Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

www.ispeboston.org

NEWSLETTER

July 2013, Volume XXIII, No. 4

Return to the Table of Contents | Printing Instructions

Save page as PDF

President's Message: New England and Boston Area Chapters Unite!

Dear Fellow Boston Area Chapter Members,

As you may have read in my earlier announcement, we have a very exciting time ahead of us with the membership of the New England Chapter joining the Boston Area Chapter. Once again we will have a single ISPE Chapter serving all of New England. I would like to take this opportunity to welcome all of the New England Chapter members to our new, expanded Chapter. We are very eager to complete the integration process and look forward to seeing all of you at future events.

As we move forward with this process, we will continue to provide the exemplary services to our combined membership that have made the Boston Area Chapter the ISPE "Chapter of the Year" for four years running. In the coming months, you will be updated on the progress of this integration and all of the new and exciting opportunities it brings for the combined membership.

I encourage everyone who would like to help shape the future of our new, combined Chapter to please get involved. I know you will find working with our current base of volunteers in any of the services we offer very rewarding. If you would like to get involved, email me and I will get you introduced to the Chapter leadership so you can choose the committee or volunteer activity that most interests you.

On a different note, unfortunately all good things have to come to an end. This is my last President's Message as I will turn the Chapter's reins over to your new President in August, before the next newsletter issue is distributed. I am very grateful to have served as your Chapter President for the past year. It has been my pleasure to work with the dynamic and dedicated volunteers who have ensured another very successful year for the Chapter. I am also honored to have played a role in merging the New England and Boston Area Chapters back into a single entity. My heartfelt thanks go out to all the board members, committee chairs, committee members, the staff at CAMI and all the others who have given their time over the past year. Your contribution is very much appreciated by our entire membership!

As this is my final President's Message, I wanted to take this opportunity to recap what we have achieved over the past year. Because the integration of the expanded membership has not yet been finalized, these achievements are based on the existing Boston Area Chapter (just imagine what the combined Chapter will accomplish next year!).

Major Goals for the Year

- **Membership Growth**
  The Boston Area Chapter is now #1 - the largest Chapter in the world with 1283 members! Our goal this year is to add 50 new regular Members and 15 new Young Professional Members. And this means "net" new Members. So the challenge has been to add new members over and above the normal attrition rate. As of June 2013, we have added 12 regular Members and 15 Young professionals - and we still have another month to go! Plus, we added new Members when most other Chapters did not, so this is definitely a win for the Boston Area Chapter. Lastly, our Member retention rate grew to 81 percent - one of the highest retention rates within ISPE.
- **Student Chapter Growth and Development**
  Our goal for Student Chapters this year is 50 new Student Members. We are so close at 47 (and, again, we still have a month to go), I feel confident we will achieve our goal and more. This dramatic

surge in student membership is an outgrowth of an expanded and re-energized program of student-related activities sponsored by the Chapter. Congratulations to all the hard working volunteers who have made this program so successful!

- **Educational Program Excellence**
  We continue to bring first class educational events to the membership and with all the positive feedback I have received, this goal has been achieved and even exceeded. Looking forward to the upcoming year, there is a planning meeting open to all Members on July 18 to help choose the educational topics for next year's program. This is a great opportunity for everyone to get involved and let us know what topics are important to you and your peers in the industry.

Soft Goals for the Year

- **CPIP™ Program**
  The Boston Area Chapter CPIP program has led the world in producing Certified Pharmaceutical Industry Professionals. There are currently 70 CPIPs worldwide and 28 of those, fully 40 percent, practice their craft right here in the greater Boston area. This is due in large part to the CPIP study groups sponsored by the Chapter over the last two years. To all those involved in making this program a success, thank you for a job exceptionally well done. And congratulations to our local CPIPs for earning the highly-regarded CPIP credential.
- **Scholarship Program**
  In 2013, the Chapter expanded the Joel Goldenberg Memorial Scholarship fund available each year for deserving applicants from $10K to $20K. We have had the privilege of providing assistance to many deserving applicants over the past year and will continue to do so. I encourage all members to visit the Chapter website to learn more about this program and utilize it to its full advantage.

These achievements combine to make us the #1 ISPE Chapter worldwide! Again, thank you all for affording me the honor of serving as President of the Boston Area Chapter for the past year and giving me the opportunity to help orchestrate the integration of the New England Chapter membership to form the world's strongest Chapter of ISPE.

Sincerely,

Jay Zaino
President ISPE Boston Area Chapter

Chapter Bulletin Board

Become a Chapter Sponsor Today - We've Just Made it Easier & Added a Discount!

Ever wonder how to become the sponsor of a Chapter educational program or social event? 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 with all the information you need to become a Chapter sponsor. Simply open the sponsorship application, choose as many or as few sponsorships as you want - and your sponsorship investment and discount are automatically calculated. When you're happy with your choices, you can pay by credit card online. It's that simple!

Even more exciting, you can view your savings as you select various combinations of sponsorship options. And the more you choose, the bigger your discount. Choices include:

- Educational Program Sponsors
- Social Event Sponsors
- Newsletter Sponsors
- Website Sponsors

So don't delay! Visit the Sponsorship page on the Chapter website at 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.
Still have questions? Contact the Chapter office at (781) 647 4773 or office@ISPEboston.org and we'll be happy to help.

Congratulations to Our Newest Certified Pharmaceutical Industry Professionals

Internationally, ISPE just awarded its 70th CPIP credential. So when we say that this is an exclusive club, maybe now you can appreciate what we mean. The Chapter is proud to boast that 28 (fully 40 percent!) of the world's 70 CPIPs practice their craft right here in the greater Boston area.

The Chapter continues to lead the way with the CPIP program, having just completed another CPIP study group this past spring. This month, we are pleased to congratulate two new CPIPs on attaining their CPIP credential.

- Brent Arbogast, CPIP, Critical Process Filtration
- Maurizio Cattaneo, CPIP, BioVolutions

Look for the recently completed spring study group to start adding to the Chapter's CPIP ranks soon!

Momentum for the next study group, planned for this fall, has already peaked with the Pfizer site in Andover agreeing to host the program. Interest on the Pfizer campus is already high, plus the Andover location gives Chapter members living or working north of Boston an opportunity to participate. Brian Hagopian, CPIP and former Chapter President, will be one of the CPIPs leading this session. This will be Brian's third stint as a study group leader. Look for announcements about this study group over the summer and be sure to join the group. You won't believe how much you can learn!

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.

Young Professional Members Receive Discount for Educational Programs

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 Young Professional Members to attend the Chapter's educational programs at a discounted rate: $20 for early registration and $30 after that date. In addition, in a prior vote, the Board elected to allow Student Members to attend Chapter educational and related events for free. Membership in the Boston Area Chapter truly does have its privileges!

Chapter Donates $1000 to One Fund Boston

On behalf of the Members of the Boston Area Chapter, the Board of Directors recently elected to donate $1000 to One Fund Boston in support of the victims of the Boston Marathon bombing and their families. This contribution reflects the Chapter's continued commitment to serving those in need in the Boston area community.

Educational Program Committee Seeks Member Input at July 18th Planning Meeting

Each year, the Educational Program Committee (EPC) polls Members for input regarding topics of current interest. Survey participants qualify for a chance to win a valuable gift. This year's lucky winner of an iPad was Mead Lotz of Commissioning Agents who provided the following feedback when notified of his good fortune:

I like having input into the educational programs the Boston Area Chapter has to offer. The survey is a way to get my voice heard and provide feedback to help shape decisions about educational content. By participating, I am able to give information about what I would like to see so that planners can make informed decisions about upcoming programs. I am glad to help!

Thanks to Mead and to everyone who participated in the survey. Your input helps make our educational programs timely and relevant. And don't miss the upcoming EPC Planning Meeting on Thursday, July 18th when the EPC will review the feedback received and finalize the educational program content for the upcoming Chapter year. All Chapter Members are invited to participate. For more information, visit the Chapter website at www.ISPEBoston.org.

Upcoming Chapter Events - Mark Your Calendar

Tuesday, July 16, 2013
Young Professionals Volleyball Social
Bunker Hill Community College, 250 Rutherford Ave, Charlestown, MA 02129

Come join the ISPE Boston Area Chapter Young Professionals for a fun-natured, yet competitive evening of outdoor volleyball on Tuesday, July 16th. We'll have two nets set up for tournament-style play and then head over to the Warren Tavern for post-game nourishment and networking.

Both skilled players and recreational players should feel free to play! If volleyball isn't your thing, come down and cheer on your co-workers and industry peers and join us at the Warren Tavern later that night!

Availability is limited to the first 36 participants who sign up!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=377

Thursday, July 18, 2013
Educational Programs 2014 Season Planning Meeting
The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451

This summer, the Boston Area Chapter received valuable input on educational programs of interest to our Members. The Educational Program Committee has reviewed this information and we would like YOUR help to finalize the educational program content for the upcoming Chapter year. Please join us on Thursday, July 18, 2013.

Schedule 5:30 PM - 8:30 PM Dinner, planning the 2014 programming year, and brief committee meeting

Attendance and parking are free (we want your assistance) and food will be provided!

ISPE Membership is required in order to participate in any Chapter Committee. To become a member, click **here** and select the Boston Area Chapter.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=375

Wednesday, August 14, 2013
Product Show Training Camp: How to make October 2nd Easy, Fun and Profitable!
Gillette Stadium, Foxborough, MA 02451

Want to get the most out of your Product Show experience? Do you see other companies breezing in and out of Gillette and wonder how they do it? This informative session will take you from pre-Show marketing, to display best practices, materials load-in, trade show etiquette and a tour of Gillette Stadium that will Show you the quickest way to get around.

Previous Issues

Hear from Product Show veterans, Gillette Stadium representatives and Capital Convention personnel.

Who Should Attend:

* Any Pre-Registered Exhibitors

* First Time Exhibitors

* Anyone that wants to get the most out of their Product Show experience!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=365

Wednesday, October 2, 2013
22nd Annual Product Show
Exhibitor Registration Now Available Online!

ISPE + is the theme for this year's Show. It means being greater than the sum of our parts. Be a part of the greater sum and exhibit at the 22nd Annual Product Show at Gillette Stadium in Foxborough, MA. With an expanded exhibition area + education sessions + career fair + vendor show case + entertainment zone + after party + even more to be announced soon, this year's Show promises to be better than ever. Reserve your space today and become one of the great parts bringing members, educators and customers together.

