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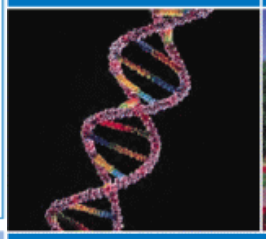

NEWSLETTER

November 2016, Volume XXVI, No. 6

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President's Message: The ISPE - It Grows On You

Esteemed Members,

The time since our last newsletter has been extraordinary for the Boston Area Chapter. In September the Chapter was well represented at the ISPE Annual Meeting in Atlanta. Four current and former Chapter officers covered a variety of committee meetings. Our two Student Poster Competition winners competed at the global level - Connor Williams of UMass Lowell in the undergraduate division and John De La Parra of Northeastern in the graduate division. Nearly 80 Chapter Members attended for the rich offering of educational programs and at least four delivered educational programs to the global pharmaceutical community at the premier event of its type. And we hosted the Japanese delegation at our annual Boston Area Chapter. See Jack Campion's article for another perspective on this exciting gathering.

On October 5 we presented the 25th Anniversary Edition of the Product Show at Gillette Stadium and it was a wild success. Attendance surged to 3,060 (up 12 percent) despite the challenge of a related show being held nearby. We were pleased to host John Bournas, ISPE CEO, and members of ISPE International Board of Directors: current Chair (and BAC Member!) Mike Arnold, outgoing Chair (and keynote speaker) Joe Famulare and Tim Howard, as well as three key members of ISPE staff.

It was a joy to present the Annual Chapter Awards recognizing Members and groups who go "above and beyond" in service to the Chapter and the pharmaceutical community. Volunteer of the Year Awards were presented to Ying Cai, Membership Committee Chair, for her extreme diligence, creativity and collaboration with other committees; and Howard Sneider for his contributions as Chair of the Educational Program Committee, codifying best practices for the future in SOPs while extending the planning horizon to 18 months.

This year's Outstanding Achievement Award recognized the Scholarship Committee, which over the last five years has made 78 scholarship awards totaling over $105,000. They are launching a charitable foundation to expand this program named in memory of Joel Goldenberg, a Chapter Past President dedicated to student development. The committee has done all this under the steady leadership of Committee Chair and long-time Board Secretary Janet Tice who accepted the award on behalf of the committee.

Our Student Chapter of the Year is Massachusetts Maritime Academy. This Student Chapter has incredible participation and retention rates, and has exhibited strong leadership and sound management practices. They have been a sterling example of how best to organize and run a Student Chapter - opening up the opportunities of our Chapter and our industry to their members.

The big finish was the presentation of the Hank Moes Lifetime Achievement Award to Doyle Johnson. Hank Moes was a founding member of the Boston Area Chapter. This award, given not annually but only when appropriate, is for lifetime achievement and contributions to the Chapter and the Society worldwide. Doyle is a past Chapter president, member of the ISPE international board of directors, and contributor to Good Practice Guides that serve our industry. He is also a good friend and mentor to many, including me. It was an honor to present him with this well-deserved recognition for his many years of service to ISPE!

What a fantastic job by the Product Show Committee members who work all 12 months to out-do themselves year after year. Special kudos to Chair Mark Levanites and Co-Chair Tom Struble for this fantastic performance. Thanks also to Past President Steve Kennedy for his contributions to this year's outstanding success. See Mark's article for more details and lots of great photos from the event. And click here [create link] to see a short video about the evolution of the Product Show presented during the plenary session.

And make no mistake - recognition is in order for all our volunteers. Our Chapter is blessed with some of the most dedicated and creative volunteers in the industry. Over 100 of your colleagues and more than 50 students gave freely of their time and talents to produce 47 events last year for the benefit and enjoyment of our Members and to award over $25,000 in scholarships to those preparing themselves to work in our industry or honing their professional skill sets.

