **Annual Chapter Awards Presented at Product Show**

*by Janet Tice, GMP Piping, with photos by Alistair Battson Photography*

Well on its way to becoming an annual tradition, Chapter President Chris Opolski presented this year's Chapter Awards during the Product Show plenary session. The awards were introduced in 2013 as a way to honor the exceptional contributions of the Chapter's volunteers.

The Volunteer of the Year Award recognizes Chapter Members who have demonstrated an exceptional 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 these goals. This year's winners are Mark Levanites of Sequence Validation for his efforts on the Product Show Committee; and Michael Levesque of GE Healthcare for his contributions as Co-Chair of the Educational Program Committee.



Annual Award winners (l to r) Mark Levanites and Michael Levesque (Volunteer of the Year), and Student Chapter Secretary Steven Alves and President Nathaniel Swanson of UMass Lowell (Student Chapter of the Year) with Chapter President Chris Opolski.



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 the Geographical Outreach (GO) Committee which has enabled the Chapter to bring its educational programs to a wider audience via remote simulcasts.



Chris Blackwell, Darren Wolter, Tulsa Scott, Jim Stout and John Spohn  
celebrate their Outstanding Achievement Award with Chapter President  
Chris Opolski.

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 participating in Boston Area Chapter student-related activities to the greatest extent possible. This year's winner is UMass Lowell.

The Chapter would like to extend its thanks and congratulations to this year's winners and to all the volunteers whose efforts ensure the Chapter's success.

### **Young Professionals and Student Chapters Team up at the Product Show**

*by Chris Ciampa, Thermo Fisher Scientific, with photos by Alastair Battson Photography*

On Wednesday, October 1, the Chapter held its Annual Product Show at Gillette Stadium. The Product Show is a mix of exhibits by operating companies (i.e. biopharma companies) and manufacturers, as well as career fairs and educational seminars. The Show also gives Members access to networking and other benefits they have come to expect from the ISPE. There are hundreds of exhibitors and thousands of attendees, not to mention spectacular views of Gillette Stadium typically reserved for Corporate sponsors and season ticket holders!



The Product Show always provides a great mix of education,  
entertainment and networking for the Chapter's young professionals  
and students.

The Product Show is a great way for Young Professional Members just starting out in their careers to learn about the industry, brush up on skills, network and possibly find their next job. Two of this year's educational programs, "Biotechnology: The Challenge for Tomorrow" and "Water Based Critical Utilities-RO, WFI, Steam" were introductory level presentations perfect for YPs as well as other professionals just entering the biopharm industry. Best of all, the event is free!

This year, as part of the programming, the YPs teamed up with the Student Chapters to host a networking reception. The event was hosted from 3-4pm in the West Clubhouse and provided a great forum for YPs and Student Members to get together and collaborate for an hour. After all, the Chapter's Student Members will be the YPs of the future once they graduate! A raffle was also held with fun prizes including Amazon and Starbucks gift cards. Hope you had a chance to stop by and enjoy the festivities!

As well as enjoying all that the Show had to offer, the YPs did their part to help grow the Chapter's membership base with a sign-in sheet to capture the names and email addresses of young professionals interested in attending YP meetings, dual track educational programs and other YP activities, not to mention next year's Product Show.

Now that the Product Show is behind us, watch for more great events from the YP side. Under consideration are a combined Student Chapter/YP event and a November/December beer social. Stay tuned – there will be lots of exciting things happening!

### **Product Show Guide Mobile App Launch**

*by H. Steven Kennedy, Chair Product Show Committee, and Samir Gondalia, Pfizer*

This year's Product Show marked another first, the launch of our new Product Show Guide Mobile App. The app is designed to replace the printed show guide which will be discontinued for 2015. (Be sure to hang onto your 2014 printed copy – it's now a collector's item!) The new app has everything the print version had and more. Some of its features include:

- General info on the Product Show and the Chapter.
- A way to connect with people you meet or want to meet at the Show. You can add your contact card and share it with people before, during and after the Show. It also has a shortcut to LinkedIn.
- Directions to Gillette.
- The Product Show schedule.
- Descriptions of the educational sessions and speakers.
- Interactive map of the Show layout and a list of exhibitors. You can even create your own personal schedule.
- And most important, the food menu, locations and timing. Want to make sure you snag a Dove Ice Cream Bar? With the app, you would have known they were in the Northeast and Northwest concession stands at 4 pm.

So be sure to download the app now. It has the complete list of exhibitors from this year's Show and will be kept active until exhibitor registration opens in the spring.

And now a special request: if you used the app at the Show, please provide us with your feedback by completing the survey that has been added to the app. Your input will help us make the app an even better tool for the 2015 Product Show!



### **Educational Program Season Kicks Off with “Good Engineering Practices**

*by Robert Mitchell, Robert Mitchell Engineering, with photos by Joyce Chiu, Honeywell Safety Products*



**The stunning atrium at Genzyme Center in Kendall Square greeted attendees at September's educational program.**

The ISPE Boston Area Chapter 2015 educational program season kicked off on September 18, 2014 with a panel lecture in the Dr. Roscoe Brady auditorium at Genzyme Center in Cambridge. The topic for this event was “ISPE Good Engineering Practice, aka How to Make Friends with your Validation Group.” The panel was comprised of industry experts who must each operate within the precepts of Good Engineering Practice (GEP) on a daily basis.

The evening began with a presentation by Howard Sneider, a Senior Process Engineer at Clark, Richardson & Biskup (CRB) Consulting Engineers. Mr. Sneider discussed the typical engineering requirements that all engineers must abide by in order to satisfy the needs of the client. His presentation followed the natural progression from user requirements to risk assessment through design deliverables. Mr. Sneider demonstrated that the relatively recent guidance from ISPE and standard from ASTM closely align with the historical design sequence that he presented in the first part of his presentation. Mr. Sneider concluded with a few examples of how additional reviews and non-GMP regulated management systems can benefit the efficiency and thoroughness of the design.