Exhibitors, Register Here:
http://www.ispeboston.org/ProductShow/vendor_registration_page1.html?formName=Exhibitor%20Registration

Hiring Companies, Register Here:
http://www.ispeboston.org/ProductShow/vendor_registration_page1.html?formName=Hiring%20Company%20Registration

---

Sneak Preview of Upcoming Events

Thursday, September 19, 2013
Educational Program focusing on CIP & SIP

Thursday, November 14, 2013
Educational Program focusing on Emerging Markets

Thursday, December 12, 2013
Educational Program focusing on Engineering Project Management

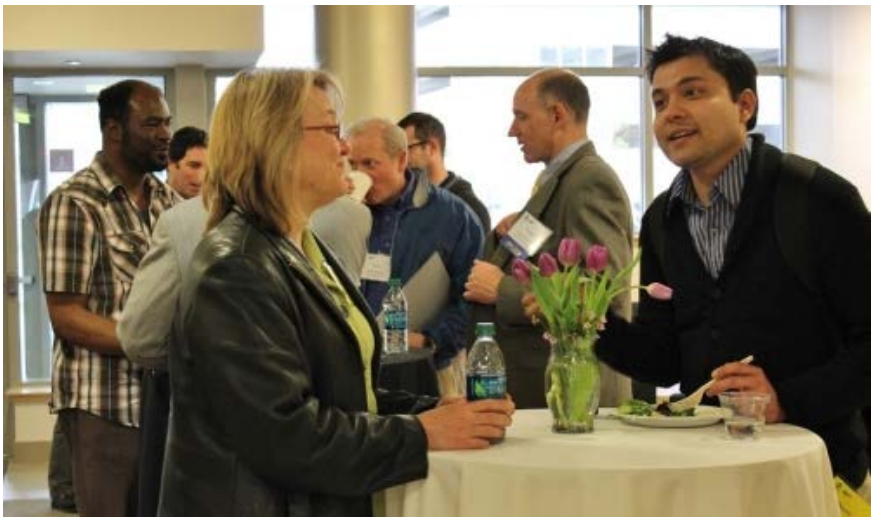
WPI's Biomanufacturing Education and Training Center Draws Members to Worcester

by Brian Hagopian,CPIP, Clear Water Consulting, Janet Tice, GMP Piping, and Jillian Willard, Genzyme with photos by Joyce Chiu, CPIP, Honeywell Safety Products.

Hosted by WPI in Worcester, April's dual-track educational program included something for everyone: an introductory presentation (the ever-popular Biotech 101) for industry newbies and students and an advanced presentation on Process Validation for industry veterans - not to mention a facility tour, sumptuous dinner buffet and networking reception. With well over 100 ISPE Members and guests in attendance, it was clear the Chapter had yet another success on its hands!

August 2008, Volume... (10)
June 2008, Volume... (11)
April 2008, Volume... (10)
February 2008, Volume... (10)
December 2007, Volume... (13)
October 2007, Volume... (10)

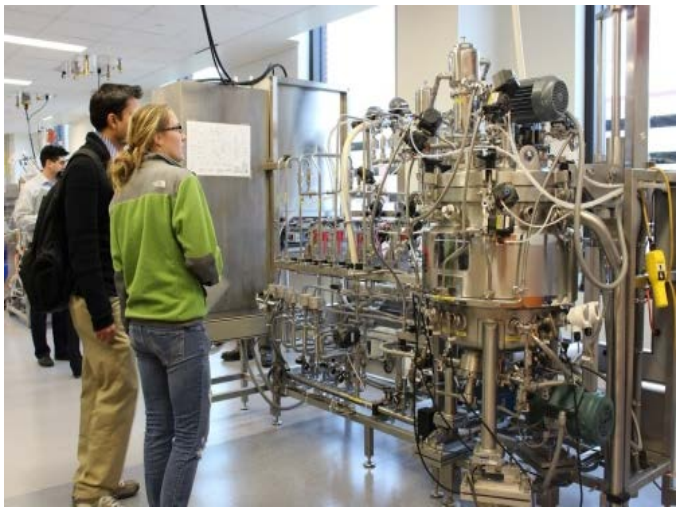
Newsletter Archive



The opening networking reception always provides a great opportunity to touch base with friends and colleagues.

The evening began with attendees gathering in the comfortable lobby of WPI's Life Sciences and Engineering Center at the Gateway Park complex. After chowing down on an impressive array of appetizer, entrée and dessert choices and networking with friends, attendees were formed into small groups for the short walk next door to WPI's Biomanufacturing Education and Training Center (BETC) for guided tours of the sparkling, new state-of-the-art facility.

A first-of-its-kind in the northeast, the BETC provides "innovative workforce development" for life sciences companies in the local area and beyond. The tour highlighted areas devoted to hands-on training in process methodologies such as equipment preparation and sterilization, buffer and media prep, fermentation and cell culture, protein capture and purification, and lab analytics. According to the very knowledgeable tour guides, WPI designed the space and chose the equipment to ensure the BETC meets the real-world training needs of the biomanufacturing industry. Based on WPI's flawless performance leading over 100 attendees through the facility and providing an informative overview of the BETC, I have no doubt they will succeed!



Guided tours of WPI's sparkling, new state-of-the-art Biomanufacturing Education and Training Center (BETC) were a hjighlight of the evening.

Following the tour, the dual-track presentations quickly got underway. Biotech 101 completely filled the auditorium space with more than 80 attendees who listened attentively to Alex Cardoso from Biogen Idec give a great talk covering this broad topic. ISPE Student Members were present in force for this presentation and came away with lots of useful information.

To begin, Alex brought us seamlessly through events we don't even think about that need to happen before

a drug is manufactured, including selecting cell types, process development, assay development and technology transfer. He then touched on upstream processing including wave bags, seed formation and a number of other processes that must be fully developed before manufacturing can actually occur and paralleled a bioreactor to the human body to give the audience a concrete grasp of all the variables involved and how their proper regulation is required to ensure the success of a process.

Biotech 101 always draw a crowd - and April's presentation by Alex Cardoso of Biogen Idec was no exception.

Next, Alex moved to downstream processing, where he used concrete analogies to guide the audience toward a better understanding of purification processes such as centrifugation, chromatography and tangential flow filtration. Finally, he gave the audience an appreciation of the complexity of producing a biomolecule by highlighting the support services required to support production such as engineering and facilities. He mentioned that Biogen Idec has even built its own power plant to ensure that a process, once started, can be completed successfully. The success of Alex's talk was reflected in the number of questions posed and the long line of attendees waiting to speak to him after the session ended.

Presented by industry veteran Rusty Morrison, the advanced track presentation on process validation was attended by more than 40 ISPE Members and non-members alike. Rusty discussed the new FDA guidance on the topic and his experiences and lessons learned in implementing the new approach. Now that the golden rule of three PV runs has been replaced by the more open-ended requirement that the number of runs be process driven, the discussion naturally gravitated toward the question, "How many runs is enough?" Other topics discussed included the requirements around continued process verification, such as how to determine the amount and type of data needed. Like Biotech 101, the lively Q&A session that followed attested to the relevance and stimulating nature of Rusty's excellent presentation.

Many thanks to our presenters, our hosts at WPI and our well-informed tour guides. The evening certainly proved that Worcester and WPI are forces to be reckoned with in the region's life sciences community.

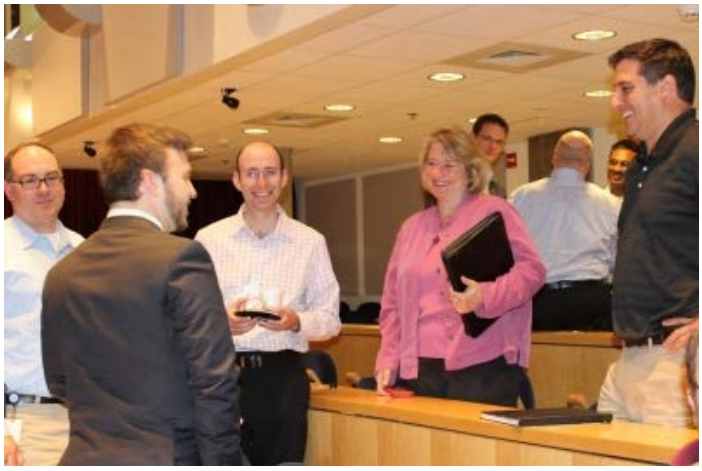
Genzyme Hosts May Educational Program on Automation

by Robert J. Wherry, PAREXEL Strategic Compliance Consulting with photos by Joyce Chiu, CPIP, Honeywell Safety Products.

The ISPE Boston Area Chapter educational program entitled "Automation: At the Crossroads with IT Interfaces" was held on Thursday, May 16 at the Genzyme Center in Cambridge. This topic was one of the key areas of interest identified in the Chapter's educational program survey and attracted over 55 attendees, both Members and non-members.

Another sold-out educational program stretches the seams at Genzyme in Cambridge.

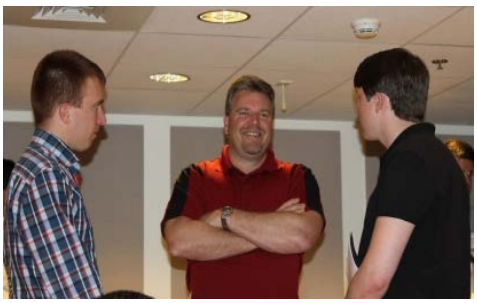
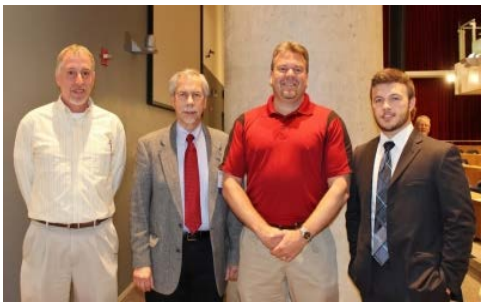
Following the traditional networking reception, which was sponsored by RCM Technologies, the evening began with opening remarks by Tom Choyce of Biogen Idec. Tom serves on the Chapter's Board of Directors and is also Membership Committee chairperson. Tom introduced Alex McKinnon, Senior Account Manager, RCM Technologies, who thanked the audience for the strong turnout. Tom then introduced Jordan Croteau, Automation Engineer for Biogen Idec, and the program's first speaker.



Speaker Jordan Croteau chats with audience members following his presentation.

Jordan reviewed the ANSI/ISA 95 Functional Enterprise-Control model which identifies the interfaces between control systems and enterprise (IT network) systems. The ISA95 model provides for five levels or layers from Enterprise Resource Planning in Level 4 down to the Level 0 Production Process. Examples of the types of computerized systems used at Level 1 through Level 4 were highlighted, with particular attention given to Level 3 Manufacturing Operations Management (MOM). He then discussed the opportunities for better data utilization through systems integration. Three case studies were presented covering systems for predictive maintenance, automated exceptions and real-time production planning. Jordan wrapped up his talk with interesting comments on the changing role of the automation engineer to that of a business analyst, so as to enable the business to better utilize the data being generated by automation and control systems.

Next up was Glenn Restivo, Director of Business Development for M+W Automation, who provided a quick look at the different aspects that must be considered for network design and integration with process control systems. Glenn then introduced the evening's second main speaker, Ken Kovacs, QA Business Systems Manager at Fujirebio Diagnostics in Malvern, PA. On a side note, Glenn and Ken had worked together on several projects over the years and Glenn had helped recruit him as a speaker.

Chapter President Jay Zaino welcomes student members and speakers (l to r) Glenn Restivo, Ken Kovacs and Jordan Croteau.

Ken presented a detailed case study on the implementation of an extensive Equipment Monitoring System (EMS). The driver for the system was the need to replace a paper-based GMP record system, with opportunities to eliminate at least 900 hours of manual record-logging and obtain data and trends faster. He noted that a dedicated EMS was initially considered, but was ruled out in favor of a server-based solution that allows for future expansion and integration of additional systems. Technical aspects of the EMS implementation were then reviewed, including system architecture, organizational requirements, equipment settings, workflow, events flowcharts and security. Ken wrapped up by highlighting his principles for project success: team involvement, a pragmatic project management methodology and plan, a procedure for the system development life cycle (SDLC), well-documented and well-understood user requirements, timely project updates and communication - and always remembering to thank the participants and contributors.