Some may ask what volunteers get for the dozens or even hundreds of hours they put in on ISPE work. To answer that question I'll circle back to Annual Meeting, where I heard what has to be the most succinct statement of the ISPE value proposition. To set the stage, Bruce S. Davis was accepting the Richard B.

Purdy award in Atlanta. The Purdy award is for significant, long-term contributions to the Society at the international level. In his remarks Bruce recounted the trajectory of his involvement in ISPE:

- He attended an event and made some professional friends.
- He enjoyed that and so eventually volunteered to work on an event. To his surprise, it was fun and something he found he was good at.
- This led to committee membership, then the chairperson role, then the Board and, over time, a succession of increasing and ultimately international-level responsibilities and publications.

Bruce is from the UK and so he summed up the value proposition with characteristic economy of expression: "The ISPE - it grows you." And that is so true. Just ask any one of our volunteers. The way to derive maximum value from ISPE is to engage and contribute. Volunteering provides unparalleled opportunity for personal and professional growth. If you are interested in volunteering, email office@ISPEBoston.org to be put in contact with a Member who can help match your interests with the Chapter's needs.

With Kind Regards,

John Spohn, CPIP
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Just Released - 25th Anniversary Product Show Video!

If you missed the plenary session at the Product Show, you also missed a special event: the premier showing of the Chapter's 25th Anniversary Product Show video. With vintage photos of the Product Show's early days at the HoJo's on Memorial Drive in Cambridge and the Newton Marriott and memory-sharing by the Chapter's leaders old and new, the video demonstrates how far we've come in 25 years. And the best news? It's available for viewing at https://vimeo.com/187995229. Enjoy!

Young Professionals Committee Seeking Volunteers

"The ISPE - It Grows You" is our President's Message theme this month and applies perfectly to volunteering as a member of one of the Chapter's many committees. The Young Professionals Committee is currently looking for members to help them design and execute events - educational, social, networking & recreational - that appeal to professionals in the early stages of their careers. So learn new skills and gain experience while working with a dedicated group of your peers to help the Chapter grow and thrive. Click here for more information.

Chapter Scholarships: It's Never Too Late!

The deadline for the November round has passed, but don't worry - the Chapter is already accepting applications for the next round with its June 1 deadline. Save yourself (and the individual writing your reference) the last minute rush and begin your online application now. As soon as it is complete, just hit "submit" and it will be added to the June round. So it may be too late for November round but it's not too early to get a head start for the June round. Good luck!

Newsletter Ad Space Expanding - Sign Up Now!
Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at (781) 647-4773 or office@ispeboston.org.

Support Your Chapter - Become a Sponsor!
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 containing all the information you need to know to become a Chapter Sponsor.

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

So don't delay, visit http://www.ispeboston.org/become_a_sponsor.html and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or, if you'd rather, contact the Chapter office at (781) 647-4773 or office@ISPEBoston.org and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Thursday, November 10, 2016

ISPE Regulatory Symposium: Quality by Design and Regulatory Fundamentals

Previous Issues

Newsletter Archive

Northeastern University, Boston, MA

And via Simulcast at:

WPI BETC, Worcester, MA

Redhook Ale Brewery, Portsmouth, NH

Community College of Rhode Island, Warwick, RI

The Advanced Track will be simulcast to these locations

PROGRAM SUMMARY

Join ISPE at Northeastern University and participate in either one of two Regulatory programs: Quality by Design or Regulatory Fundamentals. The QbD program will be simulcast to locations in NH, MA and RI. The program at each location will feature a networking reception including appetizers. The chapter will also have an outreach to non-member students at Northeastern during the reception.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=581