The next presentation was by Jeanine Gigante, the Associate Director of Global Engineering and Technology for Genzyme. Ms. Gigante identified situations where the regulated oversight of engineering design has occurred too early in the design. Her response to ensure that oversight occurs at the appropriate time is an Engineering Quality Program developed within the Genzyme Global Engineering Group and endorsed by the engineering groups throughout

the organization. The Engineering Quality Program can ensure GEP deliverables by defining roles and responsibilities, engineering processes, document management, change management and continuous improvement processes. Ms. Gigante shared her vision that a well implemented engineering Quality Program can result in an engineering deliverable with less inherent risk.



The last presentation was given by Paul Meehan, a Validation Manager at Shire. Mr. Meehan identified that the current requirements for validation have refocused the effort from a department of individuals back-checking the proposed design to anyone who obtains or generates documented evidence to verify that a system performs as specified. Mr. Meehan characterized the need for validation as the best answer to a query by a regulatory audit. In conclusion he identified that validation may not provide lower cost but may provide a higher return on investment, may not provide the most rapid start up but may minimize manufacturing downtime and may not improve the quality of an engineering design but may positively influence the culture that is responsible for that design.



Panelists (l to r) Howard Sneider, Jeanine Gigante and Paul Meehan addressed a dual audience in Cambridge, MA and (via simulcast) Warwick, RI.

The evening concluded with about a half hour of questions from the audience from both the attendees at Genzyme Center and those participating remotely at the simulcast in Warwick, Rhode Island coordinated by the Chapter's Geographic Outreach Committee. Questions included best practices for URS's, methodologies for identifying like-for-like equipment changes, stakeholder management when reviewing documents, scheduling of validation/verification activities, and implementation of E2500.

On behalf of the Boston Area Chapter, the Program Managers would like to thank Genzyme for hosting this event. We would also like to thank each of the presenters for their insight, knowledge and expertise. And lastly we would like to thank the evening's sponsor, Tufts Gordon Institute, whose support enables the Boston Area Chapter to provide high-quality educational programs such as this.

### **Student Chapters Ramp Up for Fall Semester**

*by Brian Hagopian, Clear Water Consulting with photographs by Alastair Battson Photography*

#### **Student Chapters Hit the Ground Running**

The fall semester has been busy for all of our Student Chapters. Campus visits to recruit Members and promote the Product Show were highly successful as student membership in the Chapter increased by a whopping 18 percent in September, the largest increase in the history of the Chapter!

#### **Welcome to Middlesex Community College: Our Newest Student Chapter!**

The Chapter is proud to announce that Middlesex Community College has just become our newest Student Chapter. Things are off to a great start as several students were "wowed" when they attended the Product Show.



Middlesex Community College students and Faculty Advisor Patricia Richard enjoyed their first Product Show at Gillette.

#### **Product Show a Big Hit with Students**

The Chapter sent buses to the majority of our campuses and brought about 125 students to Gillette Stadium for the Product Show. In addition to the 375 exhibitors and the Career Fair, students attended educational programs, participated in the student/young professional networking social, relaxed in the "Entertainment Zone" and attended a presentation on "How to Network at the Product Show" by past president Dave Novak. At the end of the day, students were bubbling over with enthusiasm when asked whether they enjoyed the Show.



Student attendees found time to relax in the Entertainment Zone during the Product Show.

#### **UMass Lowell Receives "Student Chapter of the Year" Award**

At this year's Product Show, UMass Lowell was selected as the Student Chapter of the Year. The ISPE University of Massachusetts - Lowell Student Chapter won the award because of increases in student membership, activities on campus and by becoming an official "club" within the University, providing ISPE with greater visibility on campus as well as access to a greater number of students. Special thanks go to Mustapher Lubega, Membership Committee Chair and Thariq Iqbal, student member, for their exemplary efforts on behalf of the Chapter.



Accepting the Student Chapter of the Year Award on behalf of UMass Lowell were Student Chapter President Nathaniel Swanson, Secretary Steven Alves and a proud group of UMass Lowell Student Chapter Members.

#### **Scholarship Program Reaches New High**

One of the biggest benefits of being a Student Member of the Chapter is that you can apply for scholarships. The Chapter's scholarship program awarded \$12,500 to its Student Members during the most recent award period. Please join the chapter in congratulating the following students who received scholarships:

Anatoliy Tereshchuk, UMass Amherst  
 Chelsea Fox, University of Rhode Island  
 Daniel Ahlstedt, Northeastern University  
 Lauren Morse, Worcester Polytechnic Institute  
 Valmik Parag Doshi, Massachusetts College of Pharmacy & Health Sciences University  
 Raymond Lawton, UMass Dartmouth  
 Bo Yang, Massachusetts College of Pharmacy & Health Sciences University  
 Connor Brown, Assumption College  
 Steven Alves, UMass Lowell  
 Jahzmin Walker, University of Maine, Orono

Remember, the next application period ends on November 15. Visit the Chapter website at <http://www.ispeboston.org/scholarship.html> for more information and a copy of the application. You can't win a scholarship if you don't apply!

#### **Students Attend Local ISPE Educational Events for Free**

Remember, once you join ISPE as a Student Member ([www.ispe.org/join-or-renew](http://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!

#### **Want to Become More Involved?**

There is no better way to give back than to volunteer. The Chapter already has a large number of dedicated volunteers coordinating all these student efforts, but all this activity takes time and we could sure use the help. If you're interested in helping out, just shoot us an email at [office@ispeboston.org](mailto:office@ispeboston.org). 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!

## 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.

### Protein Sciences and Diamyd Medical to Develop New Treatment for Diabetes

Connecticut-based Protein Sciences has broadened its commitment to diabetes and become a strategic and significant shareholder in Stockholm, Sweden-based Diamyd Medical, its long-time partner in this domain. Protein Sciences will manufacture product for upcoming late stage clinical trials for type 1 diabetes involving Diamyd Medical's recombinant GAD (glutamic acid decarboxylase) protein made using Protein Sciences' proprietary BEVS technology.