Educational Program Committee Member and Meeting Manager Bob Wherry (r) with program sponsor RCM Technologies Alex McKinnon (l)and speaker Glenn Restivo.

Program Manager Bob Wherry then concluded the presentations by thanking the speakers for sharing their knowledge with the audience and facilitating a brief Q&A. It was noted that automation and enterprise integration are becoming the norm and will be a future necessity due to new paradigms like continuous process verification (ICH Q8), knowledge management (ICH Q10) and stage 3 - continued process verification (FDA 2011 Guidance on Process Validation).

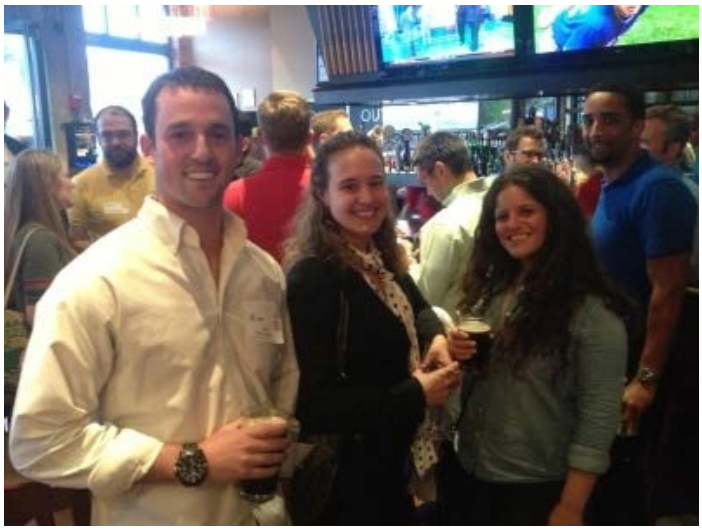
The Boston Area Chapter would like to thank the speakers and audience members for their valuable contributions to this program, RCM Technologies for sponsoring the networking reception and Genzyme for providing the venue for the event.

YPs Celebrate Summer with a Red Sox Game, Bowling & Volleyball

Text and photos by Dave Gallagher, GxP Automation

Hello fellow YPs and hope everyone has had a good spring and start to summer. The YPs have hosted two fun and successful events in the last two months and will be hosting another few before the summer is over! Our most recent event, the annual Red Sox game, had an unbelievable turnout this year. There had to be at least 40 people in attendance. With the cost at only $10 for Members, I guess that's no surprise!

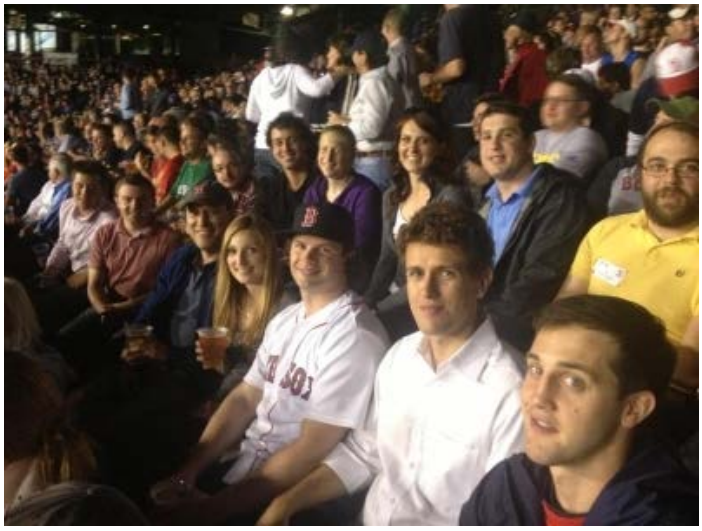
The night started off with a network social at Jerry Remy's and from there the group headed over to Fenway for the game. To finish off a great night, David Ortiz ended the game with a walk-off home run. Couldn't ask for a better ending!



The evening began with a networking social at Jerry Remy's Sports Bar & Grill before the group headed over to nearby Fenway for the Red Sox game.

The YPs also hosted a bowling social at Flatbreads in Davis Square at the end of May. There were many delicious wood-fired, clay oven flatbread pizzas on hand, as well as four lanes of bowling. This was the first time the YPs hosted a bowling event and due to the large turnout we might have to do it again next year.

As far as upcoming events go, there will be a volleyball tournament/social on July 16 at the Bunker Hill Community College fields. The event is limited to 36 people as of now, so make sure you sign up while you still can. And if volleyball isn't your thing, come down and cheer on your co-workers and industry peers, then join us at the Warren Tavern later that night.



40 Young Professionals watched David Ortiz end the game with a walk-off home run. Couldn't ask for a better ending for a great night!

On a more serious note, both the April and June educational programs were dual-track, with an introductory presentation for YPs, students and anyone new to our industry as well as an advanced level presentation for experienced veterans. YPs turned out in force for both events.

We are in the process of planning events for August and September and any feedback or suggestions are welcome. The monthly YP committee meetings are usually held on the fourth Wednesday of every month. You can contact either me (dave.gallagher@gxpautomation.com) or committee chair Andrea Massa (andrea.massa@burkert.com) if you want to get more involved. Hope to see all of you at our upcoming

events!

Student Chapter Update: AbbVie Plant Tour, Educational Programs and More!

by Brian Hagopian, CPIP, Clear Water Consulting and Neda Zahid, AbbVie, with photo by Brian Hagopian, CPIP

We have lots of great news to share about our Student Chapters! Student membership has more than doubled over the past year, a clear signal that the ISPE message is reaching campuses across the greater Boston area and beyond. Worcester Polytechnic Institute, in only its second year as a Student Chapter, has already blossomed into our largest, with over 40 members. Congratulations to Kevin Keane, Bielinsky Brea, Katherine Amato, and Callie King for their stellar on-campus recruiting efforts!

Thanks to all those from AbbVie who made this event a success: (l to r)
Beatrice Johnson, Maria Escolano, Todd Richardson, Neda Zahid, Steve Granger,
Gary Welch, Daniel Sayut, Eugene Soo, Anton Manuilov, Scott Ennis,
Chris Cuumsae and Courtney Burrell.

The Chapter completed its program year in style with a series of events designed to attract students. Biotech 101 program at WPI (see related article), a tour of the AbbVie plant in Worcester and an educational program on validation at the Tufts Gordon Institute (see related article) on June 20 where students, young professionals, and industry experts got to mingle before breaking up into groups to hear four fascinating talks on the topic of validation.

On April 22, Worcester-based AbbVie (formerly Abbott Laboratories) graciously hosted a "student specific" educational program and plant tour that attracted 50 students from UMass Amherst, WPI, Harvard, and Boston University. Students learned about the history of AbbVie and one of its blockbuster drugs (Humira) developed right here at the Worcester plant. Gary Welch, AbbVie's Plant Manager gave a great talk about the advantages and efficiencies of having research, drug development, pilot production, and scale-up capabilities all located under one roof. Steve Granger, AbbVie's Technical Support Manager described the role of engineers and the importance of engineering in the industry. The talks were followed by an excellent plant tour led by a team of dedicated AbbVie professionals, giving the students a taste of what it's really like inside of a biotech plant. AbbVie really went "above and beyond" for this program, bringing out an impressive array of products, people, demos, posters and giveaways. Special thanks to Neda Zahid from AbbVie for her superb organizing and coordinating efforts.

The Chapter is busy planning a summer and fall chock full of events for students:

- Volleyball game with Young Professionals on July 16
- Summer harbor cruise (check the Chapter website's events calendar for details)
- September membership drive at student campuses
- Product Show at Gillette Stadium on October 2 - transportation from each Student Chapter campus provided by ISPE. As always, this year's Show will be packed with opportunities for students to learn and network with young professionals and industry execs in a casual environment.

- Student-centered educational program and plant tour at Genzyme/Framingham in November

We will be sharing good news in our next newsletter when winners of the Joel Goldenberg Scholarship will be announced. The Chapter has set aside $20,000 in scholarship monies annually for ISPE Student Members enrolled in life sciences programs. See our website for details.

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

Communities of Practice: Sources of Ready-to-Use Guidance for Your Difficult Problems

by Pietro Perrone, P.E.

The objectives of the ISPE Communities of Practice (COP) groups are to share practical solutions to everyday problems and to encourage personal connections within the ISPE organization. This worldwide network provides any ISPE Member a resource of advice from colleagues and Subject Matter Experts by simply posting a note on the relevant COP(s).

The COPs are geared towards technical topics. However, interesting questions that are more management related are also posted. Three of the more popular COPs are Commissioning & Qualification, Critical Utilities and GAMP. These COPs along with HVAC and Sterile Products Processing have been some of the most active in terms of discussion posts (inquiries and responses) between Members. So, if you have a question that is hindering your work, join a relevant COP or two, post your question and await the responses.

Some posts or questions can generate a stir within the community with many responses between the members. There are also situations where differing opinions have resulted in lively discussions. While some passionate debates have surfaced, everyone always maintains an excellent level of professionalism. In general, the discussions consist of opinions and answers from subject matter experts willing to share their expertise. There is the occasional situation where the products that a supplier can provide can be a path to a solution to the question. Any Member of ISPE can join in the conversation and this can be very helpful in problem solving. Since the right answer is often specific to the requester's unique situation, getting feedback from various sources can help pinpoint satisfactory resolutions to difficult problems.

To illustrate the range of information available, a few examples of discussion topics posted in various COPs are listed below:

- In-process weight check using X-ray technology
- Mapping Requirements for Clinical Manufacture
- ASTM E2500-07(2012)
- Heat distribution pattern in a tank
- Environmental monitoring system
- Thermal validation system selection
- -80C Freezer Mapping
- Color Coding of Critical Utilities
- Clean Steam Generator Maintenance
- Product/Process Contacting Materials
- When is a potential CPP really a CPP?
- Tray drying oven supplier needed urgently
- Cost estimation ratios in Visual Inspection Equipment Projects

The COP program consists of 19 interactive communities that connect like-minded pharmaceutical industry professionals. At least one COP is bound to capture your interest or involve subject matter closely related to your work. While joining is easy and monitoring the discussions is interesting, the fun really starts when you get to help a colleague or express an opinion on something that is in your field of expertise. Try it - you'll like it!

These communities are sizable. Each has a membership in the thousands; the smallest has about 1500 members while the largest has over 5000. As their interests or job needs change, members can join or shift form one community to another. A listing of the communities with associated descriptions is provided below.