Thursday, November 10, 2016

ISPE UMass Amherst Student Only Tour of WPI

WPI BETC, Worcester, MA

PROGRAM SUMMARY

Register to come on a tour of WPI's Biomanufacturing Education and Training Center (BETC) where you be treated to a facility tour led by Dan Mardirosian, WPI's Senior Operations Manager. Dan will start by providing an overview of all the steps involved in the Biomanufacturing process. Following this overview, students will be given a tour of the labs and pilot plant at the BETC where they will be able to see these processes first-hand. Following the tour, you will have the opportunity to meet other staff from WPI-BETC as well as ISPE members currently working in industry in a relaxed social setting. Food and beverages will be provided, as well as bus transportation to and from WPI.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=741

Wednesday, November 30, 2016

ISPE Young Professionals Social at Somerville Brewing Company

Somerville Brewing Company, Somerville, MA

EVENT INFORMATION

Join ISPE Boston Young Professionals for our networking event at Somerville Brewing Company! At the American Fresh Brewhouse and Taproom, learn about the beer making process on a brewery tour and snack on some pub inspired bites. Also be sure to taste the many Slumbrew craft beers available at the bar!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=670

Wednesday, December 7, 2016

ISPE In-Source or CMO? Fill / Finish Strategies for Success (and the implications around Tech Transfer)

Novartis Institutes for BioMedical Research, Cambridge, MA

PROGRAM SUMMARY

As clinical trial pipelines continue to expand the discussion surrounding Fill/Finish is focused on time to market and the relative merits of CMO vs. In-Source solutions. Some Bio/Pharmas are utilizing both strategies as a hedge. What are the business drivers behind this thinking? What are the new technologies supporting Fill/ Finish and what flexibility do these new platforms provide? How do you successfully plan and execute projects of this complexity and control cost?

The expert panelists assembled for this program bring a broad background of industry experience ranging from CMO to large scale manufacturing operations. All share a passion for delivering value to their organizations, clients and patient populations to provide enabling technologies that bring life changing therapies to market.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=582

Sneak Preview of Upcoming Events

Thursday, January 19, 2017
ISPE CIP & SIP
TBD

Thursday, January 26, 2017
ISPE New Year's Social
TBD

Saturday, January 28, 2017

ISPE Student Career Workshop
Northeastern University, Boston, MA

25th Anniversary Product Show Breaks Records!

by Mark Levanites, Product Show Committee Chair, with photos by David Fox Photography

The week leading up to the 25th Anniversary Boston Area Chapter Product Show set the stage. With the return of Tom Brady and the gorgeous 60-degree sunny day the mood had been set. A record-breaking 3100 attendees made the trip to Gillette Stadium and with plenty to do, see, and learn regardless of your professional expertise the 2016 Product Show did not disappoint.

Chapter President John Spohn greeted a packed house at the opening Plenary Session.

The Plenary Session started with an inspiring video documenting the past, present, and future of the Product Show along with Chapter President John Spohn, reporting that the Chapter is financially sound, continues to be the largest Chapter in the world, and has some very exciting programs and initiatives planned for the upcoming year. He concluded his presentation with the Annual Chapter Awards that recognize the contributions of outstanding Chapter volunteers:

- Volunteer of the Year - Ying Cai, Membership Committee Chair
- Volunteer of the Year - Howard Sneider, Educational Program Committee Chair
- Student Chapter of the Year - Massachusetts Maritime Academy
- Outstanding Achievement Award - Scholarship Committee
- Hank Moes Lifetime Achievement Award - Doyle Johnson

Chapter Award winners (clockwise from top left) Doyle Johnson, Howard Sneider, Janet Tice (on behalf of the Scholarship Committee) and Mass Maritime Academy.

The first keynote address was delivered by Joseph Famulare, Immediate Past Chairman of the ISPE Board of Directors and Vice President, Global Quality Compliance and External Collaboration, Genentech/Roche, Pharma Technical Operations. Next up was U.S. Congressman Richard E. Neal, representing the 1st District of Massachusetts, who concluded his visit by opening the Product Show with a ceremonial ribbon-cutting and leading the assembled crowd into the Exhibit Hall. Soon to follow were 3100 attendees who visited the 375 exhibitors and the Career Fair's 44 hiring companies and set a new record for Product Show attendance.