The diabetes vaccine Diamyd (GAD formulated with alum) has been evaluated as a monotherapy for type 1 diabetes in a Phase 3 study and data suggests Diamyd may be a critical component of combination therapies that pair the tolerance-inducing GAD antigen with anti inflammatory agents for the treatment and prevention of type 1 diabetes. This is being evaluated in ongoing and upcoming Phase 2 studies.

Under the agreement, Diamyd Medical is placing an order for cGMP production of recombinant GAD protein for which Protein Sciences receives a cash payment and 400,000 new series B shares in Diamyd Medical corresponding to a 2 percent ownership in Diamyd Medical. The ownership stake will make Protein Sciences one of the largest shareholders in Diamyd Medical. (Source: Protein Sciences Website, 16 September, 2014)

### Regeneron's Eylea Receives FDA Breakthrough Therapy Designation

Regeneron Pharmaceuticals has announced that the FDA has granted Eylea (afibercept) Injection Breakthrough Therapy designation for the treatment of diabetic retinopathy in patients with diabetic macular edema (DME). The designation is based on positive results in two Phase 3 trials in which Eylea demonstrated a statistically significant improvement in a pre-specified measure of diabetic retinopathy in patients with DME after two years of treatment.

The Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs for serious or life-threatening conditions. Drugs qualifying for this designation must show credible evidence of a substantial improvement on a clinically significant endpoint over available therapies or over placebo if there is no available therapy. The designation includes all of the fast track program features, as well as more intensive FDA guidance and discussion. The Breakthrough Therapy designation is distinct from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

Diabetic retinopathy is a common complication of diabetes, causing damage to the retina, which may lead to poor vision and vision loss. Over time, patients with diabetic retinopathy are at risk of experiencing vision-threatening events. These include DME, which refers to the swelling of the macula (the part of the retina responsible for central, fine vision) and progression to proliferative diabetic retinopathy, which often results in profound visual loss. DME is the most frequent cause of vision loss in patients with diabetes and eventually can lead to blindness.

It is estimated that of the 29.1 million American adults living with diabetes, 7.7 million have diabetic retinopathy, 1.5 million have been diagnosed with DME and approximately another million cases of DME are undiagnosed.

Eylea is approved in the United States, European Union (EU) and other countries for the treatment of wet age-related macular degeneration, macular edema following central retinal vein occlusion, and DME. Regulatory submissions have been made for Eylea in the U.S. and EU for macular edema following branch retinal vein occlusion. (Source: Regeneron Website, 16 September 16, 2014)

### Concert Pharmaceuticals Initiates Phase 1 Clinical Trial under Celgene Collaboration

Lexington based Concert Pharmaceuticals announced that it has initiated a Phase 1 clinical trial of CTP-730, a novel product candidate that is being developed under its strategic collaboration with Celgene for treatment of inflammation. Concert will conduct the randomized, double-blind, single-ascending-dose Phase 1 clinical trial designed to assess the safety, tolerability and pharmacokinetics of CTP-730. The study is expected to enroll up to 40 healthy subjects. The Phase 1 clinical program will also evaluate multiple ascending doses of CTP-730 and is expected to be completed in 2015.

Concert Pharmaceuticals is a clinical stage biopharmaceutical company focused on applying its DCE platform (deuterated chemical entity platform) to create novel small molecule drugs. This approach starts with approved drugs, advanced clinical candidates or previously studied compounds that have the potential to be improved with deuterium substitution to enhance clinical safety, tolerability and efficacy. The company is developing a broad pipeline targeting central nervous system disorders, renal disease, inflammation and cancer. (Source: Concert Pharmaceuticals Website, 17 September, 2014)

### Epirus' Remicade Biosimilar Receives Final Approvals in India

Epirus Biopharmaceuticals, a Boston-based biopharmaceutical company focused on the global development and commercialization of biosimilar monoclonal antibodies, announced that it has received final marketing and manufacturing approvals for its Remicade (infliximab) biosimilar, BOW015, from the Drug Controller General of India (DCGI). BOW015 is the first infliximab biosimilar approved in India.

BOW015 is a biosimilar to Remicade, which is marketed globally for the treatment of inflammatory diseases including rheumatoid arthritis, Crohn's Disease, ankylosing spondylitis, ulcerative colitis, psoriatic arthritis and psoriasis. BOW015 will be manufactured by Reliance Life Sciences at a facility in Mumbai which was inspected and approved in July of this year. The DCGI has issued the final clearances for BOW015 and Epirus and its commercialization partner Ranbaxy Laboratories Limited (Ranbaxy) expect to launch the drug, under the brand name Infimab, by the first quarter of 2015.

Ranbaxy and Epirus signed a licensing agreement for BOW015 in January of 2014. Under the terms of the agreement, Epirus will develop and supply BOW015, and Ranbaxy will register and commercialize BOW015 in India as well as in other territories in Southeast Asia, North Africa, and selected other markets. (Source: Epirus Biopharmaceuticals Website, 15 September, 2014)

### EMD Serono and Sutro Biopharma to Partner on Antibody Drug Conjugates

EMD Serono, a subsidiary of Merck KGaA, and Sutro Biopharma, San Francisco, a biopharmaceutical company developing antibody drug conjugates and biospecific antibodies, have announced a collaboration



and license agreement to develop antibody drug conjugates (ADCs). ADCs are composed of an antibody linked to a cytotoxic drug. The antibody is thought to specifically target and deliver the cytotoxic drug to cancer cells.

The collaboration will allow EMD Serono to take advantage of Sutro's technology platforms in its oncology programs to develop ADCs for multiple undisclosed targets. Both companies believe that ADCs have the potential for directly targeting cancer cells while safeguarding healthy tissue, and will combine EMD Serono's knowledge about target biology with Sutro's technological and discovery capabilities to jointly develop ADCs.