Community	Brief Description
Active Pharmaceutical Ingredients	This COP proactively advocates the importance of API in the drug product delivery process with the objectives of providing a forum for members to

	discuss issues of common interest.
Biotechnology	The Biotech COP aims to create a global focal point of support for Pharmaceutical Professionals operating in the Biotech Sector.
Commissioning and Qualification	The C&Q COP aims to align the processes of commissioning and qualification with a science and risk based approach, provide input and guidance into other documents, and to facilitate understanding and organizational change necessary to implement this approach.
Containment	The Containment COP provides a forum for all those involved in the Safety of Patients and People from exposure, contamination and cross contamination of hazardous compounds.
Critical Utilities	The Critical Utilities COP provides a discussion forum and network for Critical Utilities professionals by encouraging the sharing of ideas relevant to topics such as system design, commissioning & qualification, process validation, re qualification, regulations, operations, and maintenance.
Disposables	The Disposables COP mission aims to create a global focal point of support for biopharmaceutical professionals working with single-use disposable technologies.
Engineering Standards Benchmarking	The goal of the Engineering Standards Benchmarking COP is to improve the processes for creation/approval/maintenance and use of corporate engineering standards and specifications in the pharmaceutical industry.
GAMP	The GAMP® COP exists to promote the understanding of the regulation and use of automated systems within healthcare industries.
Good Control Laboratory Practices	The mission of the Good Control Laboratory Practices Community of Practice (GCLP COP) is to provide a forum for members to discuss issues of common interest in the area of GCLP with the primary objective being to find solutions to common industry problems.
Heating, Ventilation & Air Conditioning	The ISPE HVAC Community of Practice is the premier global organization that serves as a one-stop shopping outlet and provides relevant, timely information and solutions to real-world problems related to HVAC for pharmaceutical facilities.
Investigational Products	The Investigational Products COP is a result of the consolidation of the CM (US-based) and IMP (EU-based) organizations into one global organization.
Operations Management	The scope of the Operations Management COP is to create a multidisciplinary and transversal ISPE online community to promote excellence.
Oral Solid Dosage	The ISPE OSD COP mission is to act as an exchange for all aspects associated with Pharmaceutical Oral Solid Dosage, recognizing the significant changes the Industry is currently experiencing.
Packaging	The Packaging COP is a community that focuses on the area of packaging from the facility to the packaging equipment, and includes labeling, warehousing, components, and equipment.
Process Analytical Technology	The PAT COP creates a global focal point of support and a discussion forum for Pharmaceutical Professionals interested in Process Analytical Technology.
Process/Product Development	The PPD COP is a dynamic forum for professionals in product/process development to discuss and address issues of common interest.
Project Management	The Project Management COP is a dynamic forum for professionals working within the Pharma Industry who have an active interest in promoting "continuous improvement" project management.
Sustainable Facilities	Sustainable Facilities COP aims to respond, on behalf of the Pharmaceutical sector, to the global issue of environmental sustainability for facilities & infrastructures.

Each COP is led by a steering committee made up of members who essentially care for and grow the

group. These folks are often passionate about the topics addressed by the COP. Steering committee participants develop a sense of ownership that can give the individual an opportunity to impact the industry. All COPs can play a large role in the industry's development. The COPs can undertake significant projects due to the commitment and availability of its many members.

For example, the Disposables COP has been gearing up to develop a Good Practice Guide for Single-Use Technology. As the industry has been accepting the use of this technology to minimize capital risk while increasing flexibility, surprises have surfaced that challenge the relatively structured and controlled industry environment. The Good Practice Guide aims to provide a roadmap for companies that are evaluating, implementing or already applying single-use technology in their processes. A core group of members, most of whom are on the steering committee, are collaborating with ISPE staffers on this major project. In a similar way, there are many other guides that have resulted from the close collaboration between COP members.

The software used for the COP database enables members to set up periodic emails sent by the database identifying new postings in the COPs of interest. This feature makes it easy to keep track of responses to your questions. If responses are posted, you will see them identified in the email the database sends to you. The software also allows for a quick check on the profile of each person who posts information or is a member of the steering committees. This quick check provides the individual's affiliation, expertise, and contact information, permitting direct communication between individuals if desired. Additionally, the software also allows for sending and tracking emails sent to members within the COP.

Can't decide on which COP to post your message (or question)? It can be helpful to post on more than one COP. Taking this approach provides you, the requester, with multiple viewpoints from a range of experts. This can easily yield an innovative solution to what is an unusual problem for you but an established problem in the industry - one that has already been solved in a variety of different ways.

Once you experience the valuable information available through the COPs, you will likely join more than one. Many existing members belong to multiple COPs. Since problems in the industry often involve various disciplines, joining multiple COPs helps both the individual member and all of the communities the member joins while enhancing the flow of information within the entire ISPE organization. This benefits the industry by providing a source of innovative solutions and a sounding board, all built into one.

There is a strong local presence in the COPs, with several hundred Boston Area Chapter Members registered in one or more community. Furthermore, among these are over 20 who actively participate in the COP steering committees (see below). In addition, long time Chapter Member Paige Kane leads the entire COP program in her role as chair of the COP Council, a group comprised of the chairs and co-chairs of the 19 COPs.

Community of Practice	**Boston Area Chapter** **Steering Committee Members**
Active Pharmaceutical Ingredients	Jonathan C. Walker - Chair
Biotechnology	Andre L. Walker, CPIP Doyle R. Johnson, Jr
Commissioning & Qualification	Eric D. Felz (Task Team Member) Brian Pochini, CPIP (Task Team Member)
Critical Utilities	Andre Gill - Co-Chair Brian Pochini, CPIP Brian M. Hagopian, CPIP Anthony C. Bevilacqua Gary V. Zoccolante
Disposables	Pietro P. Perrone, PE - Chair Yuk Chun Chiu - Secretary Ryan J. Adams Mark C. McElligott James D. Vogel, PE Mert Aktar Kevin D. Lear
GAMP Americas	Paige E. Kane Robert J. Wherry
Process/Product Development	Brody J. Stara - Secretary
Operations Management	Patricia M. Seymour James Curry Juan M. Espinal

To begin sharing your ideas as well as learning from other experts, please visit ISPE's Community of Practice homepage and sign up for the COP - or COPs - of your choice à http://www.ispe.org/cops.

As a member of the COP program, you can view and monitor the interactions within the COPs. But that's only the beginning. As an active member who posts questions or comments, you can gain practical knowledge that you can apply directly to your work while having a sounding board of colleagues that stretches around the world.

###

Pietro Perrone, P.E. is a Single-Use Systems Engineer at EMD Millipore (EMD Millipore is a division of Merck KGaA, Darmstadt, Germany) where he oversees the engineering and design of single-use assemblies, systems, and associated components for the pharmaceutical industry. Perrone is a Professional Engineer registered in Massachusetts with a degree in chemical engineering from Tufts University and more than 20 years of purification/separation technology experience in process development and optimization, equipment scale-up, and project management. He recently earned a Graduate Certificate in Nanotechnology from the University of Massachusetts, Lowell and is presently enrolled in its Biomedical Engineering and Biotechnology program. Perrone is an active member of ISPE and his activities include Editorial Reviewer and Chair of Disposables Community of Practice, Industry Advisor to the Tufts University Student Chapter, and member of the Communications Committee of the Boston Area Chapter. You can reach him at pietro.perrone@emdmillipore.com. (The contents of this article are the author's own and do not necessarily represent EMD Millipore's positions, strategies, or opinions.)

Industry News In Brief

by Janet Tice, GMP Piping

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.

Biogen Idec Partners with WPI Training Center

Worcester Polytechnic Institute said it's signed an agreement with biotechnology firm Biogen Idec to help develop and deliver programs at the school's Biomanufacturing Education and Training Center (BETC), at WPI's Gateway Park. The first Biogen Idec program, a two-week course for 20 of its employees, is the first corporate class at the BETC and began May 20.

The Weston-based company joins AbbVie (formerly Abbott Laboratories), Bristol-Myers Squibb and Shire Human Genetic Therapies in affiliations with the BETC. The firms collaborate with the BETC to developed programs that support their specific needs and along with WPI faculty and BETC subject matter experts, company leaders serve as instructors and mentors for the center's students.

"Working with an academic institution like WPI greatly expands the tools we have to develop and train our workforce," said Ed Goodreau, vice president of manufacturing at Biogen Idec. "The modern and relevant facility at WPI gives staff both knowledge and hands-on experience that they can bring back to our site for immediate impact." (Source: Jacquelyn Gutc, Worcester Business Journal, 30 May, 2013)

Massachusetts Life Sciences Center Launches International Program

At the 2013 BIO International Convention, the Massachusetts Life Sciences Center (MLSC) announced the launch of its new International Collaborative Industry Program (ICIP). The MLSC will partner with Victoria, Australia; the Wallonia region of Belgium; Quebec, Canada; and Alsace in France to award funding to support winning projects demonstrating innovative and collaborative research and development (R&D) in Massachusetts and in the partnering regions. Companies from biotechnology, pharmaceuticals, medical devices, diagnostics and bioinformatics are eligible to submit collaborative project applications.

An eligible project will be in late-stage R&D, and will consist of one Massachusetts company and one company from one of the four international partner regions. Winning partners emerging from this competitive process will each be funded by an agency in their own geography.

During this inaugural round of ICIP, the MLSC Board of Directors has authorized a total of up to $1.5 million for winning Massachusetts companies. Grants will range from a minimum of $100,000 to a maximum of $500,000, and companies will match the funding that MLSC provides. The international agency will fund their local company winners. The Phase I project applications are due in September, 2013 and announcement of the winners is expected in March, 2014.

An informational session will be held at 6pm on July 25th at 1000 Winter Street, Waltham in the North Entrance Conference Room. For more information about ICIP, visit www.masslifesciences.com/icip. If you have any questions after reviewing the information posted, please contact icip@masslifesciences.com. (Source: MLSC Website)

Harvard Bioscience Products Used In Trachea Transplant

A tracheal scaffold and bioreactor system manufactured by Holliston-based Harvard Bioscience were used in the first successful transplant of a regenerated trachea in the United States, the company announced. The recipient of the implant, 2-year-old Hannah Genevieve Warren, is recovering at Children's Hospital of Illinois, where the surgery was performed April 9, the company said. The surgery was also the world's first successful pediatric regenerated trachea transplant using a synthetic scaffold.

The patient was born without a trachea and was only able to breathe through a tube inserted in her esophagus that connected to her lungs, the company said. No child born with the condition has ever lived beyond the age of 6. Hannah, who was born in South Korea, lived in the intensive care unit at a hospital in Seoul before she was transported to Illinois for the surgery.

The procedure was performed by a team led by Dr. Paolo Macchiarini of Karolinska University Hospital and Karolinska Institutet in Huddinge, Stockholm, and Drs. Mark J. Holterman and Richard Pearl, both of Children's Hospital of Illinois. The surgery was approved by the FDA under an Investigational New Drug application made by Dr. Holterman, according to a statement from Harvard Bioscience. (Source: Worcester Business Journal, 01 May, 2013)

Karyopharm Therapeutics Raises $48.2M to Advance Cancer Drug

Karyopharm Therapeutics, a clinical-stage Natick firm that's developing a cutting-edge cancer treatment drug, has completed a Series B round of financing that will take the biotechnology startup to the next level. The company said it raised $48.2 million in its latest series, which was supported by private investors along with the healthcare investment firm Delphi Ventures of California. Michael Kauffman, Karyopharm's CEO and co-founder, said the money will be used to bring its lead drug, KPT-330, through full clinical development.

The cash infusion follows a $30 million Series A financing round, which allowed Karyopharm to enter its first human trials to test the oral cancer drug last summer. Combined with initial seed funding, Karyopharm has raised $80 million since it was founded in 2008. "We appreciate the support of our current and new investors and their belief in the potential of (our) platform as a source of truly novel therapeutics," Kauffman said in a statement.

The company bills itself as a leader in the new field of nuclear transport modulators, which treat aggressive blood-borne cancers and solid tumors in humans and animals. Developed by Dr. Sharon Shacham, co-founder of Karyopharm, the drug works by returning displaced proteins to the nuclei of affected cells, where they can audit the cells for damage in cases in which cancer had disabled this process. There are no other cancer drugs on the market that treat cancer in this way, according to Karyopharm.

