



Connecting a World of
Pharmaceutical Knowledge

Boston Area Chapter

www.ispeboston.org



NEWSLETTER

January 2014, Volume XXIV, No. 7

Complete Facility Automation & Compliance Solutions for the Life Science Industry

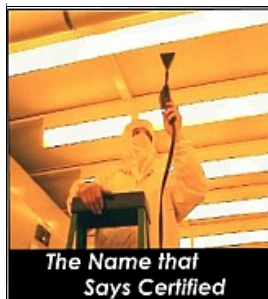


- Turnkey HVAC / Facility Automation
- GMP Monitoring / Process Integration
- Commissioning / Validation Services
- Technology Project Management
- UL508A Panel Fabrication Facility
- Rockwell Automation VFD Products

25 Mulberry Lane
Pelham NH 03076
(603) 898-6825

99 Hayden Ave. Suite 230
Lexington MA 02421
(781) 860-7900

www.GxPAutomation.com



**For Accurate
Certification
of 99.99% +
HEPA Filters
100% of the
Time, Trust the
Service
Professionals
At B & V.**

**The Name that
Says Certified**



**B&V
TESTING, INC.**

Call 800-851-9081
For GMP Contract
Testing and
Certification
Services Today.

www.BandVTesting.com

- Process & High-Purity Piping
- Skid Fabrication

GMP PIPING INC.
Connect with Quality

- Field Installation
- In-house Fabrication & Assembly
- 20,000 sq ft Facility

978-534-5800

[Return to the Table of Contents](#) | [Printing Instructions](#)

Save page as PDF

President's Message: What a Year It's Been for the Boston Area Chapter!



Dear Boston Area Chapter Members,

What a year it's been for the Boston Area Chapter! In the past twelve months BAC Members and volunteers have proven why the Chapter is recognized as the most active and successful ISPE Chapter/Affiliate in the world. A couple of the highlights from 2013:

Member Growth: Through sustained services to our Members – now covering all of New England – we have seen our membership grow to over 1750 members, far and away the largest ISPE Chapter/Affiliate in the world.

Product Show: The October 2013 Product Show had almost 2400 attendees and over 350 exhibitors, making it the largest one-day event for life sciences in the country.

Student Chapters We now have eight active Student Chapters, bringing our student membership to 150 members! These include:

- Massachusetts Maritime Academy
- Northeastern University
- University of Rhode Island
- Tufts University
- UMass Amherst
- UMass Lowell
- University of New Hampshire
- Worcester Polytechnic Institute

Monthly Events – The BAC continues to host world-class training and social networking events - over 25 events this past year!

As we move into the New Year, there are multiple opportunities for Members to assist and volunteer. Some of the benefits of volunteering include:

- growing your network of professional contacts,
- developing your leadership skills,
- increasing your industry knowledge, and
- expanding your future career options.

A list of our volunteer committees is below. Take a look and see where your interest may lie. Joining one of these committees will give you a chance to work with some highly motivated people and make valuable connections that will last throughout your career!

Product Show Plan and implement the Chapter's annual Product Show at Gillette Stadium. Volunteers are responsible for all aspects of this world-class event including sales and marketing, communications, exhibits, sponsorships, career fair and after-party.

Geographic Outreach Develop the plan for bringing the Chapter's programs – educational, networking and recreational – to all of New England, with special focus on areas outside of the Boston-Cambridge core. Coordinate with the Educational Program and Social committees.

Educational Program Plan and execute the Chapter's schedule of monthly educational programs, including the Product Show's educational offerings.

Student Development Develop activities designed to attract students, support the growth of existing Student Chapters and add new ones, including the annual Student Poster Competition and Career Forum.

Social Plan and implement the Chapter's schedule of social networking and recreational activities, including annual golf outings and ski trip.

Come On and Claim Your
Free Ride to Interpex



Click Here to Register

MASY SYSTEMS, INC.

VALIDATION

Chambers, sterilizers, warehouses with IQ/OQ/PQ

CALIBRATION

NVLAP Accredited and NIST traceable calibrations

GMP STORAGE

From -196°C to 70°C in controlled, secure
monitored environments

RENTALS/SALES

For validation and calibration

MONITORING

Continuous, wireless solutions



10 Lomar Park
Pepperell, MA 01463
978.433.6279

masy@masy.com
www.masy.com

Training in Pilot-Scale Lab



BIOMANUFACTURING
EDUCATION

Membership Find new ways to grow the Chapter's membership with a special focus on areas outside of the Boston-Cambridge core. Conduct membership drives at selected area companies.

Young Professionals Join with other Young Professionals to plan activities of special interest to this key demographic group. Coordinate with the Educational Program, Social and Product Show committees.

Communications Take responsibility for Chapter communications including the bimonthly eNewsletter and website.

2014 is going to be a great year for the Boston Area Chapter. We look forward to welcoming you as a volunteer and seeing you at our upcoming events.

Happy New Year!

Dan Ramsey

President

ISPE Boston Area Chapter

Chapter Bulletin Board

Northeastern Students Win ISPE International Poster Competition

Exciting news from the ISPE Annual Meeting held in early November where grad student Batur Ercan and undergrad Kassi Stein represented the Boston Area Chapter at the ISPE International Poster Competition: We had a winner! Congratulations to Kassi Stein from Northeastern who – together with Miglia Cornejo, also from Northeastern, won the undergraduate category! This is a huge achievement for Kassi and Miglia – and for the Boston Area Chapter. See below to find out how you can compete in 2014.

Enter the Chapter's Annual Student Poster Contest in April

Would you like to showcase your research? Do you have a project you want to share? Start planning now and participate in the Chapter's Annual Student Poster in April. Winners will receive an all-expenses-paid trip to the ISPE Annual Meeting in Las Vegas in October 2014 where they will compete for cash and other

prizes at the International Student Poster Competition. In 2013, Student Members from Northeastern won both the graduate and undergraduate categories at the Chapter level. And undergraduate winners Kassi Stein and Miglia Cornejo went on to win the International Competition, gaining valuable exposure among our industry's key movers and shakers. See the Chapter website or contact our office at office@ispeboston.org or 781.647.4773 for details.

eNewsletter Ad Space Expanding – Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1600 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Visit the sponsorship page on our website at <http://www.ispeboston.org> and open the sponsorship application. Choose the eNewsletter option that works best for you - ads are available in two sizes and run for six months or a full year - then pay by credit card online. It's that simple!

And while you're there, be sure to explore the full range of sponsorship options available in addition to eNewsletter ads, including educational programs, social events and website ads. Using the sponsorship application as your worksheet, you can view your savings as you select various combinations of sponsorship options - the more you choose, the bigger your discount!

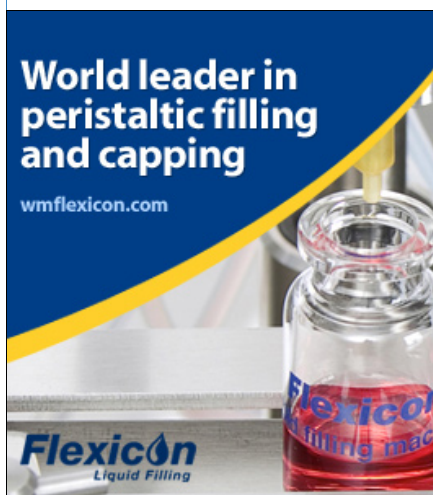
So don't delay! Visit <http://www.ISPEBoston.org/sponsorship> and add your name to the growing list of sponsors who gain valuable exposure while supporting the Chapter's activities. Have questions? Contact the Chapter office at 781.647.4773 or office@ispeboston.org and we'll be happy to help!

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

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at <http://www.ispeboston.org/sponsorship.html>, containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Discounts Available for Unemployed Chapter Members

Between jobs? Changing careers? In partnership with International ISPE, the Boston Area Chapter



Between jobs / Changing careers / In partnership with international ISPE, the Boston Area Chapter makes it cost-effective for unemployed Chapter Members to maintain their membership and attend Chapter educational programs, both of which are more valuable than ever during career transitions. The ISPE Hardship Program enables Members in good standing to retain their membership at a significantly reduced rate for one year. Instead of print, Hardship Members get an electronic copy of Pharmaceutical Engineering magazine, along with all other Member benefits. Contact the international ISPE office at ask@ispe.org for more information or to discuss your membership status. At the local level, the Chapter allows unemployed members to attend most Chapter-sponsored educational programs at the student rate (\$5 or \$10 per event) - simply call or email the Chapter office (781.647.4773 or office@ispeboston.org) when registering to attend. Lastly, joining one of the Chapter's volunteer committees is another great way to maintain and expand your professional network during career transitions, while simultaneously supporting the Chapter's activities. Visit the Chapter website at http://www.ispeboston.org/Boston_Area_Chapter_Committees.html to learn more about the many volunteer opportunities available.