Under the terms of the agreement, Sutro and EMD Serono will collaborate to discover and develop multiple ADCs utilizing Sutro's cell-free protein synthesis platforms, Xpress CF and Xpress CF+. Sutro will be responsible for delivering ADCs for Phase I clinical trials. EMD Serono will be responsible for clinical development and commercialization of any resulting products.

EMD Serono will make an upfront payment to Sutro and will fund certain R&D activities. Sutro is also eligible to receive payments on completion of certain research, development and regulatory milestones potentially totaling approximately \$375 million as well as royalties on product sales. Further financial details are not being disclosed. (Source: EMD Serono Website, 17 September, 2014)

#### **Merck KGaA to Acquire Sigma-Aldrich**

Merck KGaA and Sigma-Aldrich announced that they have entered into a definitive agreement under which Merck KGaA, Darmstadt, Germany, will acquire Sigma-Aldrich for \$17.0 billion (€13.1 billion). Merck KGaA will acquire all of the outstanding shares of Sigma-Aldrich for \$140 per share in cash. The agreed price represents a 37% premium to the latest closing price of \$102.37 on September 19, 2014, and a 36% premium to the one-month average closing price. Merck KGaA, expects to achieve annual synergies of approximately €260 million (approximately \$340 million), which should be fully realized within three years after closing.

Merck KGaA plans to maintain a significant presence in St. Louis, and in Billerica, following completion of the transaction, as well as in important EMD Millipore sites such as Darmstadt and Molsheim, France.

The transaction has been unanimously approved by Sigma-Aldrich's Board of Directors; a merger agreement will be presented to Sigma-Aldrich shareholders for approval at a special meeting of shareholders. The transaction has the full support of Merck KGaA, Darmstadt, Germany's Executive Board and E. Merck KG including its Board of Partners, and a Merck KGaA, Darmstadt, Germany, shareholder vote will not be required. Bridge financing has been secured for the all-cash transaction, and Merck KGaA, Darmstadt, Germany, expects the final financing structure will comprise a combination of cash on Merck KGaA, Darmstadt, Germany's balance sheet, bank loans and bonds. Closing is expected in mid-year 2015, subject to regulatory approvals and other customary closing conditions. (Source: EMD Serono Group Website, 22 September, 2014)

#### **Bristol-Myers Squibb Withdraws Application for Asunaprevir in the U.S.**

Bristol-Myers Squibb has decided that it will not pursue FDA approval of the dual regimen of daclatasvir and asunaprevir for the treatment of HCV (hepatitis C virus) genotype 1b patients in the United States and has therefore withdrawn its new drug application (NDA) for asunaprevir. The company will continue to pursue FDA approval of daclatasvir, which is currently being investigated globally in multiple treatment regimens for HCV patients with high unmet need.

BMS received regulatory approval for the dual regimen of daclatasvir and asunaprevir in July from Japan. The dual regimen was developed to meet the need of the Japanese patient population, as well as in other markets where the HCV patient population is similar to Japan. In the EU, daclatasvir was recently approved for use in combination with other medicinal products across genotypes 1, 2, 3 and 4 for the treatment of HCV infection in adults.

BMS plans to submit additional data for daclatasvir to the FDA from their ongoing clinical trial program focused on difficult-to-treat patients, including patients with HCV genotype 3, patients who are pre- and post-liver transplant, and patients co-infected with HIV. (Source: Bristol-Myers Squibb Website, 07 October 2014)

#### **Johnson & Johnson Acquires Alios BioPharma**

Johnson & Johnson will be acquiring Alios BioPharma for approximately \$1.75 billion in cash payable upon closing of the transaction. The transaction has been approved by the boards of directors of both companies.

Alios BioPharma is a clinical stage biopharmaceutical company based in South San Francisco developing novel therapies for the treatment of viral diseases. The Alios discovery and development platform consists of a proprietary chemical library of nucleoside analogs as well as novel, proprietary virology-based screening systems. Alios is developing a portfolio of potential therapeutics for viral infections including those caused by respiratory syncytial virus, influenza, rhinovirus, coronavirus and HCV. (Source: Alios BioPharma Website, 30 September, 2014)

#### **Takeda Announces Reorganization and Creation of Oncology Specialty Business Unit**

Takeda Pharmaceuticals has announced plans to redesign its global organizational structure. The company's new organizational structure will redefine all regional commercial divisions into five Regional Business Units and two Specialty Business Units. The five newly established Regional Business Units will be Japan Pharma, Emerging Markets, United States, Europe-Canada, and Japan Consumer Healthcare, while the two newly established Specialty Business Units will be Oncology and Vaccines. The details of the transition plans are currently under consideration but it is planned that the changes announced will be fully implemented by April 1. Millennium, the Takeda Oncology Company is currently based in Cambridge, MA. (Source: Takeda Website, 16 September, 2014)

#### **Infinity and AbbVie to Collaborate on Cancer Drug Duvelisib**

Cambridge-based Infinity Pharmaceuticals and AbbVie have announced that they have entered into a global collaboration to develop and commercialize duvelisib (IPI-145), Infinity's oral inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, for the treatment of patients with cancer. Duvelisib has shown clinical activity across a broad range of blood cancers, including indolent non-Hodgkin lymphoma (iNHL) and chronic lymphocytic leukemia (CLL). Infinity is conducting registration-focused trials evaluating the safety and efficacy of duvelisib.

Under the terms of the agreement, Infinity will receive an upfront payment of \$275 million and is eligible to receive up to \$530 million in additional payments for the achievement of development, regulatory and commercial milestones, including up to \$405 million for the achievement of milestones through the first

commercial sale of duvelisib. In the U.S., the companies will jointly commercialize duvelisib and will share equally in any potential profits. Outside the U.S., AbbVie will be responsible for the conduct and funding of commercialization of duvelisib, and Infinity is eligible to receive tiered double-digit royalties on net product sales.