Karyopharm is developing the drug for both human and veterinary applications, but bringing the drug to market is likely still years away, it said. To support the next phase of development, the company said it will add a handful of new managers to its firm. The company is still in the middle of two Phase 1 clinical studies testing the effectiveness of the drug on patients with advanced cancer, and anticipates initiating pivotal trials on KPT-330 for drug marketing approval in the first half of 2014, according to a statement. (Source: Emily Micucci, Worcester Business Journal, 23 May, 2013)

Cambridge Biotech bluebird bio Raises $101M in IPO

Shares of the Cambridge life sciences company bluebird bio Inc. soared almost 60 percent on their first day of trading, an impressive debut for a business that endured years of stagnation and another encouraging sign for the biotechnology industry. The local gene therapy company raised $101 million in an initial public offering priced at $17 per share, higher than the $14 to $16 estimated by investment bankers.

The IPO came after a long wait and a name change. The company was founded 21 years ago under the name Genetix Pharmaceuticals Inc. with a focus on treating rare diseases.
Genetix toiled for 17 years before a 2010 study showed that its therapy had slowed the progression of a genetic brain disorder called childhood cerebral adrenoleukodystrophy, or CCALD, in two patients. That year, Boston venture capital firm Third Rock Ventures and Genzyme Corp. of Cambridge led an investment team that poured $35 million into the company, changed its name to bluebird bio, and installed Third Rock partner Nick Leschly as chief executive.

Investors now appear eager to back a promising company like bluebird, which remains far from taking a gene therapy to market. Later this year, bluebird will begin a clinical trial, administering its latest version of the CCALD therapy to as many as 15 patients. (Source: Callum Borchers, The Boston Globe, 20 June, 2013)

Biogen Idec Seeks FDA Approval of New MS Drug

Biogen Idec has announced it has submitted a Biologics License Application (BLA) to the FDA for approval of Plegridy (peginterferon beta-1a), the company's pegylated subcutaneous injectable candidate for relapsing forms of multiple sclerosis (RMS). Data collected during a Phase 3 clinical trial demonstrated that Plegridy met all primary and secondary endpoints by significantly reducing disease activity including relapses, disability progression and brain lesions compared to placebo, and showed favorable safety and tolerability profiles at one year.

"This filing demonstrates our dedication to the treatment of MS, both through the discovery of new medications and the development of innovative solutions that enhance treatment for people living with this disease," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "We believe that based on the efficacy and safety Plegridy has demonstrated, in addition to its less frequent dosing schedule, it has the potential to become a preferred interferon treatment option."

In addition to the BLA filing with the FDA, Biogen Idec plans to submit a Marketing Authorisation Application (MAA) for Plegridy to the European Medicines Agency (EMA) in the coming weeks. The company anticipates hearing from regulatory authorities regarding the status and acceptance of these submissions within the next couple of months.

Plegridy is a new molecular entity in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body, enabling study of a less frequent dosing schedule. It is a member of the interferon class of treatments and, if approved, would be a new addition to this class, which is often used as a first-line treatment for MS.

Biogen Idec has been the leader in the development of MS therapies for three decades and its robust treatment portfolio and development pipeline provides options that may help manage the disease from its earliest signs through its later stages. (Source: Biogen Idec Website, 21 May, 2013)

BIND Therapeutics and AstraZeneca Ink Deal for Cancer Nanomedicine

BIND Therapeutics and AstraZeneca have entered into a strategic collaboration to develop and commercialize a targeted and programmable cancer nanomedicine from BIND's Medicinal Nanoengineering platform, based on a molecularly targeted kinase inhibitor developed and owned by AstraZeneca. The collaboration is based on emerging data suggesting that nanomedicines selectively accumulate in diseased tissues and cells, leading to higher drug concentrations at the site of the tumor and reduced exposure to healthy tissues.

Under the terms of the agreement, the companies will work together to complete Investigational New Drug-enabling studies of the lead nanomedicine identified from a previously-completed feasibility program. AstraZeneca will then have the exclusive right to lead development and commercialization and BIND will lead manufacturing during the development phase. BIND could receive upfront and pre-approval milestone payments totaling $69 million, and more than $130 million in regulatory and sales milestones and other payments as well as tiered single to double-digit royalties on future sales. (Source: BIND Therapeutics Website, 22 April, 2013)

Forma Therapeutics and Celgene Corporation Establish Strategic Collaboration

Watertown-based Forma Therapeutics has announced a strategic collaboration agreement with Celgene Corporation under which the companies will discover, develop and commercialize drug candidates to regulate protein homeostasis targets. Protein homeostasis, which is important in oncology, neurodegenerative and other disorders, involves a tightly regulated network of pathways controlling the biogenesis, folding, transport and degradation of proteins.

The collaboration will be launched with an undisclosed up-front payment that will enable Celgene to evaluate selected targets and lead assets in protein homeostasis pathways during the pre-clinical phase. Based on such evaluation, Celgene will have the right to obtain exclusive licenses with respect to the development and commercialization of multiple drug candidates outside of the United States, in exchange for research and early development payments of up to $200 million to Forma.

Under the terms of the collaboration agreement, Forma is incentivized to advance the full complement of drug candidates through Phase 1, while Celgene will be responsible for all further global clinical development for each licensed candidate. Forma is eligible to receive $315 million in potential payments based upon development, regulatory and sales objectives for the first ex-US license. Forma is also eligible to receive potential payments for successive licenses, which escalate for productivity, increasing up to a maximum of $430 million per program. In addition, Forma will receive royalties on ex-US sales and additional payments if multiple drug candidates reach defined cumulative sales objectives, providing a significant incentive for Forma to advance multiple drug candidates. (Source: Forma Therapeutics Website, 29 April, 2013)

FDA Grants Fast Track Designation for Cubist's Late-Stage Antibiotic Candidate

Lexington-based Cubist Pharmaceuticals has announced that the FDA has granted the Company's late-stage antibiotic candidate, ceftolozane/tazobactam, also known as CXA-201, fast track review status in treating hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP), along with complicated urinary tract infections (cUTIs). The FDA granted fast track status for ceftolozane/tazobactam in complicated intra-abdominal infections (cIAIs) in February 2013.

"We are pleased that ceftolozane/tazobactam has now received fast track designation in all of its potential indications," said Steven Gilman, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Cubist Pharmaceuticals. "This incentive, enabled by the GAIN Act, will help us expedite

the development of ceftolozane/tazobactam across many types of serious and potentially life-threatening infections."

The GAIN Act provides pharmaceutical and biotechnology companies with incentives to develop new antibacterial and antifungal drugs for the treatment of life-threatening infectious diseases caused by drug resistant pathogens. Qualifying pathogens are defined by the GAIN Act to include multi-drug resistant Gram-negative bacteria, including *Pseudomonas, Acinetobacter, Klebsiella*, and *Escherichia coli* species; resistant Gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococcus*; multi-drug resistant tuberculosis; and *Clostridium difficile*.

Ceftolozane/tazobactam is currently being studied in pivotal Phase 3 trials as a potential intravenous therapy for the treatment of cIAI and cUTI caused by Gram-negative pathogens, including those caused by multi-drug resistant *Pseudomonas aeruginosa*. Cubist expects to initiate a Phase 3 VABP program for ceftolozane/tazobactam by mid-year. (Source: Cubist Website, 07 May, 2013)

Algeta Wins FDA Approval for Xofigo for Advanced Prostate Cancer

The FDA has approved Xofigo (radium Ra 223 dichloride) from Norwegian drug maker Algeta ASA. Xofigo is designed to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. Algeta set up a commercial office in Kendall Square in September 2012 where it employs about 20.

Algeta will comarket Xofigo in the US with German pharma Bayer AG. Bayer, which filed the new drug application with the FDA as well as with European regulators, has exclusive rights to market Xofigo outside the US.

The FDA reviewed Xofigo under the agency's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. Xofigo was approved more than three months ahead of the date the agency was scheduled to complete its review of the drug application. (Source: FDA Website, 15 May, 2013; The Boston Globe, 16 May, 2013)

Promising Cancer Drugs Lift Merck & BMS Stocks

Experimental drugs to help the immune system detect otherwise invisible cancer cells shrank tumors and extended the lives of patients with advanced melanoma, according to early research some analysts are hailing as an approach that could become the gold standard of care for multiple cancer types. Data presented on drugs being developed by Merck & Co. and Bristol-Myers Squibb were the talk of a five-day conference of cancer specialists in Chicago, hosted by the American Society of Clinical Oncology.

Both companies' drugs for advanced melanoma are in a new class called PD-1 therapies, for "programmed death." The antibody drugs enable the immune system to identify tumor cells that otherwise would evade detection. Once the cells are ‘‘uncloaked," powerful immune system cells called T cells can target and destroy the cancer cells.

The promising results, while from small studies, pumped up the shares of Merck and Bristol-Myers to 52-week highs following the meeting, as several analysts issued encouraging reports stating the drugs seem effective and have relatively minor side effects. The reports also noted that both companies are studying their drugs in a few other types of cancer.

A few analysts wrote that combinations of two or more such immune drugs, or one of them with another type of cancer drug, could be the future of cancer therapy and might shorten its duration. Merck's drug is called lambrolizumab. Bristol-Myers' is nivolumab. (Source: Linda A. Johnson, The Boston Globe, 04 June, 2013)

Epizyme Soars in First Trading Day

Shares of Cambridge biotechnology company Epizyme Inc. soared by more than 50 percent on their first day of trading May 31, a good sign for a wave of other life science businesses hoping to launch initial public offerings later this year. Epizyme, which aims to develop treatments targeting genetic-based cancers, raised $77.1 million in the IPO priced at $15 per share - the high end of a range estimated by investment bankers.

"The IPO is a home run for Epizyme and also for the industry," said Douglas MacDougall, president of Wellesley-based MacDougall Biomedical Communications. MacDougall's firm has served as a consultant to Epizyme in the past but no longer represents the company. Epizyme is the third Bay State biotech company to go public this year - following TetraPhase Pharmaceuticals and Enanta Pharmaceuticals, both of Watertown - and another half dozen could follow as the industry's IPO market thaws from a deep freeze. The Globe reported last month that roughly 25 biotech companies nationwide could go public this year, which would be the most since 2007. Only eight biotechs launched IPOs in 2008 and 2009 combined.

Investor interest in Epizyme is particularly encouraging for the biotech industry because the company is still so early in the process of developing its most advanced therapy. The drug, called EPZ-5676, remains in

the first phase of a clinical trial that will test its effectiveness against a group of genes that cause two common forms of acute leukemia. Results will be published in the second half of the year. Epizyme also is working on a drug to treat non-Hodgkin lymphoma as part of the company's broader goal of commercializing personalized medications for patients with cancers caused by genetic mutations.

The opportunity to raise much-needed capital is what is driving young biotech companies to the public marketplace, said Jonathan P. Gertler, a partner at Back Bay Life Science Advisors. Epizyme, for instance, had accumulated an operating deficit of $60.1 million through the end of March after six years in business. (Source: Callum Borchers, The Boston Globe, 01 June, 2013)

Valeant Pharmaceuticals International to Acquire Bausch & Lomb for $8.7 Billion

Valeant Pharmaceuticals International and Bausch & Lomb announced that they have entered into a definitive agreement under which Valeant will acquire Bausch & Lomb for $8.7 billion in cash. Valeant Pharmaceuticals is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, neurology and branded generics. Bausch & Lomb is a leading global eye health company that operates in three segments: Pharmaceutical (including prescription brands, generics and over-the-counter), Vision Care (contact lenses and solutions), and Surgical (intraocular lenses and surgical equipment).