Upcoming Chapter Events - Mark Your Calendar

Thursday, January 16, 2014

Professional Development: Tech Skills Get the Meeting, Soft Skills Get the

Promotion

Genzyme Center, 500 Kendall Street, Cambridge, MA

In a competitive job market, technical skills get you in the door but soft skills set you apart. Critical to career advancement, people skills will make you a valued employee and open doors to promotion and new opportunities. Whether leading a team, collaborating with colleagues, networking at professional events or interacting with a client, strong communication skills are indispensable. But how best to develop your unique skill set? Not just to achieve results, but to set you apart as a valuable employee? This interactive session will focus on and provide training for the soft skills needed for leadership, mastering the art of networking, and improving communication. Drawing from a wealth of experience in leading and developing talent, and complete with anecdotes & "case studies" from their professional history, the panelists will provide insights for boosting personal and career success for a working professional.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=397

Thursday, January 30, 2014

New Year's Social

Taza Chocolate, 561 Windsor Street, Somerville, MA

Come join the ISPE Boston Area Chapter for our first social of the season! New and returning members, young and old professionals are all welcome to enjoy in a night of socializing and networking as we taste chocolate with wine and tour the Taza Chocolate Factory!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=435

Sneak Preview of Upcoming Events

Thursday, February 20, 2014

ISPE Standards, Practices & Guides

Thursday, March 20, 2014

Design and Construction

Friday, March 7, 2014

Annual Ski Trip

April 28, 2014

ISPE Golf Tournament

August 18, 2014

ISPE Golf Tournament

Product Show – Call for Volunteers

by Product Show Committee Co-Chairs Steve Kennedy and Sean Burgess

The Boston Area Chapter Product Show Committee is seeking volunteers who will be active and engaged members of the committee working to make the Product Show the best show of its kind in 2014 and 2015. Our last Show was a huge success and we are looking for new blood to help take the Show to the next level.

The Committee is divided into three subcommittees, each responsible for different aspects of the Show:

Social, Traffic Builders, and Marketing (Attendees) Subcommittee Chaired by Mark Levanites, this subcommittee is responsible for ensuring that the Product Show continues to attract record breaking attendance. It creates the buzz that makes the Product Show stand out from all other shows. Volunteers

OLYMPIC SYSTEMS CORPORATION
"THE SINGLE SOURCE"

Olympic Systems is a manufacturing business
Servicing customers in the Pharmaceutical,
Biotechnology, Medical, Analytical Inst.
& Gas /Fluid processing Industries.

www.olympicsystemscorp.com

781-721-2740

ASTRO PAK®
www.astropak.com

- High Purity Cleaning
- Derouging & Passivation
- Electropolishing
- Precision Cleaning

508.458.7361

Allegheny Bradford Corporation

- ✓ Heat Exchangers
- ✓ Sampling Systems
- ✓ Filter Housings
- ✓ Custom Tanks

Chuck Ridenour
Regional Sales Manager
814-362-2590
alleghenybradford.com

**SPECIALIZING IN SOLUTIONS
LOCALLY AND WORLDWIDE**

VALIDATION
COMMISSIONING
QUALITY & COMPLIANCE
PROCESS IMPROVEMENT

Local Contact: Tulsa Scott
Cell: 860.460.1195
Tulsa.Scott@CAgents.com

CAI
Commissioning Agents, Inc.
an International Company

WWW.COMMISSIONINGAGENTS.COM

Your challenges **today**
are not what they were **yesterday**
and will not be the same **tomorrow**.

We Listen. We Deliver... **more flexibility.**

Shannah Schodde | 617.475.3050
Shannah.Schodde@crbusa.com

Jamie Miller | 617.475.3050
Jamie.Miller@crbusa.com

SEQUENCE
Validation Consulting Services

Validation Consulting | Project Leadership
Assessment and Remediation | Regulatory Compliance
21 CFR Part 11 Compliance | Training

P 800 888 7171 E 781 716 8888

will:

- Develop a regional approach to the marketing of the show to attendees for posters and email blasts. We are looking for volunteers who will take "ownership" of selected regions and identify and cultivate relationships with site advocates at each operating company site in their respective regions. Site advocates will support our marketing efforts by posting Product Show fliers and posters at their respective company locations.

Sign Up to be a Site Advocate

As a site advocate, you will be our touch point at your company site, distributing Product Show fliers, posters and email blasts to help create buzz about the event. Interested? Contact Chapter Manager Amy Poole at office@ispeboston.org and let her know!

- Develop a plan to attract attendees from beyond the greater Boston area to the Show, including buses and hotels for visitors.
- Develop and manage a plan to ensure attendees visit all exhibit areas, including a "passport" plan that could also be used as a revenue enhancement by offering sponsorships.
- Develop and manage the "traffic builders" that help draw attendees to the Show. These could include a battle of the bands, DJs, entertainment acts, etc.
- Develop and manage a charity fund raising event in conjunction with the Patriots' cheerleaders.
- Review and manage the food and drink plans.
- Develop and manage the after party including theme, food, beverage, and entertainment.

Sales and Marketing (Exhibitors) Subcommittee: Chaired by Jack Campion, this subcommittee is responsible for developing, marketing, and selling all revenue generators and enhancements. This includes tables, booths, and sponsorships. They work with the Show Manager and outside consultants to develop the marketing materials (postcards, emails, etc.) that are used to sell the exhibit booths, sponsorships and other revenue generators. We are looking for volunteers to:

- Actively sell all exhibit and sponsorship opportunities.
- Improve the loading/unloading process for vendors
- Develop a "training camp" webinar to be posted on the website to help exhibitors get the most value possible out of their participation at the Show.
- Work with an outside consultant to develop a Product Show guide/floor plan phone app and implement floor plan kiosks.
- Develop and implement a plan to promote the "vendor showcase" activity.
- Update the Vendor Agreement and Show Guidelines.
- Investigate alternative forms of marketing including social media.
- Working with our consultant, complete a video that can be used to market the event.

Career Fair Subcommittee: Chaired by Alex McKinnon, this subcommittee is charged with making the Career Fair a "Show within a Show." They are empowered to break away from our traditional model and work with the hiring companies to make the Career Fair better year to year. They also create and manage an educational session relevant to prospective hires and help to market and sell the Career Fair tables.

Product Show Committee volunteers must be ISPE Members in good standing. Volunteers are expected to attend all meetings, either in person or virtually via conference call if physical presence is not possible. The full committee meets once a month on the first Monday of the month (twice a month as the Show date gets closer) in Waltham (see below). Subcommittees also meet at least once a month. Volunteers will need to be able to commit at least one hour on the day of the Product Show to help man the various help stations that attendees and exhibitors rely on for information and assistance during the Show.

If you are truly interested in joining the committee and can commit the necessary time, please contact Chapter Manager Amy Poole at office@ispeboston.org, let her know which subcommittee you would like to work with and plan to attend the next committee meeting on Monday, January 6. Thank you for your interest and we look forward to having you join us!

2014 Product Show Committee Meeting Dates:

- Monday, January 6
- Monday, February 3
- Monday, March 3
- Monday, April 7
- Monday, May 5
- Monday, June 2
- Monday, July 7
- Monday, August 4
- Monday, August 18
- Monday, September 8
- Monday, September 22

!! SAVE THE DATE !!

**The 2014 Boston Area Chapter Product Show will
be held on
October 1, 2014 at Gillette Stadium.
Exhibitor registration will be opening soon!**

**Biotechnology Professional
Development & Advancement**
 Limited space, registering NOW for
 Spring/Summer 2014!
www.uri.edu/prov/BPDA.BPM_seminars.html
 THINK BIG WE DO®

Comprehensive Compliance Solutions Validation & Verification Compliance
 Click here for details, or contact
 Theresa Pinnell
 (C) 857-205-4301
 Quality Assurance
 Technology Transfer
WWW.PROPHARMAGROUP.COM

PCI The leading provider of reliable and compliant instrumentation services
 • 877-724-2257 • www.pci-llc.com
 PCI specializes in equipment management and documentation compliance with FDA and ISO requirements
 • Process and analytical calibrations & maintenance services
 • Calibration & maintenance program implementation
 • Local resources in Boston and New England


Previous Issues

[November 2013, Volume... \(14\)](#)
[September 2013, Volume... \(17\)](#)
[July 2013, Volume... \(12\)](#)
[May 2013, Volume... \(12\)](#)
[March 2013, Volume... \(12\)](#)
[January 2013, Volume... \(11\)](#)
[November 2012, Volume... \(15\)](#)
[September 2012, Volume... \(16\)](#)
[July 2012, Volume... \(12\)](#)
[May 2012, Volume XXI... \(13\)](#)
[March 2012, Volume... \(11\)](#)
[January 2012, Volume... \(10\)](#)
[November 2011, Volume... \(16\)](#)
[September 2011, Volume... \(15\)](#)
[July 2011, Volume XXI... \(12\)](#)
[May 2011, Volume XXI... \(16\)](#)
[March 2011, Volume XXI... \(16\)](#)
[January 2011, Volume... \(13\)](#)
[November 2010, Volume... \(14\)](#)
[September 2010, Volume... \(16\)](#)
[July 2010, Volume XX... \(13\)](#)
[May 2010, Volume XX... \(16\)](#)
[March 2010, Volume XX... \(15\)](#)
[January 2010, Volume... \(14\)](#)
[November 2009, Volume... \(11\)](#)
[September 2009, Volume... \(13\)](#)
[July 2009, Volume XIX... \(11\)](#)
[May 2009, Volume XIX... \(9\)](#)
[April 2009, Volume... \(11\)](#)
[February 2009, Volume... \(10\)](#)
[December 2008, Volume... \(13\)](#)
[October 2008, Volume... \(12\)](#)
[August 2008, Volume... \(10\)](#)
[June 2008, Volume... \(11\)](#)
[April 2008, Volume... \(10\)](#)
[February 2008, Volume... \(10\)](#)
[December 2007, Volume... \(13\)](#)
[October 2007, Volume... \(10\)](#)

November Program Explores the Massachusetts Biotech Super Cluster

by Jack Campion, Hart Design Group, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

The Thanksgiving holiday reminds us to appreciate what we have and the opportunities we have been afforded. It also reminds us of the roots of our local economy, when a few dozen motivated souls with great vision and a willingness to work hard changed the fortunes of many for centuries to come. The Boston Area Chapter's November program entitled "The Massachusetts Biotech Super Cluster" showed that these values still drive our local economy forward – with our own biopharmaceutical industry at the center.