Attendees enjoyed keynote presentations by (l to r) Joseph Famolare, Immediate Past Chair of the ISPE Board of Directors, and Congressman Richard E. Neal.

Congressman Neal opened the Product Show with a ceremonial ribbon-cutting (and a little help from his friends).

The full slate of educational programs offered throughout the day in the plenary session area thanks to the efforts of the Educational Program Committee attracted almost 400 attendees: "Implementing Lifecycle Process Validation Practices at CMOs" led by Rusty Morrison; "Unique Challenges of Executing Expansion and Retrofit Projects Concurrent with GMP Manufacturing" led by Joseph Musiak; "Project Delivery: Which Method of Contracting is Best?" led by Dean Poillucci; and "Biotech 101" led by Kamal Rashid. If you missed them, don't worry - you can view them on the Product Show website.

On the Innovation Stage, showcasing their latest breakthrough technologies and techniques throughout the afternoon were: M+W Group, G&G Technologies, AutomaTech, Kneat Solutions, ClorDiSys Solutions, Environmental Systems Corporation, Harrington Pure/E&S Technologies and The Windshire Group. And the Student Development Program was a huge success with its session "How to Make the Most of Your Product Show Experience" led by Brian Hagopian.

Brian Hagopian had students prepare for the Product Show by practicing their elevator speeches.

The Career Fair, truly a "show within a show," was expanded this year to include 44 hiring companies eager to meet with potential new employees. Partnered with Career Builders to help source talent, the Career Fair attracted over 650 Product Show attendees - another record setting number. Many of the visitors took advantage of our professional photographer to get a new headshot - free of charge. Feedback on the Career Fair was overwhelmingly positive all around. So if you are a hiring company, contact us now at office@ispeboston.org if you're interested in next year's Career Fair.

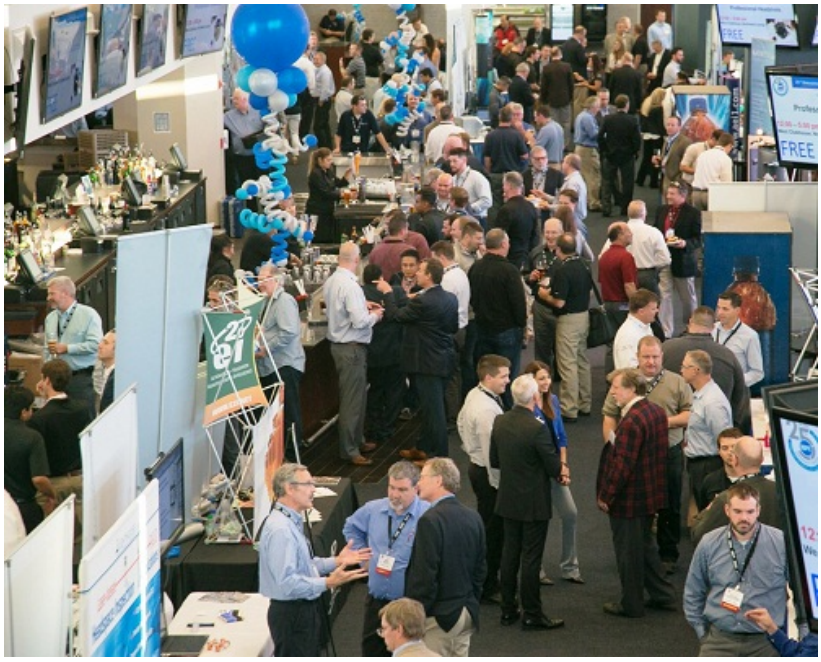
We are excited to report that our Champions for Charity pavilion was a huge success once again. People generously donated over $2700 to the National Kidney Foundation and had their photo taken with Patriots alumni Jermaine Wiggins and Ronnie Lippett and Pats cheerleaders. These donations helped to support our team - the ISPE Nephronators - participating in this year's Boston Kidney Walk on October 16th.