Bausch & Lomb will retain its name and become a division of Valeant. Valeant's existing ophthalmology businesses will be integrated into the Bausch & Lomb division, creating a global eye health platform with estimated pro forma 2013 net revenue of more than $3.5 billion. The acquisition positions Valeant to capitalize on growing eye health trends driven by an aging patient population, an increased rate of diabetes and demand from emerging markets. The combined business will also benefit from access to a strong product portfolio and a late stage pipeline of innovative, new products.

Valeant's Chairman and Chief Executive Officer, J. Michael Pearson, said, "We are excited to announce the acquisition of Bausch & Lomb, which will transform Valeant into a global leader in eye health by significantly strengthening our capabilities in ophthalmic pharmaceuticals, contact lenses and lens care products, and ophthalmic surgical devices and instruments. Bausch & Lomb's world-renowned brand, comprehensive portfolio of leading eye care products, and promising late stage pipeline are an ideal strategic fit for our current ophthalmology business and we are strongly committed to continuing to build a sustainable eye health business. With this transaction, Valeant will be a worldwide leader in both dermatology and eye health."

The transaction, which is expected to close in the third quarter, is subject to customary closing conditions and regulatory approvals. (Source: Valeant Pharmaceuticals Website, 27 May, 2013)

Massachusetts Life Sciences Center Awards $100M for Projects in Western Mass

Governor Deval Patrick and the Massachusetts Life Sciences Center (MLSC) announced over $100 million in grants for life-sciences-related capital projects in western Massachusetts, including $95 million for UMass Amherst and $5.5 million for the Pioneer Valley Life Sciences Institute (PVLSI), a joint venture of Baystate Medical Center in Springfield and UMass Amherst.

Through the MLSC, Massachusetts is investing $1 billion over 10 years in the growth of the state's life sciences supercluster. These investments are being made under the Massachusetts Life Sciences Initiative, passed by the state Legislature and signed into law by Governor Patrick in 2008.

The grant for UMass Amherst will fund construction to fit out and equip a substantial portion of the university's new $157-million Life Sciences Laboratories. This building will house three new research centers led by faculty and will be dedicated to partnering with regional life sciences and precision manufacturing companies to develop innovative products and services.

The grant for PVLSI, located adjacent to Baystate Medical Center's main campus in Springfield's North End, will support the development of a new Center of Innovation in Health Informatics and Technology, focused on advancing public/private-sector partnerships and incubating innovative technology solutions developed by start-ups and larger, more established vendor firms in areas such as population health management, health care quality, "big data" analytics and mobile health.

The MLSC is a quasi-public agency of the Commonwealth tasked with implementing the Massachusetts Life Sciences Act. The MLSC's mission is to create jobs in the life sciences and support vital scientific research that will improve the human condition. This work includes making financial investments in public and private institutions that are advancing life sciences research, development and commercialization as well as building ties among sectors of the Massachusetts life sciences community. For more information, visit www.masslifesciences.com. (Source: Massachusetts Life Sciences Center Website, 06 June, 2013)

Roche and AstraZeneca Launch Data-Sharing to Accelerate Drug Discovery

Roche and AstraZeneca announced a new collaboration to share a specific type of early research data

related to drug design, which could further accelerate the discovery of high quality compounds with an increased chance of clinical success. Using a dedicated technology, Matched Molecular Pair Analysis or MMPA, modifications will be identified which companies can apply to their compound structures in order to improve their metabolism, pharmacokinetics or safety, without divulging confidential information about their chemical structures.

This data-sharing gives both companies the opportunity to efficiently reapply useful medicinal chemistry know-how embedded in their combined databases of experimental results in order to identify potential new drug candidates using fewer rounds of design, synthesis and testing. Both Roche and AstraZeneca will make their selected databases available for this type of joint analysis and are committed to making the data generated available to the broader research community, including research foundations, charities and academia.

The data-sharing will be managed through the intermediary company, MedChemica, which has expertise in the key technology of MMPA. The consortium is open to other large companies to add their knowledge thereby gaining access to and enhancing this resource. More data added to this system will raise the quality and specificity of drug design rules.

Alexander Dossetter, Managing Director at MedChemica said, "We congratulate both companies for taking the courageous first step of sharing medicinal chemistry knowledge. We aim to expand this kind of collaboration and eventually go beyond facilitating chemical building blocks into chemical lead hunting and optimization. The goal is that resources will be better utilized and patients better served." (Source: AstraZeneca Global Website, 26 June, 2013)

J & J Opens Boston Innovation Center, Announces First Collaborations

Johnson & Johnson announced the opening of the Johnson & Johnson Innovation center at One Cambridge Center in Kendall Square, the third of four regional hubs being established in the world's leading life science hotspots. A part of Johnson & Johnson Innovation, the goal of the Boston Innovation Center is to advance healthcare by catalyzing collaborations in science and technology between regional innovators and the Johnson & Johnson Family of Companies across a diverse spectrum of early-stage opportunities.

In addition to the new center in Boston, a center in London opened in March, a center in California opened in early June, and a fourth is planned to open in Shanghai by the end of the year. Each city was selected for its robust life sciences community, which provides a rich environment for identifying investment, in-licensing and collaboration opportunities.

The Boston Innovation Center is home to a team of business, science and transaction experts who are focused on identifying and building novel early-stage collaborations with emerging companies, entrepreneurs and academic centers across eastern North America. This team has full and broad deal-making capabilities, with flexibility to adapt deal structures to match early-stage needs and opportunities. Representatives of Johnson & Johnson Development Corporation (JJDC), the venture capital subsidiary of Johnson & Johnson, are co-located at the Boston Innovation Center to identify and invest in external opportunities.

Johnson & Johnson Innovation today announced the Boston Innovation Center's first collaborations and new initiatives, including new relationships with leading academic researchers and emerging biotech companies, as well as funding to support the needs of the next generation of startup life science ventures. New collaborations and initiatives include:

Research Alliance with Mount Sinai - Janssen Biotech, Inc. and Johnson & Johnson Innovation have established a research alliance with The Icahn School of Medicine at Mount Sinai to advance the scientific understanding of inflammatory bowel disease (IBD) and the discovery of next generation therapeutic solutions. Scientists from the Janssen Immunology Therapeutic Area and researchers from Mount Sinai will work in partnership to investigate disease triggers, identify new opportunities for therapeutic interventions and establish diagnostics to facilitate precision medicine and predictive biomarkers.
Collaboration with Rodin Therapeutics - Johnson & Johnson Development Corporation (JJDC) has made an investment in Rodin Therapeutics, a biotech focused on applying insights of epigenetics to advance novel therapeutics for neurological disorders such as Alzheimer's disease. The Boston Innovation Center and Janssen Research & Development, LLC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson, will engage in scientific collaboration with Rodin Therapeutics with the goal of sharing knowledge and expertise to advance novel solutions in CNS.

Investment in Vedanta Biosciences - JJDC has made an investment in Vedanta Biosciences to facilitate the Boston Innovation Center collaboration with Vedanta to advance a novel class of therapies that modulate pathways of interaction between the human microbiome and the host immune system. Vedanta has developed a discovery platform to mine novel mechanisms by which the microbiome modulates the immune system, and is working to advance a first-in-class preclinical candidate for autoimmune and inflammatory diseases such as Inflammatory Bowel Disease (IBD). The Janssen Pharmaceutical Companies of Johnson & Johnson have identified the human microbiome as a strategic area of research and seek to forge

collaborations with leading companies with promising programs in this emerging field of science. (Source: J&J Website, 27 June, 2013)

J & J's Janssen Labs Opens First East Coast Facility in Kendall Square

Johnson & Johnson Innovation will establish Janssen Labs at the LabCentral facility in the Kendall Square biotech hub. Janssen Labs @LabCentral marks the first East Coast expansion for Janssen Labs, which will operate with the same open-innovation, no-strings-attached approach as it does at the flagship Janssen Labs in San Diego and the recently announced Janssen Labs @QB3 with University of California, San Francisco. As a Founding Sponsor of LabCentral, Johnson & Johnson Innovation will select a few high-potential innovators for the shared-laboratory space who are focused on promising science that addresses important unmet medical needs.

LabCentral is a nonprofit organization, designed to be a "one-stop-shop," offering premier, fully equipped laboratory space, plus the infrastructure and support that emerging life sciences companies need to transition from a science/technology-focus to a successful commercial-stage enterprise. As part of this agreement, Johnson & Johnson Innovation will also have an on-site office to facilitate collaboration with other start-ups located at LabCentral. (Source: J&J Website, 27 June, 2013)

AVEO Oncology Announces Restructuring, Eliminates 140 Positions

Cambridge-based AVEO Oncology has announced a strategic restructuring that will refocus the company's efforts and resources on the ongoing clinical development of tivozanib in colorectal and breast cancer, as well as advancing key pipeline and preclinical assets. This restructuring is expected to extend the company's cash runway for at least two years, which is beyond anticipated data read-outs from ongoing trials of tivozanib and AV-203.

"... we believe that it is likely that tivozanib will not receive FDA approval for renal cell carcinoma or RCC," said William J. Slichenmyer, M.D., chief medical officer of AVEO. "With the decision of our partner, Astellas, not to proceed with a European filing for tivozanib or financially support future clinical trials in RCC, AVEO has no plans at this time to pursue tivozanib development in RCC. We deeply regret the impact that this decision may have on the RCC community...Tivozanib will continue to be available to those patients who remain on therapy."

AVEO and Astellas are continuing the BATON Phase 2 clinical trials of tivozanib in breast and colorectal cancer. The BATON-CRC study of tivozanib in patients with colorectal cancer completed patient enrollment earlier this year and results are expected in 2014. The BATON-BC study of tivozanib in triple negative breast cancer is currently enrolling patients and data results are expected in late 2014 or early 2015. Both of these trials incorporate pre-specified biomarker analyses.

AVEO intends to continue the development of AV-203, our clinical-stage ERBB3 (HER3) inhibitory antibody candidate, currently in Phase 1 with expansion cohorts in specific biomarker-defined patient populations. ERBB3 is believed to be an important biologic pathway for multiple solid tumors.

As previously announced, the company intends to focus its efforts on further ficlatuzumab development through external collaborations at this time. Ficlatuzumab is a potent hepatocyte growth factor (HGF) inhibitory antibody that blocks the HGF/c-Met pathway by binding to the HGF ligand with high affinity and specificity. Recently presented industry data have demonstrated that inhibition of this pathway can improve clinical outcomes in a variety of tumor types.

AVEO's strategic restructuring will eliminate approximately 140 positions, or 62 percent of AVEO's workforce, across the company. (Source: Aveo Oncology Website, 05 June, 2013)

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.

US Supreme Court Sets Aside Ruling Allowing Myriad Genetics to Patent Genes Linked to Breast and Ovarian Cancer

On July 13, the US Supreme Court set aside a ruling that allowed a company to patent two genes linked to breast and ovarian cancer and limit access to potentially life-saving genetic tests for at-risk women.

The Public Patent Foundation (PUBAT) and the American Civil Liberties Union (ACLU) challenged the patents held by Myriad Genetics on the BRCA1 and BRCA2 genes, which a divided 2-1 Court of Appeals for the Federal Circuit last year ruled were valid (although it ruled other challenged patents on methods of

genetic diagnosis were invalid).