Genzyme's auditorium was filled to overflowing with attendees eager to learn more about the biotech "super cluster" from a new point of view.

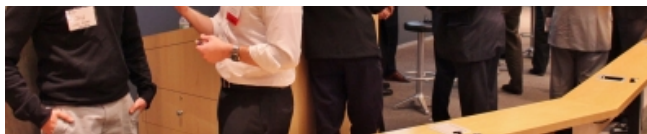
The program, led by Chapter Past President Jim Grunwald, featured a panel of experts deeply involved in the life sciences economy in greater Boston. They explored the drivers of the current boom and future trends from the perspective of the real estate market. Appropriately, the program was held at Genzyme headquarters abutting Kendall Square in Cambridge - the super cluster's epicenter. Panelists included Dan Cordeau of Alexandria Real Estate Equities; Jeremy Hood of T3 Advisors; Peter Abair, Director of Economic & Global Affairs at the Mass Biotech Council (MassBio); and Phil Plottel, Senior Director of Global Real Estate and Facilities for Ariad Pharmaceuticals.

Top take aways from the evening's discussion included the following:

- The concentration of biotech R&D and manufacturing facilities in and around Cambridge is unmatched anywhere in the world. Kendall Square, the heart of the Massachusetts "super cluster," continues to be a magnet for innovative life science companies that deliver new drug candidates to the product pipeline. Adding to the Kendall Square phenomenon is the proximity of three medical schools, world-renowned universities, associated research institutes and the many research hospitals that are household names. All are accessible by jumping on the T.
- Beyond the reach of subway cars, communities across the Commonwealth are vying for biotech research and manufacturing facilities. Generally reachable by car only, these areas offer much lower real estate costs.
- The permitting process is multifaceted and commonly involves approvals by multiple interests in any town – planning and zoning boards, health departments and fire departments, to name a few. Cities and towns that have established guidelines and administrative procedures that provide certainty to the permitting process have seen the greatest success. In addition to Cambridge, Lexington and Worcester are notable for their strong history of locating new facilities.
- The importance of incubator facilities was discussed, noting that demand has outstripped supply. Facilities associated with universities and/or sponsored in part by the Commonwealth are most attractive because of their cost competitiveness. Woburn and Worcester were noted as standout hometowns of desirable incubator space.
- Manufacturing has not seen the same level of enthusiasm lately as R&D with respect to the real estate market. This is not surprising given the much higher level of commitment and investment needed to build a GMP facility versus a laboratory. However it was noted that the concentration of mammalian cell culture capacity just in eastern Massachusetts, northern Rhode Island, and southern New Hampshire is 600,000 liters. Like the concentration of life science R&D square-footage, this too is unmatched by any other region in the world.

During the Q&A session it was noted that the health of the biomanufacturing economy in this area and its attractiveness going forward has much to do with the expertise represented by the membership of the Boston Area Chapter. ISPE Members design, build, validate, operate and maintain biopharmaceutical facilities and the Boston Area Chapter - now serving the entire New England region - is the largest ISPE Chapter in the world, bar none. And this is not a co-incidence. The high concentration of qualified and experienced engineers, scientists and other professionals comprising the Chapter is a key asset supporting biomanufacturing in our region.





Attendees stayed long after the program ended for a personal Q&A with the panelists.

The Chapter is working with the Massachusetts Life Sciences Center and MassBio to attract more biotech manufacturing to the area. We are highlighting the key contributions of our Members to the "value proposition" offered to manufacturers who are deciding where to locate their next facility. The Chapter's Board of Directors is planning to expand this effort to other agencies and organizations throughout New England. If you have knowledge or experience that might help, please contact the Chapter office at 781 647 4773 or office@ispeboston.org.

The Chapter would like to thank the presenters for an informative and thought-provoking discussion; and Genzyme for hosting the program.

Echoing the Message

Coincidentally in early December, an organization known as Massachusetts Biomedical Initiatives (MBI) issued a report in conjunction with MassBio advocating the expansion of manufacturing in central Massachusetts. The group is promoting the formation of a public-private partnership to jumpstart the effort. The report points out that, in the future, biopharmaceutical molecules will be produced for smaller and smaller target populations of patients. This will call for facilities using flexible manufacturing technologies including disposables. Development and application of these technologies is already well-

founded in Massachusetts. In particular, the partnership would target clinical manufacturing for the 1100+ molecules now under development by Massachusetts companies.

December Program Helps PMs and PEs Blend Skills for a Common Goal

by Mark J Jodoin, Symbotic LLC with photos by Joyce Chiu, CPIP, Honeywell Safety Products,

The Boston Area Chapter educational program entitled "Engineers and Project Managers: Blending Skills for a Common Goal" was held at Biogen Idec in Cambridge on Thursday, December 12 with over 80 ISPE Members and non-members in attendance.

Following the customary networking reception, the evening began with opening remarks by Boston Area Chapter Vice President Chris Opolski. Chris provided Chapter updates including upcoming events and the geographic outreach (GO) initiative. The GO initiative is exploring ways to provide access to programs for Chapter Members who are too far from the venue to make the trip. Stay tuned for more news regarding progress on this important new effort. Meeting Manager Mark Jodoin followed, introducing the evening's speakers and providing a summary of the program to come.



A roomful of engineers and project managers turned out for December's educational program at Biogen.

Almost every project has an engineer and a project manager, but their perspectives are not the same. The engineer lives within the more detailed world, whereas the PM looks at the big picture and the overall success of the project. Andrew Faden, CPIP, PMP, presented the perspective of the engineer and Neeraj Shah that of the project manager. The presentations dovetailed perfectly, since both speakers were well versed in the material presented by the other. Besides the higher level material presented, several project management tools were covered in enough detail so that the audience left with actionable knowledge at the end of the evening.

Andrew Faden is a project manager and senior electrical engineer at Lantheus Medical Imaging with many years of experience in the pharmaceutical industry. He earned his Bachelor's degree in electrical engineering at UMass Amherst and holds ISPE CPIP and PMI PMP certifications. Andrew's presentation concentrated on the role of project engineer. Andrew covered four areas:

- industry guidance including ICHQ8, ICHQ9, cGMP and the ISPE FSE Guide,
- the project engineer's role as the subject matter expert,
- a review of ASTM E2500 and, lastly,
- how the project engineer works within the project management lifecycle.

Andrew stressed that projects benefit greatly when a project engineer and a project manager are paired up throughout the project lifecycle and when the PM and the PE both understand their respective roles and expectations. He also spent a good amount of time discussing the work breakdown structure (WBS) tool and how it should be used from early stages of development all the way through a project's life, helping to keep the deliverables as planned.

Neeraj Shah, PMP, is an associate director at Shire HGT in the IT Business Partner Global Supply group.

Neeraj also holds the PMP certification and serves as a PMP coach. Neeraj earned his bachelor's degree in industrial engineering from Bangalore University, an MBA from Babson College and has completed an Advanced Project Management program at Stanford University.



Meeting Manager Mark Jodoin and speakers Andrew Faden (l) and Neeraj Shah (r) fielded many excellent questions following the presentations

Neeraj's presentation focused on the project manager. He identified improper management of stakeholders as a prime risk for project failure and covered stakeholder identification and management, methods of communication with stakeholders and overall stakeholder strategies in detail. He also presented some analytical tools for these practices and stressed that it is critical to engage stakeholders as soon as project planning begins and maintain their engagement throughout the project lifecycle. In summary, Neeraj felt that it is the responsibility of the project manager to proactively manage stakeholders.

Both speakers shared new and insightful information that will help PMs and PEs better understand each other's role and how best to complement one another for the benefit of the project. Audience members were fully engaged throughout, asking many questions during the presentations, and staying after the program ended to talk one-on-one with the presenters.

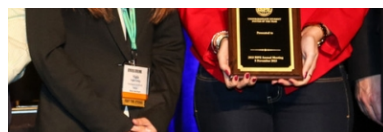
The Boston Area Chapter and Meeting Managers Mark Jodoin and Robert Beane would like to thank the speakers and audience members for their valuable contributions to this program and Biogen Idec for providing the venue for the event. Special thanks to Board Member Tom Choyce for acting as onsite liaison for this event.

Chapter Student Membership Triples in 2013!

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

First, some exciting news from the **ISPE Annual Meeting** held in early November. Batur Ercan (graduate) and Kassi Stein (undergraduate) represented the Boston Area Chapter at the ISPE International Student Poster Competition. And we had a winner! Congratulations to Kassi Stein from Northeastern! She won the undergraduate category! This is a huge achievement as it's been over five years since the Boston Area Chapter has had a winner at this event! Great work Kassi (and Miglia Cornejo, her fellow team member)! See below to find out how you can compete in 2014.





Poster Competition winners and Northeastern University undergrads, Miglia Cornejo (l) and Kassi Stein (r) happily accept their award at the ISPE Annual Meeting.