ISPE and Chapter VIPs join the fun with Pats greats Jermaine Wiggins and Ronnie Lippett (not to mention the Pats cheerleaders).

The Young Professionals held a Networking/Educational Social hour which was highlighted by a panel of industry experts who provided resume reviews. And when the exhibitor floor closed at 6:30pm, both attendees and exhibitors made their way to Splitsville/Howl At The Moon to relax, bowl, dance, and socialize with new and old friends and meet special guest, Patriots defensive end Rob Ninkovich. A great end to a tremendous day!

The After Party at Splitsville/Howl at the Moon offered the opportunity to socialize with friends, plus photos with Rob Ninkovich and a chance to show off your bowling skills.

The Boston Area Chapter is pleased that this event continues to be offered free of charge, supported in full by our generous exhibitors. This includes free parking, free admission, free food, free soft drinks, free educational seminars, and free autographs. This show is our Chapter's flagship event and the revenue generated funds the Chapter and allows us to bring many worthwhile benefits to our Members.



With over 3000 attendees, the Product Show continues its 25-year reign as one of our industry's premier annual events.

So on behalf of the Chapter, thank you to all of our exhibitors for your continued support. We look forward to your participation next year and encourage you to pre-register. To make it easy, you can preregister now and pay your deposit online on our Product Show website so don't delay - half of the booths and tables are already reserved for 2017!

It goes without saying that a Show like this doesn't happen without a lot of help from many people. Our volunteers are the backbone of our Chapter and we are grateful for their help in making the Product Show the success that it is, year after year. The Product Show Committee is already hard at work planning how to top this year's tremendous result and we are always looking for enthusiastic, imaginative, and fun people to help us run this event. If that is you and you would like to join us, please contact the Product Show Committee at office@ispeboston.org.

So mark your calendars - October 4, 2017 at Gillette Stadium - and watch this space throughout the coming year to learn what we have planned. Thanks for your support and see you at the Show in 2017.

ISPE Annual Meeting Brings Worldwide Members to Atlanta

by Jack Campion, The Hart Companies

The 2016 ISPE Annual Meeting of the international membership took place in the sunny city of Atlanta September 17-21 with over 1400 attendees from around the world. Many, MANY activities were jam-packed into 4 ½ days.

To start with, international governance gatherings, comprised of Affiliate representatives from around the world, were attended by your Chapter officers John Spohn, Jack Campion and Steve Kennedy, and Chapter Manager Amy Poole. These were great opportunities to share ideas and learn about the new directions of the ISPE internationally - all very encouraging.

Chapter Officers had a chance to share best practices with their peers from North and South Americas during the NASAAC conference at Annual Meeting in Atlanta.

Keynote and Plenary Addresses Something that made the Annual Meeting especially memorable were the inspiring words delivered to audiences of over 1000 by a pharma CEO, a doctor, and the mother of a patient - a spectrum of pharma stakeholders including its ultimate stakeholders.

Joseph Jimenez, CEO of Novartis, presented a talk entitled "Reimagining Medicine." He predicted that the next decade will bring more new medicines than the last 50 years and discussed his company's technical innovations including:

- Restoration of hearing using a viral vector to "turn on" the production of intra-aural hairs necessary for hearing.
- Cartilage replacement by stimulating stem cells via an injection into knee joints.
- Collaborations with technology companies, such as with Google to develop a microchip-embedded contact lens that can autofocus like the eye.
- Capacity expansion and productivity improvements using continuous manufacturing, single-use systems and high-density perfusion

Joseph also recognized the need for greater worldwide access to the benefits delivered by the drugs we make - even in countries with no system of health coverage. Novartis is responding with a new brand called "Novartis Access." The program provides 15 medicines in the 30 lowest income countries at a cost of $1 per month per patient - a price almost anyone can afford. Kenya was the first beneficiary of the new program.