"Nobody 'invents' genes, so no one should be able to claim ownership of them," said Daniel B. Ravicher, executive director of PUBPAT. "We are not talking about a new drug or a new tool to fight cancer. We are talking about a genetic marker that occurs naturally in the human body. That cannot, and should not, be patented."

With the judgment vacated, the case will be sent back to the same Court of Appeals who issued the split July decision. They can decide the next steps and the timeline for the case and then issue a decision with the same or a different outcome.

"In light of recent rulings from the court that mere laws of nature cannot be patented, we hope that the lower court will come to the correct conclusion this time around," said Chris Hansen, staff attorney with the ACLU Speech, Privacy and Technology Project and co-counsel in the lawsuit. "It's inconceivable that a company can own a patent on something as naturally occurring as DNA."

The Supreme Court ordered the Federal Circuit to reconsider its decision in light of the high-court's ruling last week in Mayo Collaborative Services v. Prometheus, where the justices unanimously invalidated a patent on a medical test because it covered a "law of nature." (Source: Public Patent Foundation Website, 13 June, 2013)

FDA Approves Abuse-Deterrent Labeling for Reformulated OxyContin

The FDA has approved updated labeling for Purdue Pharma's reformulated OxyContin (oxycodone hydrochloride controlled-release) tablets. The new labeling indicates that the product has physical and chemical properties that are expected to make abuse via injection difficult and to reduce abuse via the intranasal route (snorting).

Additionally, because original OxyContin provides the same therapeutic benefits as reformulated OxyContin, but poses an increased potential for certain types of abuse, the FDA has determined that the benefits of original OxyContin no longer outweigh its risks and that original OxyContin was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will not accept or approve any abbreviated new drug applications (generics) that rely upon the approval of original OxyContin.

The FDA, together with other public health agencies, continues to encourage the development of abuse-deterrent formulations of opioids and believes that such products will help reduce prescription drug abuse. At the same time, the FDA remains committed to ensuring that patients with pain have appropriate access to opioid analgesics. (Source: FDA Website, 16 April, 2013)

FDA Approves Kcentra for Urgent Reversal of Anticoagulation

The FDA approved Kcentra (Prothrombin Complex Concentrate, Human) for the urgent reversal of vitamin K antagonist (VKA) anticoagulation in adults with acute major bleeding. Plasma is the only other product approved for this use in the United States.

Patients receiving chronic anticoagulation therapy with warfarin and other VKA anticoagulants to prevent blood clotting in conditions such as atrial fibrillation or the presence of an artificial heart valve sometimes develop acute bleeding. Like plasma, Kcentra is used in conjunction with the administration of vitamin K to reverse the anticoagulation effect and stop the bleeding. Unlike plasma, Kcentra does not require blood group typing or thawing, so it can be administered more quickly than frozen plasma. Kcentra is made from the pooled plasma of healthy donors. It is processed in a way to minimize the risk of transmitting viral and other diseases.

Kcentra will be manufactured at CSL Behring's Marburg, Germany facility. CSL Behring is headquartered in King of Prussia, PA. (Source: FDA Website, 29 April, 2013)

FDA Approves Orphan Drug Procysbi for Rare Genetic Condition

The FDA has approved Procysbi (cysteamine bitartrate) for the management of nephropathic cystinosis in children and adults. Procysbi was granted orphan product designation because it is intended to treat a rare disease or condition.

The FDA approved drugs used to treat cystinosis include Cystagon (cysteamine bitartrate), an immediate-release tablet that was approved in 1994, and Cystaran (cysteamine ophthalmic solution) eye drops, approved last year to treat corneal cystine crystal accumulation. Procysbi is a delayed-release capsule intended for patients ages 6 years and older. While Cystagon is taken every six hours around the clock to control cystine levels, Procysbi is a long-acting formulation that is taken every 12 hours.

Procysbi is marketed by Novato, CA-based Raptor Pharmaceuticals; Cystagon is marketed by Canonsburg, PA-based Mylan; and Cystaran is marketed by Gaithersburg, MD-based Sigma-Tau Pharmaceuticals. (Source: FDA Website, 30 April, 2013)

FDA Approves Breo Ellipta to Treat Chronic Obstructive Pulmonary Disease (COPD)

The FDA has approved Breo Ellipta (fluticasone furoate and vilanterol inhalation powder) for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

COPD is a serious lung disease that worsens over time. Symptoms can include chest tightness, chronic cough and excessive phlegm. Cigarette smoking is the leading cause of COPD, according to the National Heart, Lung, and Blood Institute, and COPD is the third leading cause of death in the United States. Breo Ellipta works by decreasing inflammation in the lungs and helping the muscles around the airways of the lungs stay relaxed to increase airflow and reduce exacerbations in patients with COPD.

Breo Ellipta was developed by GlaxoSmithKline of Research Triangle Park, NC, in collaboration with San Francisco-based Theravance. (Source: FDA Website, 10 May, 2013)

FDA Approves First Companion Diagnostic to Detect Cancer-Associated Gene Mutation; New Use For Genentech's Tarceva Also Approved

The FDA has approved the cobas EGFR Mutation Test, a companion diagnostic for the cancer drug Tarceva (erlotinib). This is the first FDA-approved companion diagnostic that detects epidermal growth factor receptor (EGFR) gene mutations, which are present in approximately 10 percent of non-small cell lung cancers (NSCLC). The test is being approved with an expanded use for Tarceva as a first-line treatment for patients with NSCLC that has metastasized and who have certain mutations in the EGFR gene.

The cobas EGFR Mutation Test is manufactured by the Roche Molecular Systems in Pleasanton, CA. Tarceva (erlotinib) is co-marketed by CA-based Genentech, a member of the Roche Group and OSI Pharmaceuticals of Farmingdale, NY. (Source: FDA Website, 14 May, 2013)

FDA Approves Bayer's Xofigo for Advanced Prostate Cancer

The FDA has approved Xofigo (radium Ra 223 dichloride) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone. Xofigo is marketed by Wayne, NJ-based Bayer Pharmaceuticals.

Xofigo was approved more than three months ahead of the product's prescription drug user fee goal date of August 14, 2013, the date the agency was scheduled to complete review of the drug application. The FDA reviewed Xofigo under the agency's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. (Source: FDA Website, 15 May, 2013)

FDA Approves Simponi to Treat Ulcerative Colitis

The FDA has approved a new use for Simponi (golimumab) injection to treat adults with moderate to severe ulcerative colitis.

Simponi works by blocking tumor necrosis factor (TNF), which plays an important role in causing abnormal inflammatory and immune responses. Previously approved to treat rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis (arthritis affecting the joints in the spine and the pelvis), Simponi is now approved to treat adults with moderate to severe ulcerative colitis that is resistant (refractory) to prior treatment or requires continuous steroid therapy.

Ulcerative colitis is a chronic disease that affects about 620,000 Americans. It causes inflammation and ulcers in the inner lining of the large intestine and is one of two main forms of chronic inflammatory bowel disease. The inflammation can lead to abdominal discomfort, gastrointestinal bleeding, production of pus and diarrhea.

Simponi is marketed by Horsham, PA-based Janssen Biotech. (Source: FDA Website, 15 May, 2013)

FDA Allows Marketing of First A1c Test for Diagnosing Diabetes

The FDA has announced that it is allowing marketing of the COBAS INTEGRA 800 Tina-quant HbA1cDx assay (Tina-quant HbA1cDx assay) for the diagnosis of diabetes by health care professionals. This is the first HbA1c test that FDA has allowed to be marketed for this use.

The HbA1c tests, or A1c tests, currently on the market are FDA-cleared for monitoring a patient's blood glucose (sugar) control, but not for diagnosing diabetes. A1c tests measure the percentage of hemoglobin A1c that is bound to glucose, giving a patient's average glucose level over a three-month period.

Diabetes is a serious, chronic metabolic condition where the body is unable to convert glucose into the energy needed to carry out daily activities. An estimated 25.8 million people in the United States have diabetes, including seven million people who remain undiagnosed. If left untreated, high blood glucose

levels (hyperglycemia) can lead to serious long-term problems such as stroke, heart disease, and damage to the eyes, kidneys and nerves.

The Tina-quant HbA1cDx assay is manufactured by Roche of Basel, Switzerland. Roche's North American headquarters are located in Indianapolis, IN. (Source: FDA Website, 23 May, 2013)

FDA Announces Import of Injectable Nutrition Drugs in Critical Shortage

The FDA has announced that injectable drugs used in total parenteral nutrition (TPN) in critical shortage will be imported into the United States and available to patients this week.

TPN is an intravenous food solution containing several drugs that have been in short supply, including trace elements, potassium phosphate, and sodium phosphate. Hospitals nationwide rely on TPN, which is primarily used to treat premature infants who are unable to eat or drink by mouth or who are experiencing other deficiencies. Cancer patients and those who have had gastrointestinal surgeries who are also unable to eat or drink by mouth have been affected by these shortages.

The shortages are largely the result of a decision by American Regent/Luitpold, a large manufacturer of TPN products, to temporarily shut down at the end of 2012. The FDA worked with American Regent in an effort to avoid a shutdown. The company, however, ultimately decided that it had to cease operations temporarily in order to address quality issues that included particulate matter in its injectable products. The FDA continues to work with the company to prioritize the most critical drugs in shortage as it restarts production, and on the quality issues, to protect patient health. (Source: FDA Website, 29 May, 2013)

FDA Approves Two Drugs & Companion Diagnostic Test for Advanced Skin Cancer

The FDA has approved two new drugs, Tafinlar (dabrafenib) and Mekinist (trametinib), for patients with advanced (metastatic) or unresectable (cannot be removed by surgery) melanoma, the most dangerous type of skin cancer and the leading cause of death from skin disease. The National Cancer Institute estimates 76,690 Americans will be diagnosed with melanoma and 9,480 will die from the disease in 2013.

Tafinlar, a BRAF inhibitor, is approved to treat patients with melanoma whose tumors express the BRAF V600E gene mutation. Mekinist, a MEK inhibitor, is approved to treat patients whose tumors express the BRAF V600E or V600K gene mutations. Approximately half of melanomas arising in the skin have a BRAF gene mutation. Tafinlar and Mekinist are being approved as single agents, not as a combination treatment.

The FDA approved Tafinlar and Mekinist with a genetic test called the THxID BRAF test, a companion diagnostic that will help determine if a patient's melanoma cells have the V600E or V600K mutation in the BRAF gene. Zelboraf (vemurafenib) and Yervoy (ipilimumab) were approved in 2011 for the treatment of metastatic or unresectable melanoma.

"The co-approval of Tafinlar and Mekinist and the second companion diagnostic for BRAF mutation detection demonstrates the commitment of pharmaceutical and diagnostic partners to develop products that detect and target the molecular drivers of cancer," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostic Devices and Radiological Health in the FDA's Center for Devices and Radiological Health.

Tafinlar and Mekinist are marketed by GlaxoSmithKline, based in Research Triangle Park, NC. The THxID BRAF Kit is manufactured by bioMérieux of Grenoble, France. Yervoy is marketed by New York City-based Bristol-Myers Squibb, and Zelboraf is marketed by South San Francisco-based Genentech. (Source: FDA Website, 29 May, 2013)

GlaxoSmithKline Awarded Up to $200M by US to Develop New Antibiotics

GlaxoSmithKline plc and the Biomedical Advanced Research and Development Authority (BARDA), part of the US Department of Health and Human Services (HHS), have agreed to a first of its kind collaboration that will support the development of several antibiotics to fight antibiotic resistance and bioterrorism.