The Chapter had a **huge influx of new Student Members** as a result of recruiting efforts and the Annual Product Show, where students learned about cutting edge products, mingled with other ISPE Members, attended educational programs and won prizes at the YP/student social trivia contest. Many thanks to Sean Burgess from Integrated Builders and Andrea Woods from Mangan Biopharm for all their hard work to ensure that this event was a resounding success!

When the year started, the Chapter had about 50 student members. Less than a year later, our ranks have tripled to over 150 students! In fact, in the last month alone, Mass Maritime and UMass Lowell had the largest influx of new student members and deserve special recognition.

The Chapter has a full slate of activities in the planning stages for the spring semester, with these events already firm. Be sure to read those Chapter emails and check the events calendar on the Chapter website for more information:

- **February 8 Career Forum** at Northeastern to prepare students to interview and make the right first impression in order to successfully land internships, co-ops and jobs.
- **March plant tour at Genzyme's Framingham location.**
- **April Student Poster Competition.**

Do you want to show off your research? Do you have a project you want to share? Start planning now and participate in the Chapter's Annual Student Poster Competition in April. Winners will receive an all-expenses-paid trip to the ISPE Annual Meeting in Las Vegas in October where they will compete for cash and other prizes at the International Student Poster Competition. In 2013, Student Members from Northeastern won both the graduate and undergraduate categories at the Chapter level; and undergraduate winners Kassi Stein went on to win the International Competition, gaining valuable exposure among our industry's key movers and shakers. Now it's your turn! See the Chapter website or contact our office at office@ispeboston.org or 781.647.4773 for details.

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

Industry News in Brief

by Jillian Willard, Genzyme, a Sanofi Company

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

Vertex Eliminates 175 Positions in Massachusetts

Vertex Pharmaceuticals has announced the company will focus its investment on future opportunities in cystic fibrosis and other high-potential research and development programs. The company will be reducing its workforce related to the support of its hepatitis C drug Incivek following the continued and rapid decline in the number of people being treated with Incivek as other new medicines for hepatitis C near approval. The company will focus its investment on future opportunities in cystic fibrosis and other high-potential research and development programs.

The company is eliminating 370 positions, primarily related to the support of Incivek, representing approximately a 15 percent reduction in the company's global workforce. Approximately 175 positions are being eliminated in Massachusetts. Following the changes, Vertex expects to have approximately 1,800 employees worldwide, including approximately 1,300 in Massachusetts. (Source: Vertex Website, 29 October, 2013)

Anylam Receives Fast Track Designation for RNAi Therapeutic

Anylam Pharmaceuticals has announced that the FDA has granted Fast Track designation to patisiran (ALN-TTR02) for the treatment of transthyretin (TTR)-familial amyloid polyneuropathy (FAP). According to the FDA, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

Anylam is developing patisiran for the treatment of ATTR patients with FAP. The company recently announced positive Phase II data for patisiran. Transthyretin (TTR)-mediated amyloidosis (ATTR) is an inherited, progressively debilitating, and fatal disease caused by mutations in the TTR gene. Mutations in TTR cause abnormal amyloid proteins to accumulate and damage body organs and tissue, such as the peripheral nerves and heart. Familial amyloidotic polyneuropathy (FAP) affects approximately 10,000 people worldwide and familial amyloidotic cardiomyopathy (FAC) affects at least 40,000 people

worldwide. FAP patients have a life expectancy of five to 15 years from symptom onset, and the only treatment options for early stage disease are liver transplantation and tafamidis (approved in Europe).

In 2012, Aplyx entered into an exclusive alliance with Genzyme, a Sanofi company, to develop and commercialize RNAi therapeutics, including patisiran and ALN-TTRsc, for the treatment of ATTR in Japan and the broader Asian-Pacific region. Aplyx plans to develop and commercialize the ALN-TTR program in North and South America, Europe, and rest of the world. (Source: Aplyx Website, 11 November, 2013)

FDA Approves Sunovion's Aptiom for Seizures

Sunovion Pharmaceuticals has announced that the FDA approved Aptiom (eslicarbazepine acetate), an antiepileptic drug (AED), for use as adjunctive treatment of partial-onset seizures. Epilepsy is one of the most common neurological disorders and, according to the Centers for Disease Control and Prevention, affects nearly 2.2 million people in the United States. Partial-onset seizures are the most prevalent seizure type, accounting for 60 percent of new epilepsy diagnoses. Aptiom is taken in a once-daily oral dosage. The FDA has determined that Aptiom will not be classified as a controlled substance. Sunovion expects Aptiom to be available in U.S. pharmacies in the second quarter of 2014. (Source: Sunovion Website, 08 November, 2013)

British Company to Distribute RXi Pharmaceuticals RXI-109

RXi Pharmaceuticals has announced that they have signed a distribution agreement with Ethicor Ltd., a UK-based unlicensed medicinal products ("Specials") pharmaceutical company. The agreement provides Ethicor with the distribution rights to RXI-109 in the European Union, with the possibility to extend it to other regions of the world, excluding the United States, Canada and Mexico, prior to and until the registration of the product in the different countries covered by the agreement. Under the terms of the agreement, the gross profit generated from this "Specials" sale will be shared between RXi Pharmaceuticals and Ethicor. Once RXI-109 becomes an approved drug in a given country, the marketing rights to the approved product in that country revert back to RXi.

RXi Pharmaceuticals is a biotechnology company based in Westborough, MA. The company is focused on discovering, developing and commercializing innovative therapies based on its proprietary, self-delivering RNAi platform. Therapeutics that use RNA interference, or "RNAi," have great promise because of their ability to down-regulate the expression of a specific gene that may be over-expressed in a disease condition. RXI 109, targeting connective tissue growth factor (CTGF) to reduce dermal scarring (fibrosis), entered into human clinical trials in June 2012. The first clinical trials of RXI 109 showed excellent safety and tolerability with ascending single or multiple doses. (Source: RXi Pharmaceuticals Website, 18 November, 2013)

AbbVie Releases Positive Phase III Trial Results for Hepatitis C Treatment

AbbVie released phase III results for the investigational three direct-acting-antiviral (3D) regimen plus ribavirin in patients with chronic, genotype 1 (GT1) hepatitis C virus (HCV) infection. Globally, approximately 160 million people are chronically infected with hepatitis C. GT1 (with subtypes 1a and 1b) is the most prevalent genotype worldwide, with a higher prevalence of 1a in the U.S. and 1b in Europe.

Following SAPPHERE-I, SAPPHERE-II is the second placebo-controlled trial and the second of six phase III trials supporting AbbVie's investigational 3D regimen for the treatment of GT1 hepatitis C patients. AbbVie will disclose detailed SAPPHERE-II results at future scientific congresses and in publications.

The most commonly reported adverse events in both the 3D and placebo arms were headache, fatigue and nausea. Discontinuations due to adverse events were reported in three (1 percent) patients receiving the 3D regimen and no patients receiving placebo. Virologic relapse or breakthrough was noted in 2 percent of patients receiving the 3D regimen plus ribavirin. (Source: AbbVie Website, 10 December, 2013)

Shire Announces Positive Test Results for Eating Disorder Drug Vyvanse.

Shire has announced positive top-line results from two identically designed randomized placebo-controlled Phase 3 studies evaluating the efficacy and safety of Vyvanse (lisdexamfetamine dimesylate) Capsules (CII) versus placebo in adults with binge eating disorder (BED). In both studies Vyvanse was found to be statistically superior to placebo on the primary efficacy analysis (p-value <0.001) of the change from baseline at weeks 11 to 12 in terms of number of binge days per week. The safety for Vyvanse in these two studies appears to be generally consistent with the known profile established in studies in adults with Attention-Deficit/Hyperactivity Disorder (ADHD). The Company is reporting the data sooner than originally anticipated because of faster than expected completion of both studies.

In addition to the positive top-line primary results, both studies showed statistically significant (p-value <0.001) and consistent treatment effects for Vyvanse across the key secondary efficacy endpoints that have been analyzed thus far in the top-line data. Shire anticipates presenting the efficacy and safety data from both studies at a major scientific meeting in 2014. The company plans to file for FDA regulatory approval of Vyvanse for the treatment of BED in adults (ages 18 to 55) by Q3 2014.

Vyvanse is a prescription medicine currently only approved for the treatment of ADHD in the United States, Canada, Australia, several European countries (trade name: Elvanse/Tyvanse) and Brazil (trade name: Venvanse). Vyvanse should only be used in accordance with locally approved prescribing information. The safety profile for Vyvanse in these two studies, based on top-line data, appears to be generally consistent with the known profile established in studies in adults with ADHD. (Source: Shire Website, 05 November, 2013)

Natrick's Parcell Laboratories Receives Patent for Stem Cell Technology

Stem cell therapeutics provider Parcell Laboratories announced that the U.S. Patent and Trademark Office has issued a patent entitled "Multipotent Stem Cells and Uses Thereof". The newly issued patent concerns the Early Lineage Adult (ELA) stem cell and relates to providing an isolated population of stem cells that exist in the synovial fluid, blood, and other tissues in the body, and related therapeutic methods.

Parcell Laboratories holds the exclusive worldwide license to the ELA stem cell platform technology, which was originally discovered by scientists affiliated with the Brigham and Women's Hospital and Harvard Medical School. This multipotent stem cell patent has a term extending through 2028.