Nicole Pierson, the mother of Gavin, a pediatric brain tumor survivor, shared their personal story of how compassionate use contributed to saving Gavin's life. Gavin was diagnosed at age five with a rare brain tumor. He was the first pediatric patient to receive compassionate use for the Pfizer drug Palbociclib, before it had received FDA approval. Nicole is an advocate for pediatric brain tumor research and is also the author of "Be Strong and Brave," a memoir about how Gavin's faith and hope helped save his life.

Other distinguished keynote speakers included:

- Flemming Dahl, Senior Vice President and Head of Quality, Novo Nordisk, who spoke about innovations in the industry's workforce.
- Stephan Grupp, MD, PhD, Children's Hospital of Philadelphia, who gave a FACINATING presentation on a new Leukemia treatment, now in trials, that uses autologous cell therapy.

Attendees can view videos of the presentations on the ISPE Annual Meeting website, http://www.ispe.org/2016-annual-meeting. (Hint: If you didn't attend, find someone who did. The videos are worth seeing!)

There were nearly 70 sessions over the course of four days within six tracks - from "End-to-End Supply Chain Management" to "Facilities and Equipment" to "Regulatory Compliance and Quality Systems." Speakers from the Boston Area Chapter included Paige Kane, John Spohn, Brian Hagopian, Rick Kotosky, Doyle Johnson, Andre Gill and others.

A seventh track focused on Women in Pharma, part of a broader initiative within ISPE. Key female executives in pharma shared their journeys with attendees from both a personal and a professional perspective. A round table discussion focused on the challenges and opportunities each embraced as they progressed though their careers. In addition to the education sessions, the Women in Pharma initiative raised $3,555 towards a scholarship for women pursuing careers in the pharmaceutical industry.

Facility of the Year (FOYA) Awards Prior to the Annual Meeting, awards had been presented in six categories:

- Equipment Innovation
- Facility Integration
- Operational Excellence
- Process Innovation
- Project Execution
- Sustainability

From among these, the overall FOY Award was announced at the Wednesday Awards Breakfast. It was presented to the Roche-Genentech, Vacaville CA site for its "CCP2 Manufacturing Facility and Return to Service (RTS)" project. Notably the Equipment Innovation Award went to our Chapter's own Pfizer, Groton facility for its Portable Continuous Miniature and Modular (PCMM) collaboration. Congratulations to Boston Area Chapter Member Jeff Silcox of Hallam-ICS and the entire project team!

The Annual Meeting was also punctuated by numerous networking sessions in the vendor exhibition, and the famous Tuesday night party, held this year at the VERY STUPENDOUS Georgia Aquarium. Talk about pump capacity! (Not to mention some amazing aquatic life forms! Ever see an albino alligator?)

Next year's Annual Meeting will be held in San Diego, 29 October - 01 November. Time to make plans for next Halloween! Visit http://www.ispe.org/2017-annual-meeting for more information and add it to your calendar for 2017.

Boston Harbor Cruise Delivers Food, Fun & Views Galore (Selfies, Anyone?)

by David Sun, Genzyme, with photos by Howard Sneider, CRB

On September 8 the Young Professionals hosted their annual boat cruise aboard the Samuel Clemens leaving from Rowe's wharf in Boston's financial district. The event was a huge success with a record-high 75+ attendees consisting of both the young and young at heart. From 6:30 to 9:30, most guests had a general plan laid out for their evening. First and foremost, they filled their empty stomachs with the catered sandwiches, wings and more, then grabbed a drink from the bar and settled in for an evening of socializing.

This year's Harbor Cruise provided live music, great food and the Boston skyline in the background - what's not to like?

With hunger satisfied, attendees were treated to a live band filling the night air with jazz/swing music. With great music in the background and a beautiful view of the Boston skyline, people grouped up into small circles and began getting to know one another. With so many guests, there was plenty of networking and chit-chat to go around. Another popular option was taking selfies with Boston in the background.