This public-private agreement marks the first time that HHS has taken a "portfolio approach" to funding drug development with a private sector company. This unique collaboration provides flexibility to move funding around GSK's antibacterial portfolio, rather than focusing on just one drug candidate and allow medicines to be studied for the potential treatment of both conventional and biothreat pathogens.
As one of the few large pharmaceutical companies still pursuing antibacterial research, GSK also has creative collaborations and funding partnerships with other companies, academia, and funding bodies such as the Innovative Medicines Initiative, Europe's largest public-private initiative and the Defense Threat Reduction Agency, which is part of the US Department of Defense. (Source: GlaxoSmithKline PLC Website, 22 May 2013)

Generics Manufacturer Ranbaxy Pleads Guilty, Agrees to Pay $500M

In the largest drug safety settlement to date with a generic drug manufacturer, Ranbaxy USA, a subsidiary

of Indian generic pharmaceutical manufacturer Ranbaxy Laboratories Limited, pleaded guilty today to felony charges relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India, the Justice Department announced today. Ranbaxy also agreed to pay a criminal fine and forfeiture totaling $150 million and to settle civil claims under the False Claims Act and related State laws for $350 million.

Ranbaxy USA pleaded guilty to three felony FDCA counts, and four felony counts of knowingly making material false statements to the FDA. The generic drugs at issue were manufactured at Ranbaxy's facilities in Paonta Sahib and Dewas, India. Under the plea agreement, the company will pay a criminal fine of $130 million, and forfeit an additional $20 million. (Source: US Department of Justice Website, 13 May, 2013)

New Members

Mr. Mohammad A. Alshuqaiq, *Student,* Worcester Polytechnic Institute

Ms. Katherine A. Amato, *Student,* Worcester Polytechnic Institute

Ms. Catherine A. Bannish, *Student,* Worcester Polytechnic Institute

David Barabani

Ms. Kirby E. Beranger, *Student,* University of New Hampshire

Mr. Ronald J. Boidi, *Student,* Massachusetts Maritime Academy

Mr. Erik Borgendale, *Reliability Engineer,* Genzyme Corp

Christina J. Bottom, *Student,* Worcester Polytechnic Institute

Mr. Ray Boudreau, Rockwell Automation

Mr. Ryan Brennan, *Manager, Corporate Learning and Development,* Worcester Polytechnic Institute

Mr. Ronald Bustos, *Process Eng II,* PFIZER

Miss Kellie M. Chadwick, *Student,* Worcester Polytechnic Institute

Mrs. Rashmi Chonkar, *Systems Engineer,* New England Controls

Mr. Charles W. Cochrane, *President,* Cochrane Ventilation Inc

Mr. Ralph Codio, *Plumber,* Organo Genesis

Steve Conroy, *Lead Investigato,* Shire

Mrs. Josie K. Corcoran, *Project Executive,* Suffolk Construction Company

Jeff D'Italia, *Director, Consulting Services,* StratAcuity

Jeffrey De Jesus, *Sr. Quality Engineer,* Genzyme

Ms. Ana M. Dede, *Student,* Worcester Polytechnic Institute

Mr. Nicholas R. DeFilippo, *Student,* Worcester Polytechnic Institute

Mr. Michael J. Foshey, *Student,* University of Massachusetts Dartmouth

Ms. Jennifer M. Garbarino, *Student,* Worcester Polytechnic Institute

Jackie Gomes, *Student,* Massachusetts Maritime Academy

Mr. John Griffin, *Vice President & General Mgr,* SourceOne, Inc

Michael Haas, *Instrumentation / Automation,* PERRIGO, INC

Mr. Jose DJ Hernandez, *Quality Engineer,* Biogen Idec

Heather Hochuli, *Sr. Process Technician II,* Pfizer

Thariq Iqbal, *Student,* University of Massachusetts Lowell

Mr. Brendan Isabelle, *Student,* UMass Lowell

Thomas J. Izbicki, *Facilities-Maintenance Mgr,* Lonza Biologics Inc.

Dr. Willem Kools, *Director,* EMD Millipore

Mr. Michael J. Korocinski, *Manager,* Vertex Pharmaceuticals

Ashwini R. Krishnan, *Process Engineer II,* Genzyme Corporation

Miss Courtney E. Langley, *Student,* Worcester Polytechnic Institute

Mr. David Lechner, *Student,* University of Massachusetts Lowell

Benjamin J. List, *Student,* Worcester Polytechnic Institute

Theodore Loney, *Process Sciences Associate III,* Regeneron Pharmaceuticals

Mrs. Kathleen Long, *Site Technical Services Investigations Manager,* Pfizer

Nixon Luc, *MFG Manager,* Shire

Dr. Rao Maddula, *Senior Manager,* Ariad Pharmaceuticals

Mr. Alex M. Margiott, *Student,* Worcester Polytechnic Institute

Ms. Udaya K. Maruvada, *Systems Engineer,* Pfizer

Jibin J. Matthew, *Student,* Worcester Polytechnic Institute

Mr. Jared Moskowitz, *Validation Engineer,* Valsource, LLC

Ms. Livia M. Motz, *Student,* Worcester Polytechnic Institute

Mr. Jeffrey R. Mungul, *QA Supervisor,* Shire plc.

Mr. Michael Murphy, *Student,* Worcester State University

Mr. Nolan S. Murphy, *Project Engineer,* Design Group

Ray Murray, Procter & Gamble

Mr. Armen Najjarian, *Customer Service Manager,* Olympic Systems Corporation

Kelly Nashawaty, White Mountain Process LLC

Ms. Edith A. Neidhardt, *Senior Principal Scientist,* Pfizer

Joshua Obeiter, *Manager,* Advanstar Communications

Kristin C. Olson, *Student,* Worcester Polytechnic Institute

Mr. Erik J. Osterlund, *IT Compliance & Validation Spc.,* Ariad

Benyoussef Ouaissa, *MFG Technician,* Shire

Mr. Vinay C. Pai, *Student,* Worcester Polytechnic Institute

Joshua M. Palmer, *Student,* Worcester Polytechnic Institute

Mr. John R. Parry, *Student,* Massachusetts Maritime Academy

Mr. Raj D. Patel, *Student,* Worcester Polytechnic Institute

Ms. Heather Peruffo, *Validation Engineer,* Barry-Wehmiller Design Group

Benjamin Pierce, *Sr. Project Mgr.,* Mangan Biopharm

Mr. Binesh Prabhakar, *Partner,* Cambridge IT Compliance LLC

Vivek Puthezath, *Automation Engineer,* GxP Automation LLC

Mr. James Putney, *Director of Operations,* Olympic Systems Corporation

Matthew Reynolds, *Lead Investigator,* Shire

Mr. Saad Riaz, *Student,* Worcester Polytechnic Institute

Caroline M. Rufo, *Student,* Syracuse University

Ms. Mary E. Schwartz, *Student,* Worcester Polytechnic Institute

Mr. Nishant Sharma, *Student,* Northeastern University

Carl Soderberg, *MFG Supervisor,* Shire

Mr. Jason M. Spooner

Ms. Yunwen Sun, *Student,* Worcester Polytechnic Institute

Mr. Chi N. Ta, *Student,* Worcester Polytechnic Institute

Ms. Dawn M. Tavalsky, *Director,* Genzyme

Mr. Michael S. Temple, *Student,* Massachusetts Maritime Academy

Mr. Dominique Throop, *Student,* Worcester Polytechnic Institute

Ms. Lina Tran, *President,* Worcester Polytechnic Institute

Mr. Peter Trearchis, *Student,* University of Massachusetts Lowell

Mr. Zachary Tropeano-Lovatt, *Process Engineer,* Bind Therapeutics

Mr. Michael S. Walsh, *Vice President,* Suffolk Construction

William Washington, *Director QA,* Rhodes Pharmamaceuticals

Ben Wynn, *Manager,* Endeavor Group

Ms. Marissa Zaino, *Student,* Eckerd College

Lukowz Zawada, *Student,* Worcester Polytechnic Institute

Ms. Fengfan D. Zhu, *Student,* Worcester Polytechnic Institute

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

Mr. Saboo Aghababayan, Genzyme Corp

Mr. John P. Alleruzzo

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

Mr. Richard P. Capobianco,

Mr. Raymond J. Cardin, PharMax Consulting LLC

Mr. Michael S. Cheney, Biogen Idec

Dr. Charles L. Cooney, Massachusetts Institute of Technology

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

Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. Daniel J. Dumont, Dynamic Systems Inc

Mr. John H. Evers, Lantheus Medical Imaging

Mr. Henry Fitzgerald

Mr. William R. Fraga

Dr. Roy F. Greenwald, DENS Partners, Inc.

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

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

Mr. David C. Hardy

Mr. Edwin L. Harmon, III, Genzyme Corp

Mr. David G. Harney, Microfluidics

Ms. Shelly Henderson, NNE Pharmaplan

Mr. Stephen R. Higham, PE, Genzyme Corp

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

Mr. Thomas R. Jerome

Mr. Robert W. Juffras, MS, Olympus Biotech

Mr. Jerome E. Justin, Shire HGT

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

Dr. Richard V. Levy, PhD, PDA

Peter F. Levy, PL Consulting, LLC

Mr. Robert C. Livingston, Arion Water Inc

Mr. Dwight C. Long, Integra Companies Inc

Mr. Frank J. Manning, VNE Corp

Mr. Daniel J. Mariani, M+W Group

Mr. H. Stafford McCoart, Stafford Technical Sales

Stephen P. Miraglia, Primecore Program Management

Mr. Hank Moes

Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc

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

Mr. Armen J. Nahabedian, Pfizer

Mr. Christopher R. Perley, Dyax

Mr. Stephen R. Potter, Baxter

Mr. Richard D. Priester, Strategic Facility Planning LLC

Dr. John J. Prior, Genzyme Corp

Mr. Thomas A. Ramundo, New England Controls Inc

Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc

Mr. David A. Rielly, Novartis Institutes for BioMedical Research, Inc.

Mr. Stephen P. Rossmeisl

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

Mr. John M. Ruggieri, CPI Controls Inc

Mr. Gregory M. Ruklic, Independent

Mr. Pasquale M. Sacco, Shire HGT

Mr. Hooman F. Sajedian, Pfizer Inc

Mr. Robert J. Sheehan

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

Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

Mr. Michael J. Sweeney, Hart Design Group

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

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

15 Year Anniversary

Mr. H Steven Kennedy, PE, M+W Group

Mr. Richard G. Kotosky, Integrated Process Technologies, Inc.

10 Year Anniversary

Mr. Alan Opper, Finesse Solutions, LLC

Mr. Tom S. Penney, Vertex Pharmaceuticals, Inc.

Mr. Stephen Smith, Cambridge Valve Fitting, Inc.

Mr. John M. Thomas, Dakota Systems, Inc.

5 Year Anniversary

Mr. Arturo R. Blanquera, Shire HGT

Mr. Benjamin Greenbowe, Vertex Pharmaceuticals

Mr. Zebulon J. Jones, Genzyme

Mr. Rich McCampbell, Jr., CRB Consulting Engineers

Mr. Mark Muscato, Amgen

Mr. Andrew G. Torchia, QA Experts

« 1 2 23 »

Chapter Manager: Amy Poole, CAMI - Tel: 1.781.647.4773 and E-mail: office@ispeboston.org