For sales of duvelisib in the U.S., AbbVie and Infinity will share equally the existing royalty obligations to Mundipharma International Corporation Limited/Purdue Pharmaceutical Products L.P., and Infinity will be responsible for these royalty obligations outside of the U.S. Infinity will also be responsible for the existing royalty obligations to Millennium: The Takeda Oncology Company for sales of duvelisib worldwide.

As part of the strategic collaboration, the companies will share responsibility for the conduct of specific trials, with each company leading the development of certain trials within the plan. For the initial global development plan agreed to by the companies, Infinity will fund the trials it conducts and the companies will share equally the funding of trials conducted by AbbVie. The agreement includes plans to launch multiple Phase 2 and Phase 3 studies of duvelisib in hematologic malignancies over the next several years. (Source: Abbvie Website, 03 September, 2014)

#### **Sarepta Therapeutics Publishes Results of Ebola and Marburg Phase I Clinical Study**

Cambridge-based Sarepta Therapeutics has announced the publication of results from two single ascending-dose studies that demonstrated no clinical or toxicologic safety concerns with the company's drug candidates for the treatment of Ebola and Marburg virus, respectively.

These drug candidates use Sarepta's advanced and proprietary PMOplus® chemistry, which is also the basis of the company's clinical-stage influenza drug candidate, AVI-7100. Results from previous viral challenge studies of AVI-6002 and AVI-6003 in non-human primates demonstrated prevention of disease development and death following exposure to Ebola or Marburg virus. Subsequent animal studies demonstrated that for each combination therapy, only one oligomer contributed to efficacy, and therefore, the lead drug candidates for Ebola and Marburg have since become the single compounds AVI-7537 and AVI-7288.

Sarepta develops RNA-based therapeutics for serious and life-threatening rare and infectious diseases. The company's pipeline includes its lead program eteplirsen and follow-on drug candidates for Duchenne muscular dystrophy, as well as potential treatments for some of the world's most lethal infectious diseases. Sarepta's PMOplus® chemistry is an advanced generation of Sarepta's phosphorodiamidate morpholino oligomer, or PMO, technology pioneered by Sarepta. The PMO platform is designed to provide a stable chemistry backbone with drug-like characteristics for Sarepta's advanced RNA-based therapeutics. PMOplus® chemistry includes specific molecular charges positionally inserted into the PMO's inherent charge-neutral backbone. (Source: Sarepta Website, 16 October, 2014)

#### **Abbvie and Shire Agree to Terminate Proposed Merger**

AbbVie and Shire have agreed to terminate their proposed merger following the decision by AbbVie's Board to withdraw support for the proposed transaction. The company's decision was based upon its assessment of the September 22, 2014 notice issued by the U.S. Department of Treasury, which re-interpreted longstanding tax principles, reducing the financial benefits of inversions. The notice introduced an unacceptable level of risk and uncertainty given the magnitude of the proposed changes and the stated intention of the Department of Treasury to continue to revise tax principles to further impact such transactions.

AbbVie has confirmed that it does not wish to switch to a contractual takeover offer. Under the U.K. Takeover Code, except with consent of the U.K. Takeover Panel, AbbVie must not, among other things, announce a further offer for Shire within 12 months from the date of the announcement. AbbVie has agreed to pay Shire the break fee of approximately USD\$1.635 billion. Shire's right to receive the break fee will be Shire's sole and exclusive remedy for all losses and damages in connection with the transaction. (Source: Abbvieinvestor.com, 20 October, 2014)

#### **Roche Purchases InterMune**

Roche and InterMune have announced that Roche's wholly owned subsidiary Klee Acquisition Corporation completed its tender offer for all outstanding shares of common stock of InterMune at \$74.00 per share in cash. Roche then completed the acquisition of InterMune through a merger of Klee Acquisition Corporation with and into InterMune. In the merger, all shares of InterMune not owned by InterMune, Roche or their respective wholly owned subsidiaries (other than shares as to which appraisal rights have been validly exercised under Delaware law) will be converted into the right to receive the same cash consideration per share, less any applicable withholding taxes, as was paid in the tender offer. Following completion of the merger, InterMune will become a wholly owned subsidiary of Roche and InterMune's shares will cease to be traded on NASDAQ Stock Market.

InterMune is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and orphan fibrotic diseases. In pulmonology, the company is focused on therapies for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive, irreversible, unpredictable and ultimately fatal lung disease. InterMune's research programs are focused on the discovery of targeted, small-molecule therapeutics and biomarkers to treat and monitor serious pulmonary and fibrotic diseases. (Source: Roche Website, 29 September, 2014)

#### **Bayer HealthCare Partners with Dimension Therapeutics on Hemophilia A**

Bayer HealthCare (Bayer) and Cambridge-based Dimension Therapeutics have entered into a collaboration for the development and commercialization of a novel gene therapy for the treatment of hemophilia A.

Dimension Therapeutics is a gene therapy company focused on developing novel therapies to treat rare diseases. The company is focused on building its adeno-associated virus (AAV) therapeutic capabilities and advancing multiple gene therapy programs in rare diseases, and is advancing a wholly-owned hemophilia B program towards clinical development. Dimension Therapeutics' AAV vector technology allows for systemic intravenous administration of the clotting factor gene in vivo, which has been shown in preclinical studies to target the liver resulting in long lasting expression of FVIII protein at therapeutic levels. Dimension Therapeutics' vectors are enabled by REGENX Biosciences' proprietary NAV technology.