ELA cells represent the industry's newest stem cell platform technology, offering potential uses in a number of different therapeutic applications. The cells may be distinguished from other adult stem cells in several ways. First, ELA cells appear to harbor the flexibility one would normally associate with only embryonic stem cells (ESCs), offering greater potential to differentiate into a wider array of more developed cell types. In contrast to ESCs, ELA cells are not associated with higher tumor-generating potential and come without the ethical controversies attached to embryonic cells. Furthermore, ELA cells

do not express the surface markers generally associated with other adult stem cells, thereby reaffirming the ELA cell population as unique.

ELA cells are easily harvested from the synovial fluid of patients with osteoarthritis of the knee, but evidence suggests that they can be found throughout the body, an avenue of investigation that Parcell Laboratories is actively pursuing. Importantly, the patent allows for the culture expansion of the ELA cell into large master cell banks, which enables the company to grow the cells in tissue culture for therapeutic use. (Source: Parcell Laboratories Website, 26 November, 2013)

UMass Medical Licenses Anti-Cancer Technology

UMass Medical School has licensed "anti-gal" technology, Alphaject, developed by Uri Galili, PhD, professor of surgery and medicine, to newly formed biopharmaceutical company Agalimmune Ltd. for the purpose of developing innovative immunotherapies for the treatment of solid tumor cancers. Alphaject is based on more than 20 years of biomedical research carried out by Dr. Galili, who discovered the anti-gal immune response and its role in organ transplant rejection. Using the same anti-gal immune response, Alphaject can treat solid tumors in such a way that the body actively rejects them, akin to a non-matched graft or transplant.

Injected directly into solid tumors, the Alphaject compound coats the cancer cells in alpha-gal, to which humans naturally have a high antibody concentration. The alpha-gal antigen is then recognized by the immune system as foreign, allowing it to begin destroying the cancerous cells immediately. Because the immune system now identifies the cancer cells as foreign, going forward it is able to recognize and remove any stray cancer cells that might be left after conventional surgery or that may have migrated away from the main tumor. The effect is analogous to a personalized cancer vaccine, acting continuously to prevent both metastasis and recurrence. (Source: UMass Medical Website, 26 November, 2013)

GSK Heart Drug Fails to Meet Primary Endpoint in Phase III Trial

GlaxoSmithKline announced top-line results from the Phase III trial, STABILITY (Stabilisation of Atherosclerotic plaque By Initiation of darapLadlb Therapy), evaluating the efficacy of its investigational Lp-PLA2 inhibitor darapladib in adults with chronic coronary heart disease (CHD). Darapladib is not approved for use anywhere in the world.

The study did not meet the primary endpoint measure, which was time to first occurrence of any major adverse cardiovascular event (MACE) from the composite of myocardial infarction (heart attack), stroke, and cardiovascular death. There were greater reductions (nominal $p \leq 0.05$) in some of the pre-defined secondary endpoints that require further analysis. Additional data will be forthcoming from the second Phase III study, SOLID-TIMI 52.

In STABILITY, the overall safety profile showed no major imbalance in serious adverse events between the active and placebo groups. Further analysis of the data is ongoing. Full results of the STABILITY study will be submitted for presentation at a scientific meeting in 2014. The data from this study will contribute to any future regulatory submissions for darapladib. (Source: GlaxoSmithKline Website, 12 November, 2013)

Broad Institute Receives \$100 Million Gift

American philanthropists and entrepreneurs Eli and Edythe Broad announced today they are investing an additional \$100 million into the Broad Institute to launch a new decade of transformative work to harness recent biomedical discoveries to benefit patients. This gift brings their total contributions to the institute to \$700 million since its founding nearly a decade ago — and makes the Broads the second largest donors ever to a university, hospital or research institute for biomedical research.

The Broad Institute was founded in 2003 as an unprecedented model of research collaboration, bringing together scientists from across the MIT and Harvard communities, including the Harvard-affiliated teaching hospitals, and from diverse disciplines including biology, medicine, chemistry, and computer science.

The Broads' \$100 million gift is their fourth gift to the Broad Institute. In 2004, an initial \$100 million investment launched the institute, and was followed a year later by a second \$100 million. In 2008, the Broads pledged \$400 million to endow and establish the Broad Institute as an independent non-profit scientific research institution, making it a permanent part of the biomedical landscape. Their combined contributions make them the second largest donors to a single organization for biomedical research.

The Broad Institute includes faculty, professional staff, and students from throughout the MIT and Harvard biomedical research communities and beyond, with collaborations spanning over a hundred private and public institutions in more than 40 countries worldwide. (Source: Broad Institute Website, 14 November, 2013)

Karyopharm Therapeutics Raises \$125 Million via IPO

Karyopharm Therapeutics has announced that the gross proceeds from its recent initial public offering were \$125.1 million. Karyopharm Therapeutics is a clinical-stage pharmaceutical company focused on

the discovery and development of novel first-in-class drugs directed against nuclear transport targets for the treatment of cancer and other major diseases.

"With this successful fundraising, we are now in a strong position to look forward and focus on executing our clinical development strategy," said Michael Kauffman M.D., Ph.D., Chief Executive Officer of Karyopharm. "The preliminary evidence of anti-tumor activity seen in Selinexor, our lead drug candidate, across multiple hematologic malignancies, as well as in solid tumors, support our plans to conduct future studies of Selinexor alone and in combination with chemotherapy and/or targeted agents." (Source: Karyopharm Therapeutics Website, 11 December, 2013)

ImmunoGen Announces Novartis License Agreement

Massachusetts-based ImmunoGen, a biotech that develops targeted anticancer therapeutics, has announced that Novartis has licensed the exclusive right to use the company's antibody-drug conjugate (ADC) technology to develop anticancer therapeutics to an undisclosed target. This is the third license to be taken by Novartis — and the fifth to be taken by a major healthcare company — through November 2013.

"In the past year, Novartis, Eli Lilly and Amgen have each licensed exclusive rights to use our industry-leading ADC technology for one or more targets," commented Daniel Junius, President and CEO. "There are now numerous highly promising product candidates in the clinic through our own programs and through our partnerships, with many earlier-stage compounds advancing behind these."

ImmunoGen develops targeted anticancer compounds with its ADC technology, which uses a tumor-targeting antibody to deliver one of the Company's proprietary cancer-cell killing agents specifically to tumor cells. The most advanced compound with ImmunoGen's ADC technology is Roche's Kadcyla®, which is marketed in the US by Genentech and is also gaining approvals internationally. Consistent with several ImmunoGen and partner compounds, Kadcyla utilizes ImmunoGen's thioether (SMCC) linker and DM1 cytotoxic agent; ImmunoGen manufactured Kadcyla for non-pivotal clinical testing and developed the pivotal manufacturing process on behalf of Genentech. (Source: ImmunoGen Website, 11 November, 2013)

EU Approval of Roche's Kadcyla Triggers ImmunoGen Milestone Payment

Waltham-based ImmunoGen has announced that the European Commission has granted marketing approval for Kadcyla (trastuzumab emtansine; ado-trastuzumab emtansine in the US) in the European Union (EU). This event triggers a \$5 million milestone payment to ImmunoGen.

Kadcyla has been approved for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received Herceptin (trastuzumab) and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease; or developed disease recurrence during or within six months of completing adjuvant therapy.

As with the Kadcyla approvals that have been granted in the US, Japan, and other geographies, the approval in the EU is based on the findings in the EMILIA Phase III trial. In the EU and other international markets, the timing of the commercial availability of Kadcyla after approval can vary due to national differences in processes for establishing pricing/reimbursement, with some countries — including Germany — able to launch shortly after approval.

Kadcyla consists of Roche's trastuzumab antibody with ImmunoGen's DM1 cytotoxic agent attached using one of ImmunoGen's engineered linkers. Roche has global development and commercialization rights for Kadcyla; ImmunoGen is entitled to receive royalties on product sales as well as specified milestone payments.

Roche is conducting studies assessing Kadcyla for a number of additional potential uses. These include for the first-line treatment of HER2-positive metastatic breast cancer, for early stage HER2-positive breast cancer and for advanced HER2-positive gastric cancer. (Source: ImmunoGen Website, 20 November, 2013)

Biogen Idec's Tecfidera Now the Leading Oral MS Therapy in the US

WESTON, Mass.-- --Biogen Idec Inc. (NASDAQ:BIIB) today reported third quarter 2013 total revenues of \$1.8 billion, an increase of 32% over the third quarter of 2012. Non-GAAP diluted EPS for the third quarter of 2013 were \$2.35, an increase of 23% over the third quarter of 2012. Non-GAAP net income attributable to Biogen Idec for the third quarter of 2013 was \$561 million, an increase of 23% versus the third quarter of 2012.

GAAP diluted EPS for the third quarter of 2013 were \$2.05, an increase of 23% over the third quarter of 2012. GAAP net income for the third quarter of 2013 was \$488 million, an increase of 22% over the third quarter of 2012. A reconciliation of our GAAP to Non-GAAP financial results can be found in Table 3 at the end of this release.

Biogen Idec reported that the company's third quarter revenue gains - 32 percent over the third quarter of 2012 - were driven by Tecfidera (dimethyl fumarate) with Tecfidera revenues totaling \$286 million during the quarter. According to IMS, Tecfidera is now the leading oral MS therapy in the United States after only six months on the market. Avonex (interferon beta-1a) revenues decreased slightly versus the third quarter of 2012 to \$733 million, while Tysabri (natalizumab) revenue increased by 46 percent as a result of Biogen Idec recording 100 percent of Tysabri revenues following the Company's acquisition of full rights for the therapy from Elan in the second quarter of 2013. Global in-market sales for Tysabri for the quarter were flat as compared to the third quarter of 2012.