Under the terms of the agreement, Dimension Therapeutics will receive an upfront payment of \$20 million and will be eligible for potential development and commercialization milestone payments of up to \$232 million. Dimension Therapeutics will be responsible for all pre-clinical development activities and the Phase I/IIa clinical trial, with funding from Bayer. Depending on the results of the Phase I/IIa clinical trial, Bayer will conduct the confirmatory Phase III trial, make all regulatory submissions, and will have worldwide rights to commercialize the potential future product for the treatment of hemophilia A. Dimension Therapeutics is

eligible to receive tiered royalties based on product sales. (Source: Bayer Healthcare Website, 23 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.

### **Genzyme Drug for Gaucher Disease Wins FDA Approval**

The FDA has approved Genzyme's Cerdelga (eliglustat) for the long-term treatment of adult patients with the Type 1 form of Gaucher disease, a rare genetic disorder. Gaucher disease occurs in people who do not produce enough of an enzyme called glucocerebrosidase. The enzyme deficiency causes fatty materials to collect in the spleen, liver and bone marrow. The major signs of Gaucher disease include liver and spleen enlargement, low red blood cell counts (anemia), low blood platelet counts and bone problems.

Cerdelga is a hard gelatin capsule containing eliglustat that is taken orally. In patients with Gaucher disease Type 1, the drug slows down the production of the fatty materials by inhibiting the metabolic process that forms them. Type 1 Gaucher disease is estimated to affect about 6,000 people in the United States. (Source: FDA Website, 19 August, 2014)

### **FDA Approves Merck's Keytruda for Advanced Melanoma**

The FDA has granted accelerated approval Merck for Keytruda (pembrolizumab) for treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. Keytruda is the first approved drug that blocks a cellular pathway known as PD-1, which restricts the body's immune system from attacking melanoma cells.

Keytruda is intended for use following treatment with ipilimumab, a type of immunotherapy. For melanoma patients whose tumors express a gene mutation called BRAF V600, Keytruda is intended for use after treatment with ipilimumab and a BRAF inhibitor, a therapy that blocks activity of BRAF gene mutations. The five prior FDA approvals for melanoma include: ipilimumab (2011), peginterferon alfa-2b (2011), vemurafenib (2011), dabrafenib (2013), and trametinib (2013).

The FDA granted Keytruda breakthrough therapy designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies. It also received priority review and orphan product designation. Priority review is granted to 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. Orphan product designation is given to drugs intended to treat rare diseases. (Source: FDA Website, 04 September, 2014)

### **Eli Lilly Drug Trulicity Approved by FDA to Treat Type 2 Diabetes**

The FDA has approved Trulicity (dulaglutide), a once-weekly subcutaneous injection to improve glycemic control (blood sugar levels), along with diet and exercise, in adults with type 2 diabetes. Type 2 diabetes affects about 26 million people and accounts for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage.

Trulicity has a boxed warning that tumors of the thyroid gland (thyroid C-cell tumors) have been observed in rodent studies with Trulicity but that it is unknown whether Trulicity causes thyroid C-cell tumors, including a type of thyroid cancer called medullary thyroid carcinoma (MTC), in humans. Trulicity should not be used in patients with a personal or family history of MTC or in patients with multiple endocrine neoplasia syndrome type 2 (a disease in which patients have tumors in more than one gland in their body, which predisposes them to MTC). (Source: FDA Website, 18 September, 2014)

### **FDA Awards Grants to Stimulate Drug, Device Development for Rare Diseases**

The FDA has announced it has awarded 15 grants totaling more than \$19 million to boost the development of medical device, drug, and biological products for patients with rare diseases, with at least a quarter of the funding going to studies focused solely on pediatrics.

The program is administered through the FDA's Orphan Products Grants Program. This program was created by the Orphan Drug Act, passed in 1983, to promote the development of products for rare diseases. Since its inception, the program has given more than \$330 million to fund more than 530 new clinical studies on developing treatments for rare diseases and has been used to bring more than 50 products to marketing approval.

For the grants program therapies, a disease or condition is considered rare if it affects less than 200,000 persons in the United States. There are about 7,000 rare diseases and conditions, according to the National Institutes of Health. In total, nearly 30 million Americans suffer from at least one rare disease. (Source: FDA Website, 30 September, 2014)

### **FDA Takes Steps to Strengthen Cybersecurity of Medical Devices**

To strengthen the safety of medical devices, the FDA finalized recommendations to manufacturers for managing cybersecurity risks to better protect patient health and information.

The final guidance, titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," recommends that manufacturers consider cybersecurity risks as part of the design and development of a medical device, and submit documentation to the FDA about the risks identified and controls in place to mitigate those risks. The guidance also recommends that manufacturers submit their plans for providing patches and updates to operating systems and medical software.

As medical devices become more interconnected and interoperable, they can improve the care patients receive and create efficiencies in the healthcare system. Some medical devices, like computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. By carefully considering possible cybersecurity risks while designing medical devices, and having a plan to manage system or software updates, manufacturers can reduce the vulnerability in their medical devices. (Source: FDA Website, 01 October, 2014)

### **FDA Approves Akynzeo for Nausea and Vomiting Associated with Cancer Chemotherapy**



The FDA has approved Akynzeo (netupitant and palonosetron) to treat nausea and vomiting in patients undergoing cancer chemotherapy. Akynzeo is a fixed combination capsule comprised of two drugs. Oral palonosetron, approved in 2008, prevents nausea and vomiting during the acute phase (within the first 24 hours) after the start of cancer chemotherapy. Netupitant, a new drug, prevents nausea and vomiting during both the acute phase and delayed phase (from 25 to 120 hours) after the start of cancer chemotherapy.

Akynzeo is distributed and marketed by Eisai of Woodcliff Lake, NJ under license from Lugano, Switzerland-based Helsinn Healthcare. (Source: FDA Website, 10 October, 2014)

#### **FDA Approves First Combination Pill to Treat Hepatitis C**

The FDA has approved Harvoni (ledipasvir and sofosbuvir) to treat chronic hepatitis C virus (HCV) genotype 1 infection. Harvoni is the first combination pill approved to treat chronic HCV genotype 1 infection. It is also the first approved regimen that does not require administration with interferon or ribavirin, two FDA-approved drugs also used to treat HCV infection.

Both drugs in Harvoni interfere with the enzymes needed by HCV to multiply. Sofosbuvir is a previously approved HCV drug marketed under the brand name Sovaldi. Harvoni also contains a new drug called ledipasvir.

Harvoni and Sovaldi are marketed by Gilead, based in Foster City, CA. Olysio is marketed by Janssen Pharmaceutical based in Raritan, NJ. (Source: FDA Website, 10 October, 2014)

#### **FDA Approves Velcade for Patients with Mantle Cell Lymphoma**

This approval extends the benefit of Velcade (bortezomib) for mantle cell lymphoma (MCL) to previously untreated patients in addition to relapsed or refractory patients and is the first treatment approved by the FDA for newly diagnosed MCL patients. Velcade is co-developed by Millennium/Takeda and Janssen Pharmaceutical Companies.

MCL is a rare, aggressive type of B-cell non-Hodgkin lymphoma (NHL) that usually occurs in older adults. MCL constitutes about 6 percent of cases of NHL. The disease typically begins in the lymph nodes but can spread to other tissues, such as bone marrow and liver. The expected overall survival for MCL is approximately four to five years, and the five-year survival rate for advanced stage MCL is approximately 50 percent. (Source: Millenium Website)

#### **Orphan Drug Approvals Up, But High Costs Pose Challenges for Patients**

Although the pace of approvals for new orphan drugs - medicines that treat relatively rare conditions - have increased in the United States and Europe in recent years, patients are facing growing challenges accessing those drugs, a newly completed study by the Tufts Center for the Study of Drug Development at Tufts University has concluded.

Orphan drugs are those developed for rare diseases and conditions that affect fewer than 200,000 people in the U.S., or five per 10,000 or fewer people in the European Union. During the 14-year period 2000-2013, 86 orphan drugs were approved in the U.S., up from 65 during the prior 18-year period 1983-2000, while in Europe 96 orphan drugs were approved in 2000-2013, more than double the 44 approved in the earlier period, according to Tufts CSDD.

Among the challenges that limit patient access to orphan drugs in the U.S., relative to Europe, is higher cost-sharing by patients, which can lead to increased levels of non-compliance, according to Joshua Cohen, Assistant Professor at Tufts CSDD, who conducted the analysis. The most expensive orphan drugs can cost more than half a million dollars per year per patient in the U.S. (Source: The Tufts Center for the Study of Drug Development Website, 10 July, 2014)