"We believe the continued growth of Tecfidera is a testament to its value to patients and physicians and we are pleased with how it has complemented our robust portfolio of MS therapies," said Chief Executive Officer George A. Scangos. "Our continuing commitment to innovation also has resulted in exciting new data that show advances in many of our approved and investigational therapies as we continue to

data that show advances in many of our approved and investigational therapies as we continue to enhance options for MS patients now and in the future."

"Looking ahead, we believe we are entering an exciting period in our company's evolution as we anticipate bringing patients significant advances for the treatment of Hemophilia A and B, continue to take measures to strengthen our pipeline with new therapies to treat unmet medical needs, and further our efforts to transform our approach to early-stage research. I believe our organization is prepared to meet all of these new challenges and opportunities," Scangos added.

(Biogen Idec Website, 28 October, 2013)

Moderna Therapeutics Raises \$110M to Develop Messenger RNA Therapeutics

Cambridge-based Moderna Therapeutics, the pioneer in developing messenger RNA (mRNA) Therapeutics, a revolutionary new treatment modality to enable the in vivo production of therapeutic proteins, has announced the completion of a new financing round, raising \$110 million. In aggregate, Moderna has secured more than \$415 million in financing and partnerships to date from the pharmaceutical and government sectors, as well as from private investors.

"We are pleased with the confidence and enthusiasm that our investors continue to demonstrate by providing the resources to advance Moderna's clinical development platform," said Stéphane Bancel, president and founding CEO of Moderna. "With their support, and \$340 million in the bank and available now, we are working hard to deliver on the promise of messenger RNA Therapeutics to provide transformative medicines for patients."

This round of financing underscores a successful and significant year for Moderna. Emerging from stealth mode in December 2012, the company has garnered the attention of the scientific community, and attracted growing interest in its mRNA platform in 2013 including the completion of one of the biggest pre-clinical partnerships in biotech history with AstraZeneca, which made an upfront payment of \$240M for the right to 40 drug options in cardiovascular, metabolic diseases and oncology.

"Given the potential of Moderna's technology to transform the treatment of a wide range of diseases, we have made the strategic decision to remain private at this time, even in the face of a favorable public market environment for biotech IPOs," added Bancel. "The significant support we have received from our investor base and partners will enable us to strike the right balance between urgency and care to build a durable scientific platform and propel the field forward, without the short-term distractions that can sidetrack a young public company from its mission." (Source: Moderna Therapeutics Website, 20 November, 2013)

Leading Cancer Centers Team Up to Launch Biotech Startup

The Fred Hutchinson Cancer Research Center (Fred Hutch) and Memorial Sloan-Kettering Cancer Center (MSKCC), along with pediatric partner Seattle Children's Research Institute, have joined forces to launch Juno Therapeutics Inc., a new biotechnology company focused on bringing forward novel immunotherapies for cancer. Juno is being launched with an initial investment of \$120M, making it one of the largest Series A biotech startups in history.

Juno's approach focuses on harnessing the power of the immune system through the reprogramming of a type of immune cell called T lymphocytes ("T cells"). T cells are part of the body's natural protective defense system against infection, and Juno's technology reprograms T cells to recognize cancer cells for a precision immunologic attack. Using synthetic receptors and/or augmented natural antigen receptors, Juno's T cell reprogramming technologies enable the creation of a powerful anti-tumor immune response built from the patient's own immune system. This transformative approach has the potential to induce long-term remissions and reduce or eliminate the need for debilitating surgery, radiation and chemotherapy. (Source: Juno Therapeutics Website, 04 December, 2013)

ARIAD Gains FDA Approval to Re-launch Leukemia Drug

Cambridge-based ARIAD Pharmaceuticals has announced that the FDA has approved revised U.S. Prescribing Information (USPI) and a Risk Evaluation and Mitigation Strategy (REMS) for Iclusig (ponatinib) that allows immediate resumption of its marketing and commercial distribution. The USPI includes a revised indication statement and boxed warning, updated safety information and recommendations regarding dosing considerations for prescribers.

The FDA granted approval of the revised USPI based on its review of the Iclusig clinical-trial data, including 24-month follow up of the pivotal PACE trial. The boxed warning has been revised to alert patients and healthcare professionals to the risk of vascular occlusive events and includes a new warning for heart failure.

"In less than two months of suspending marketing and commercial distribution of Iclusig in the U.S., we addressed the issues raised by the FDA and now are able to market and distribute Iclusig again in the U.S.," stated Harvey J. Berger, M.D. chairman and chief executive officer of ARIAD. "As we look ahead to re-launching Iclusig in the U.S. and fulfilling our post-marketing requirements, we will continue to focus on understanding the benefits and risks of Iclusig treatment in patients with resistant or intolerant Philadelphia-positive leukemias."

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig was designed using ARIAD's computational and structure-based drug design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, a common mutation which has been associated with resistance to other approved TKIs. (Source: ARIAD Pharmaceuticals Website, 20 December, 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.

FDA Approves Opsumit to Treat Pulmonary Arterial Hypertension

The FDA approved Opsumit (macitentan), a new drug to treat adults with pulmonary arterial hypertension (PAH), a chronic, progressive and debilitating disease that can lead to death or the need for lung transplantation. Opsumit is marketed by San Francisco-based Actelion Pharmaceuticals US, Inc.

PAH is high blood pressure that occurs in the arteries that connect the heart to the lungs. It causes the right side of the heart to work harder than normal, which can lead to limitations on exercise ability and shortness of breath. Opsumit belongs to a class of drugs called endothelin receptor blockers, which act to relax the pulmonary arteries, decreasing blood pressure in the lungs.

Opsumit carries a Boxed Warning alerting patients and health care professionals that the drug should not be used in pregnant women because it can harm the developing fetus. Female patients can receive the drug only through the Opsumit Risk Evaluation and Mitigation Strategy (REMS) Program. This restricted-distribution program requires prescribers to be certified by enrolling in the program; all female patients to be enrolled in the program to comply with applicable pregnancy testing and contraception requirements before initiating treatment; and pharmacies to be certified and to dispense Opsumit only to patients who are authorized to receive it. (Source: FDA Website, 18 October, 2013)

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

The FDA announced it has awarded 15 grants totaling more than \$14 million to boost the development of products for patients with rare diseases.

The Orphan Drug Act was passed in 1983 to stimulate the development of products to treat rare diseases and conditions. For drugs, a disease or condition is considered rare if it affects less than 200,000 persons in the United States. For medical devices, a disease or condition is considered rare when it occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance. There are about 6,800 rare diseases and conditions, according to the National Institutes of Health. In total, nearly 30 million Americans suffer from at least one rare disease.

A panel of outside experts with experience in the disease-related fields reviewed applications for the grants, which will be administered through the FDA's Orphan Products Grants Program. (Source: FDA Website, 21 October, 2013)

FDA Takes Two Important Actions on Drug Shortages

The FDA is taking two actions to further enhance the agency's ongoing efforts to prevent and resolve drug shortages, a significant public health threat that can delay, and in some cases even deny, critical care for patients. Following the President's 2011 Executive Order on reducing drug shortages, the number of new shortages in 2012 was 117, down from 251 in 2011.

Early notification from manufacturers about possible shortages, as requested in the President's Executive Order of Oct. 31, 2011 and then codified into law, has enabled the FDA to work with manufacturers to restore production of many lifesaving therapies. Since the Executive Order, there has been a 6-fold increase in notifications to the FDA regarding potential shortages.

The notifications received under the existing requirements have resulted in real progress in addressing shortages. The FDA helped prevent 195 drug shortages in 2011 and 282 drug shortages in 2012, leading to a reduced number of new shortages in 2012. The expanded early notification requirements would further enhance the FDA's ability to address issues prior to the occurrence of a shortage. (Source: FDA Website, 31 October, 2013)

FDA Approves Genentech's Gazyva for Chronic Lymphocytic Leukemia

Drug is first with breakthrough therapy designation to receive FDA approval

The FDA approved Genentech drug Gazyva (obinutuzumab) for use in combination with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia (CLL), a blood and bone marrow disease. According to the National Cancer Institute, 15,680 Americans will be diagnosed and 4,580 will die from the disease this year.

The FDA granted Gazyva priority review because the drug demonstrated the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. And the FDA granted Gazyva orphan product designation because it is intended to treat a rare disease.

Gazyva is being approved with a Boxed Warning regarding Hepatitis B virus reactivation and a rare disorder that damages the material that covers and protects nerves in the white matter of the brain (progressive multifocal leukoencephalopathy). These are known risks with other monoclonal antibodies in this class and rare cases were identified in participants on other trials of Gazyva. Patients should be

advised of these risks and assessed for Hepatitis B virus and reactivation risk. (Source: FDA Website, 01 November, 2013)

FDA Takes Action to Speed Safety Information Updates on Generic Drugs

A proposed FDA rule would speed the dissemination of new safety information about generic drugs to

propose to make more specific dissemination of new safety information about generic drugs to health professionals and patients by allowing generic drug makers to use the same process as brand drug manufacturers to update safety information in the product labeling.

Under the proposal, generic drug manufacturers would be able to independently update product labeling (also called prescribing information or package inserts) with newly-acquired safety information before the FDA's review of the change, in the same way brand drug manufacturers do today. Generic manufacturers would also be required to inform the brand name manufacturer about the change.