### **New Members**

**Mr. Christopher Abbott**, *Assoc. Director*, Process Eng., AMRI Global

**Ms. Rebecca Adams**, *Business Dev Manger*, RDK Engineers

**Oluwatosin E. Adedokun**, *Validation Engineer*, Shire Pharmaceuticals

**Kinda Almon**, F.W. Webb High Purity

**Mr. Stephen Beck**, LeChase Construction Services

**Mr. Mark Braatz**, *Life Sciences Account Manager*, F.W. Webb Process Controls Division

**Elizabeth Burkhart**, University of Massachusetts Lowell

**Mr. Thomas J. Burns**, *Director*, Operational Excellence, Shire Pharmaceuticals

**Mr. Shawn R. Carriker**, *Student*, University of Massachusetts Amherst

**Elissa Chao**, *Student*, UMass Lowell

**Mr. Wenjie Cheng, PhD**, *Scientist*, ImmunoGen Inc

**David Crespo**, *Student*, Middlesex Community College

**David M. Crosson**, *Student*, University of Massachusetts Lowell

**Ms. Shuli Cui**, *Student*, Northeastern university

**Mr. Sean P. Curtin**, *Student*, University of New Hampshire

**Mr. Steven J. Davis**, Genzyme Biologics

**Ms. Alexandra Diaz**, *Biotechnology*, Middlesex Community College

**Ms. Lisa M. Doherty**, AHA Consulting Engineers

**Nabeh Doumit**, UMass Lowell

**Nathan Dube**, *Electrical Engineer*, CannonDesign

**Dustin Dufour**, Teleflex

**Mr. Joseph Esposito**, *Student*, University of New Hampshire

**James Ethier**

**Ms. Sarita Fajardo**, *Student*, Middlesex Community College

**Justin Ferrentino**, CPS Process Solutions

**Ms. Chelsea B. Fox**, *Student*, University of Rhode Island

**Mr. Christian Fuller**, *Student*, University of New Hampshire

**Simona Gherman**,

**Ms. Nancy Gorski**, *Business Technology Business Partner*, Pfizer Inc

**Colin R. Graham**, *Student*, University of New Hampshire

**Michael Haepers**, Lantheus Medical Imaging

**Mr. Kyle B. Haraldsen**, *Sr Dir*, Technical Operations, AMAG PHARMACEUTICALS

**Abizer Harianawala**, ARIAD Pharmaceuticals, Inc

**Matthew Hildner**, MIT

**Md Shafiul Hossain**, *Student*, University of Massachusetts-Amherst

**Emily Itzkowitz**, *Student*, University of Connecticut

**Mr. Brian T. Johnson**, Commodore Builders - Life Sciences Group

**Mr. John P. Jorschick**, Mylan Technologies

**Mr. Seth Kitchener**, *Sr. BioReactor Process Engineer*, ImmunoGen Inc

**Luiza Y. Korobkova**, *Student*, University of Massachusetts Amherst

**Mr. Arun Shankar Kumarapally**, *Lead Engineer*, Hyde Engineering + Consulting Inc

**Jemima Lamothe**, *Student*, University of Massachusetts Amherst

**Mr. Martin Landsmann**

**Jennifer Langh**, *Student*, Northeastern University

**Mr. Charles Laranjeira**, *Sr VP Technical Operations*, Cubist Pharmaceuticals

**Kyle LaVigne**

**Ms. Joan Lazauski**, *Student*, University of Rhode Island

**Mr. Michael S. Lerch**, *Student*, University of New Hampshire

**Susan Lockyer**, CRB Consulting Engineers, Inc.

**Kelsey C. Martin**, *Student*, University of Massachusetts - Lowell

**Matthew Mason**, Softworld

**Ms. Lindsay McGrail**, *Student*, Middlesex Community College

**Christopher McLaughlin**, *I&C Department Manager*, DPS Engineering

**Lindsey Mello**, Sanofi Pasteur Biologics, LLC

**Samantha D. Moran**, *Student*, Middlesex Community College

**Mr. Angela Murray**, University of Massachusetts Dartmouth

**Mr. Samuel J. Musiak**, *Student*, University of Massachusetts Lowell

**Aisha Nakato**, *Student*, Middlesex Community College

**Ms. Bonnie A. Neuhardt**, Sunovion Pharmaceuticals Inc

**Patrick Norton**, *Project Manager*, M+W USA Inc

**Mr. Matthew H. Noyes**, *Student*, Worcester Polytechnic Institute

**Mr. Miguel Pagan**

**Lauren J. Pallister**

**Tom Panella**, Design Group Facility Solutions

**Guddi Patel**, *Manager*, Risk Mgmt and Regulatory Compliance, Oracle/HSGBU

**Cheryl Plummer**, Shire

**Mr. Matthew Pratt**, *Student*, University of Massachusetts Lowell

**Michael P. Ratigan**, Microfluidics International Corporation

**Patricia V. Richard**, *M.Ed., Asst. Professor*, Middlesex Community College

**Terry Ryan**

**Mr. Benjamin William Ryter**, *Student*, Student, University of Massachusetts Amherst

**Sarah Sapouckey**, *Student*, University of Massachusetts Amherst

**Mr. Thomas Sauro**, *Mechanical Engineer*, CRB Consulting Engineers, Inc.

**Mr. Peter Schmidt**, CRB Consulting Engineers, Inc.

**Dr. Jennifer Schubert**, Vertex Pharmaceuticals

**Ms. Sophia Seryazi**, *Student*, Middlesex Community College  
**Ms. Alexandra Sneider**, *Student*, University of Massachusetts Lowell  
**Mr. Vannak Som**, *Student*, Middlesex Community College  
**Mr. Andrew Sparaco**, *Assistant Project Manager*, Commodore Builders  
**Mr. Brian J. Splaine**, Worcester Polytechnic Institute  
**Grace Stroman**, *Student*, University of Massachusetts-Amherst  
**Nicholas M. Sweeney-Cook**, *Student*, University of New Hampshire  
**Mr. Jeffrey Talka**, Architect, The S/L/A/M Collaborative  
**Tristan J. Tay**, *Student*, University of Massachusetts Amherst  
**Christopher M. Thakkar**, University of Massachusetts Amherst  
**Mr. Russell Thoman**, Pure Process Technology  
**Mr. Christopher J. Thornton**, *Student*, University of Massachusetts Lowell  
**Mr. Sean M. Towler**, *Student*, University of New Hampshire  
**Francis D. Tran**, *Student*, Middlesex Community College  
**Mr. Connor Walsh**, *Student*, University of Massachusetts Amherst  
**Michelle Wang**, Shire plc  
**Jason Wentworth**, Shire  
**Halie White**, *Student*, University of New Hampshire  
**John Wiggins**, Lantheus Medical Imaging  
**Mr. Nicholas Woodward**, *Student*, Northeastern University  
**Dr. Jill Zemianek**, Shire PLC  
**Ms. Gui Zishu**, MCPHS university

#### **Member Anniversaries**

#### **20+ Years of Membership**

**Mr. Saboo Aghababayan**, Genzyme Corp  
**Mr. John P. Alleruzzo**  
**Mr. Fred H. Arbogast**, Critical Process Filtration Inc.  
**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. Robert T. Clark**, Perrigo Inc  
**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. Abel A. Erdman**, Bristol-Myers Squibb Co

**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

**Ms. Amy Foley**, The Richmond Group Inc

**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. 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. Michael J. James**, Northeast Water Services

**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**, Synageva BioPharma

**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**, Lonza Biologicals

**Stephen P. Miraglia**, Sapphire Project Services LLC

**Mr. David Monette**, Novo Nordisk

**Mr. Peter Mosgrove**, Mettler-Toledo Thornton Inc

**Mr. Thomas W. Moss**, Applied Process Solutions, Inc.

**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**, Insko 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 Sayles**, TRG Builders LLC  
**Mr. William S. Seaver**, TEK Stainless Piping Products  
**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**  
**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. Craig Correia**, FESTO Corp  
**Mr. Timothy F. Curran**, RDK Engineers

### **10 Year Anniversary**

**Mr. Chung-Kuang Chou**, CRB Consulting Engineers  
**Mr. Joseph P. Durning, P.E.**, ASAHI America Inc  
**Mr. Thomas J. Erdenberger**, Xcellerex LLC  
**Mr. Herve I. Garant**, GreenLight Biosciences  
**Mr. Theron C. Harpole**, Biogen Idec  
**Mr. Bradford W. Horton**, MannKind Corporation  
**Mr. Peter S. Ng**, Nova BioMedical  
**Mr. Joseph St Laurent**, Chemic Laboratories, Inc.  
**Mr. Didier L. Zuendoki**, Genzyme

### **5 Year Anniversary**

**Mr. Stanford M. Bradeen**, Stenford Associates  
**Mr. Jim Busam**, Gilbane Building Company  
**Ms. Cozette Cuppett**, Waters Corporation  
**Mr. Daniel T. O'Regan**, Shire Pharmaceuticals  
**Mr. Bryan E. Thorp**, Architectual Resources Cambridge  
**Dr. Jonathan C. Walker**, Ironwood Pharmaceuticals  
**Mr. Paul Weingartner**, Levitronix