The FDA would then evaluate whether the proposed change is justified and make an approval decision on the generic drug labeling change and the corresponding brand drug labeling change at the same time, so that brand and generic drug products would ultimately have the same FDA-approved prescribing information.

Under current law, generic and brand drug manufacturers are required to promptly review safety information about their drugs and comply with the FDA's reporting and recordkeeping requirements. When new information becomes available that causes the product labeling to be inaccurate, all drug manufacturers must take steps to update the labeling. (Source: FDA Website, 08 November, 2013)

FDA Approves Imbruvica for Rare Blood Cancer

The FDA approved Imbruvica (ibrutinib) to treat patients with mantle cell lymphoma (MCL), a rare and aggressive form of non-Hodgkin lymphoma that represents about six percent of all non-Hodgkin lymphoma cases in the United States. By the time MCL is diagnosed, it usually has already spread to the lymph nodes, bone marrow and other organs.

Imbruvica is intended for patients with MCL who have received at least one prior therapy. It works by inhibiting the enzyme needed by the cancer to multiply and spread. Imbruvica is the third drug approved to treat MCL. Velcade (2006) and Revlimid (2013) are also approved to treat the disease.

Imbruvica is co-marketed by California-based Pharmacyclics and New Jersey-based Janssen Biotech. Velcade (bortezomib) is marketed by Cambridge-based Millennium Pharmaceuticals and Revlimid (lenalidomide) is marketed by New Jersey-based Celgene.

(Source: FDA Website, 13 November, 2013)

FDA Allows Marketing of Four "Next Generation" Gene Sequencing Devices

The FDA allowed marketing of four diagnostic devices that can be used for high throughput gene sequencing, often referred to as "next generation sequencing" (NGS), two of which are designed to aid in the diagnosis of cystic fibrosis. These instruments, reagents, and test systems allow labs to sequence a patient's DNA. They give physicians the ability to take a broader look at their patients' genetic makeup and can help in diagnosing disease or identifying the cause of symptoms.

Data submitted by Illumina for their cystic fibrosis tests included comparisons of the sequence results to Human Genome Build 19, a reference representation of the human genome. In addition, Illumina evaluated the performance of its instrument and reagent systems against a publically available quality-weighted human reference genome that was created through collaboration between the FDA and the National Institutes of Standards and Technology (NIST).

The FDA granted de novo petitions for the Illumina MiSeqDx instrument platform and the Illumina Universal Kit reagents, two devices that make up the first FDA-regulated test system that allows laboratories to develop and validate sequencing of any part of a patient's genome. The Universal Kit reagents isolate and create copies of genes of interest obtained from patient blood samples, and the MiSeqDx platform analyzes the genes. The software compares the patient's genomic sequence to a reference sequence and reports back any differences between the patient and the reference.

The FDA reviewed the Illumina MiSeqDx instrument platform and the Illumina Universal Kit reagents through its de novo classification process, a regulatory pathway for some novel low-to-moderate risk medical devices that are not substantially equivalent to an already legally marketed device. For the de novo petitions, the FDA based its decision on the demonstrated performance of the MiSeqDx instrument and Universal Kit reagent systems across numerous genomic segments spanning 19 human chromosomes.

Illumina MiSeqDx instrument platform, Universal Kit reagents, MiSeqDx Cystic Fibrosis 139-Variant Assay, and MiSeqDx Cystic Fibrosis Clinical Sequencing Assay are manufactured by Illumina in San Diego, California. (Source: FDA Website, 19 November, 2013)

FDA Approves Nexavar to Treat Type of Thyroid Cancer

The FDA expanded the approved uses of Nexavar (sorafenib) to treat late-stage (metastatic) differentiated thyroid cancer. Thyroid cancer is a cancerous growth of the thyroid gland, which is located in the neck. Differentiated thyroid cancer is the most common type of thyroid cancer. The National Cancer Institute estimates that 60,220 Americans will be diagnosed with thyroid cancer and 1,850 will die from the disease in 2013.

Nexavar works by inhibiting multiple proteins in cancer cells, limiting cancer cell growth and division. The drug's new use is intended for patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

The FDA approved Nexavar to treat advanced kidney cancer in 2005. In 2007, the agency expanded the drug's label to treat liver cancer that cannot be surgically removed.

Nexavar is co-marketed by Bayer HealthCare Pharmaceuticals, based in Wayne, New Jersey, and Onyx Pharmaceuticals, based in South San Francisco, California. (Source: FDA Website, 22 November, 2013)

FDA Approves New Treatment for Hepatitis C Virus

The FDA approved Olysio (simeprevir), a new therapy to treat chronic hepatitis C virus infection. Olysio is a protease inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. It is to be used as a component of a combination antiviral treatment regimen.

In clinical studies, Olysio was evaluated in combination with peginterferon-alfa and ribavirin, two drugs also used to treat hepatitis C virus infection. Olysio is intended for adults with compensated liver disease (a diseased liver that is still functioning), including cirrhosis, who have not received treatment for their infection or for whom previous treatment has not been effective.

In 2011, the FDA approved Victrelis (boceprevir) and Incivek (telaprevir) for the treatment of hepatitis C. Olysio was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that, if approved, would provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to available therapies.

Olysio is marketed by Janssen Pharmaceuticals, based in Raritan, New Jersey. Victrelis is marketed by Whitehouse Station, New Jersey-based Merck, and Incivek is marketed by Cambridge-based Vertex Pharmaceuticals. (Source: FDA Website, 22 November, 2013)

FDA Approves Sovaldi for Chronic Hepatitis C

The FDA approved Sovaldi (sofosbuvir) to treat chronic hepatitis C virus (HCV) infection. Sovaldi is the first drug that has demonstrated safety and efficacy to treat certain types of HCV infection without the need for co-administration of interferon. Sovaldi is the second drug recently approved by the FDA to treat chronic HCV infection.

Sovaldi is a nucleotide analog inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. Sovaldi is to be used as a component of a combination antiviral treatment regimen for chronic HCV infection. There are several different types of HCV infection; depending on the type of HCV infection a patient has, the treatment regimen could include Sovaldi and ribavirin or Sovaldi, ribavirin and peginterferon-alfa. Ribavirin and peginterferon-alfa are two drugs also used to treat HCV infection.

Sovaldi is marketed by Gilead, based in Foster City, California. Olysio is marketed by Raritan, New Jersey-based Janssen Pharmaceuticals. (Source: FDA Website, 06 December, 2013)

FDA Approves First Generic Versions of Eli Lilly Antidepressant Drug Cymbalta

The FDA approved the first generic versions of Cymbalta (duloxetine delayed-release capsules), a prescription medicine used to treat depression and other conditions.

Aurobindo Pharma, Dr. Reddy's Laboratories, Lupin, Sun Pharma Global, Teva Pharmaceuticals USA and Torrent Pharmaceuticals have received FDA approval to market duloxetine in various strengths.

Duloxetine and other antidepressant drugs have a Boxed Warning describing the increased risk of suicidal thinking and behavior during initial treatment in children, adolescents, and young adults ages 18 to 24. The warning says depression and other serious psychiatric disorders themselves are the most important causes of suicide and that close monitoring of patients starting these medications is necessary. Duloxetine must be dispensed with a patient medication guide that describes important information about the drug's uses and risks. (Source: FDA Website, 11 December, 2013)

New Members

Mr. Adedokun A. Adedoyin, *Student*, Northeastern University

Ali Alquraini, *Student*, Mass College of Pharmacy and Health

Mr. Steven Alves, *Student*, University of Massachusetts Lowell

Mr. Andrew C. Apel, *Process Engineer I*, Genzyme Corporation

Mr. Paul J. Asmar, *Vice President*, DTZ

Ms. Rebecca Barlage, *Assistant Project Manager*, Commodore Builders

Mr. Thomas A. Barnes, *Student*, Massachusetts Maritime Academy

Michael H. Burke

Mr. Louis Capozzi, *Project Manager*, Genzyme/Sanofi

Dr. Fiona M. Carleton, *Associate Director Drug Substance Operations*, ARIAD Pharmaceutical

Ms. MacKenzie A. Cole, University of Massachusetts Lowell

Mr. Steven J. Correale, Jr., *Process Engineer*, Design Group

Nicole DAuteuil, *Vice President*, Dyax Corp.

Mr. Peter-Joseph DeGiovanni, University of Massachusetts Lowell

John Desmond, *Director of Facilities*, Momenta Pharmaceuticals

Mr. Pradeep C. Dondapati, *Validation Engineer*, U.S. Nonwovens Corp.

Mr. Daniel Espinola, University of Massachusetts Lowell

Mr. Tyler J. Gadoury, *Process Engineer*, Alexion Pharmaceuticals

Mr. Kenneth A. Getz, *Associate Professor*, Tufts University Medical School
Mirek Gorski, *Facilities Manager*, Good Start Genetics
Daniel Hackett, *Manager*, Genzyme
Mr. Wayne R. Hopkins, *Principal*, WR Hopkins Consulting, LLC
Mr. Allen Horton, *MFG Supervisor*, Shire
Dr. Maureen A. Howley, *Lecturer*, University of Massachusetts Lowell
Mr. Thomas H. Jackson, *Student*, Massachusetts Maritime Academy
Alekya Karpurapu, *Student*, University of Massachusetts
Mr. Kevin Keane, *Student*, Boston University
Mr. Ian J. King, *Student*, Massachusetts Maritime Academy

Mr. Ian W. Knox, *Director of Compliance*, TraceLink, Inc.
Mr. Evan Koska, *Project Engineer*, Biogen Idec
Mr. Stephen R. Lee, *Student*, Massachusetts Maritime Academy
Mr. Erik K. Lustgarten, *AIA, Principal*, Steffian Bradley Architects
Jonathan C. Ly, *Research Associate I*, Cubist Pharmaceuticals
Mr. Scott W. Marquis, *Student*, Massachusetts Maritime Academy
Ms. Karen McNamara, *Infinity Pharmaceuticals*
Mr. Garrett E. Messier, *Student*, Massachusetts Maritime Academy
Ian J. Monfils, *Student*, Massachusetts Maritime Academy
Mr. Cameron S. Murphy, *Student*, Massachusetts Maritime Academy
Mr. Christopher T. Murray, *Student*, Massachusetts Maritime Academy
Ms. Juana Y. Paniagua, *Sr. QA Manager*, Coronado Biosciences
Mr. James Patterson, *President*, Static Clean International
Ms. Kristin Pelletier, *Project Manager*, Commodore Builders
Mr. Andrew J. Peterson, *Student*, Massachusetts Maritime Academy
Mr. Petar P. Petkov, *Student*, University of Massachusetts Lowell
Raju V . A . N Poosapati, *Graduate Student*, Massachusetts college of Pharmacy and Health Sciences
Mr. Jack W. Radke, *Student*, Massachusetts Maritime Academy
Mr. David Redalieu, *Boehringer Ingelheim Pharma*
Naghmeh Salimi, *Reasearch Associate*, Northeastern University
Ms. Michelle E. Scott, *Student*, University of Massachusetts - Lowell
Neeraj Shah, *PMP, Associate Director IT*, Shire Inc
Mr. Lukas M. Smith, *Student*, Massachusetts Maritime Academy
Mikhail Sooknanan, *Student*, University of Massachusetts Lowell
Mr. Nathaniel R. Swanson, *Intern*, University of Massachusetts Lowell
Mr. Edward Szczesny, *Sr. Quality Specialist I*, Rhodes Pharmaceuticals
Christopher Werner, *Process Engineer*, DPS Engineering

Member Anniversaries

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp
Mr. John P. Alleruzzo
Mr. Richard F. Caires, Jr., Shire HGT
Mr. John G. Campion, P.E., The Hart Companies
Mr. Richard P. Capobianco
Mr. Michael S. Cheney, Biogen Idec
Mr. Brian L. Clark, GMP Operations Consulting
Mr. Donald Cole, Hart Passivation Services, Inc.
Dr. Charles L. Cooney, Massachusetts Institute of Technology
Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation
Mr. Andrew A. Coull, JM Coull Inc
Michael B. Cronin, Alexion Pharmaceuticals
Mr. George A. Dainis, P.E., Industrial Facilities Design Inc
Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. Steven W. Davis, Lantheus Medical Imaging
Mr. Frederick C. DeCicco, Sharpe Mixers
Mr. William O. Downie, AstraZeneca
Mr. Brian P. Druce, Genzyme
Mr. Daniel J. Dumont, Dynamic Systems Inc
Mr. Mostafa N. Elmorsi, Boehringer Ingelheim Pharma
Mr. John H. Evers, Lantheus Medical Imaging
Mr. Ric Feldt, Jeff Smith & Associates
Mr. Christopher J. Fournier, Mar Cor Purification
Mr. William R. Fraga
Mr. Michael S. Giorgetti, Sr., Alkermes Inc
Dr. Roy F. Greenwald, DENS Partners, Inc.
Brian M. Hagopian, Clear Water Consulting, Inc.
Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz
Mr. Edwin L. Harmon, III, Genzyme Corp
Mr. David G. Harney, Microfluidics
Mr. Richard R. Harper, Flow Tech Inc
Ms. Shelly Henderson, HCA
Mr. Stephen R. Higham, PE, Genzyme Corp
Mr. Mitchell I. Hollander, Lantheus Medical Imaging
Mr. David L. Hyde, CPIP, Lantheus Medical Imaging, Inc.
Mr. Robert W. Juffras, MS, Olympus Biotech
Ms. Pauline Jurasinski, Genzyme a Sanofi Company
Mr. Jerome E. Justin, Shire HGT
Mr. Frank J. Kuszpa, Jr., Jones Lang LaSalle
Mr. Stephen P. Kuzil
Mr. Thomas G. Larkin, Amgen Inc
Mr. Howard L. Levine, PhD, BioProcess Tech Consultants, Inc.
Mr. Richard V. Levy, PhD, PDA
Peter F. Levy, PL Consulting, LLC
Mr. Robert C. Livingston, Arion Water Inc
Mr. Robert M. Luke, Georg Fischer Inc
Mr. William C. Lynch
Mr. Frank J. Manning, VNE Corp
Mr. Daniel J. Mariani, M+W Group
Mr. Denis M. Mathiowetz, DM BioPharm Associates Inc.
Mr. Gary E. McKiernan, PM Group
Mr. Todd McLaren, Kinetic Systems Inc
Ms. Lynda S. Miller, Eisai, Inc.
Stephen P. Miraglia, Primecore Program Management
Mr. Hank Moes
Mr. Peter Mosgrove, Mettler-Toledo Thornton Inc
Mr. Thomas W. Moss, Integra Companies
Mr. Armen J. Nahabedian, Pfizer
Mr. Russell B. Parry
Mr. Christopher R. Perley, Dyax
Mr. Stephen R. Potter, Baxter
Mr. Tim J. Potvin, PE, Quality Air Control
Mr. Richard D. Priester, Strategic Facility Planning LLC
Dr. John J. Prior, Genzyme Corp
Mr. Douglas A. Queen, TRG Builders LLC
Mr. Thomas A. Ramundo, New England Controls Inc
Mr. Gary L. Randall, Boehringer Ingelheim Pharma
Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc
Ms. Cheri M. Redman, Amgen
Mr. David A. Rielly, CEM, LEED GA, Novartis Pharmaceuticals
Mr. Stephen P. Rossmeisl
Mr. Stanley E. Rotkiewicz, Jr., Genzyme Corporation
Mr. Tom J. Routcliffe, Medimmune
Mr. Paul E. Rowe, Millipore Corporation
Mr. John M. Ruggieri, CPI Controls Inc
Mr. Gregory M. Ruklic
Mr. Pasquale M. Sacco, Shire HGT
Mr. Hooman F. Sajedian, Pfizer Inc
Mr. William S. Seaver, TEK Stainless Piping Products
Mr. Michael J. Severino, Festo Corporation
Mr. Robert J. Sheehan
Mr. Alexander E. Smith, Jr., M+W U.S., Inc.
Mr. Jose M. Soto, Pfizer Inc

Mr. Michael G. Sprague, Ethide Laboratories
Mr. Lester L. Starr, Jr., Cutler Associates
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises
Mr. Michael J. Sweeney, Hart Design Group
Mr. David A. Tomsik, CRB Consulting Engineers
Dr. Donald L. Towns, Donald L Towns Professional Engineer
Mr. Timothy C. Tyson, Aptuit, Inc.
Mr. Robert P. Vecchione, BWT/Christ Aqua Pharma & Biotech NA
Mr. Lawrence W. Weiner, Biogen Idec
Mr. Jack N. Wentz, Lantheus
Mr. Jeffrey L. Werner, BFS Pharma Inc
Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

[15 Year Anniversary](#)

Mr. Thomas R. Choyce, PE, Biogen Idec
Ms. Cynthia L. Corette, Unither Manufacturing LLC
Andrew D. Faden, Altran Solutions Corp.
Mr. George Koutris, Labrepco Inc
Ms. Victoria F. Rawlinson, Consultant
Mr. William A. Yakush, Boehringer Ingelheim Pharma Inc

[10 Year Anniversary](#)

Mr. Frank Armstrong, Cotter Brothers Corporation
Deven D. Chauhan
Mr. Heath J. Davis, Davis Brothers Inc.
Mr. Tyler Davis, Davis Brothers Inc
Mr. Sidney H. Goode, Rhodes Technologies
Mr. Joseph Kocinsky, MannKind Corporation
Mr. Leonard Lilley, III, Northeast Stainless Inc.
Ms. Lauren J. Melton, Anylam Pharmaceuticals
Mr. Phillip D. Paquette
Mr. Raymond E. Reilly, Millipore Corporation
Mr. Blair T. Scoble, Core Filtration LLC
Mr. Jay W. Van Billiard, Perrigo Inc
Mr. Harvinder S. Vij, Massachusetts Biologic Labs

5 Year Anniversary

Ms. Marissa J. McGarry, Momenta Pharmaceuticals
Mr. Gerard Mansfield, Parsons
Mr. Christopher A. Walton, Capaccio Environmental Eng Inc.
Mr. Stephen J. Lynch, Kleinfelder/SEA Consultants
Mr. Christian W. Phillips, AMRI Inc
Ms. Sneha H. Deshpande, Biospeq Inc
Mr. Christophe Pamelard, CQA, Purdue Pharma LP
Mr. Gary G. Gaudet, LEWA-Nikkiso America, Inc.
Mrs. Lisa M. Davis, AstraZeneca
Mr. Sterling T. Wall, Amgen, Inc.
Mr. John C. Spohn, CPIP, New England, Hargrove Life Sciences

« 1 2 26 »

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