Whether topside or below decks, the Samuel Clemens provided comfortable spaces for casual socializing.

As the evening drew to a close, incoming Chapter President John Spohn thanked everyone for coming, advertised future events, and talked about the Chapter's upcoming year and new initiatives for 2017. Then the Samuel Clemens drifted back into the harbor, the chatter of the evening quieted and everyone finally headed home after a fun evening cruising the harbor.

The "Accidental Project Manager" Draws a Crowd to Alnylam

by Stefan Tropsa, Design Group

The Boston Area Chapter educational program entitled "Accidental Project Manager, Now What?" was held on Thursday, September 15 at Alnylam Pharmaceuticals in Cambridge. This topic attracted approximately 70 attendees, both members and non-members alike.

Following the traditional networking reception, the evening began with opening remarks by Chapter President John Spohn and Meeting Manager Stefan Tropsa who captured the audience's attention with an overview of the challenges of project management. Stacy Price, Head of Operations, Process Development at Shire, followed Stefan's introduction. She described the core concepts of project management based on her 20 years managing commercial and clinical biotechnology operations at Shire. Stacy provided enlightening insights on common misconceptions, modes for project failure, and tips and tricks to ensure project success by honing management of stakeholder's, scope, communication, operations, and change. Furthermore, she provided a new perspective on aspects of project management that are often overlooked.

Alnylam hosted the Chapter for the September educational program and networking reception.

Up next was Rob Beane, Director of Regulatory Compliance at Design Group. He concentrated specifically on communication and its importance to project success. He provided a solid foundation for why it is so important and discussed the many means of communication used throughout a project including Risk Management, Action Items List, Meeting Minutes, Status Reports and Dashboards, Earned Value or other Key Performance Indicators, Change Management, Plan Report, and Lessons Learned. Rob's lively performance clearly captured the hearts and minds of the audience.

Stacy and Rob shared a great deal of information during the course of the evening that provoked one of the most engaging and dynamic Q&A sessions the Chapter has seen this year! The questions ranged from how to become a project manager, to how to incorporate all team members while keeping the project on track for success. In sum, the program succeeded in delivering quality information on a topic of keen interest and relevance to Chapter members.

The Boston Area Chapter and Meeting Managers Stefan Tropsa and Thomas Vaughan would like to thank the speakers and audience members for their valuable contributions to this program; Alnylam Pharmaceutical for hosting the event; and sponsor Commissioning Agents for their invaluable support.

200 Students Celebrate the 25th Anniversary Product Show

by Brian Hagopian, Clear Water Consulting, and Paige Kane, Merck, with photos by Brian Hagopian

The Product Show has always been a focus of the fall season for our Student Members and this year was no exception. The Chapter gave over 200 students the opportunity to attend the 25th Anniversary edition of the Product Show by sending buses to our 13 Student Chapters and transporting students to and from Gillette Stadium. Highlights of this year's Show included presentation of the coveted Student Chapter of The Year Award to Mass Maritime Academy during the plenary session. MMA was recognized for their excellent work over the past year in building membership and promoting ISPE around campus.

Proudly displaying their plaque are Student Chapter of the Year Mass Maritime Academy award recipients: (l-r) Faculty Advisor George Howe, President Ryan Galanti, Treasurer Lukas Smith and Vice President Benjamin Joyal.

To prepare for the Show, about 50 students attended a session entitled "How to Get the Most out of Your Product Show Experience" where they learned how to make the right first impression when meeting people. We surprised students by making them practice their "elevator speeches" during the session. At first they were a little hesitant but after a few minutes they were clearly enjoying themselves as they prepared to visit the exhibit area and the Career Fair.

Students practiced their elevator speeches as part of the educational session "How to Make the Most of Your Product Show Experience."

Student Development Committee members also took advantage of the Career Fair with its 44 hiring companies, meeting with as many HR representatives as possible and singing the praises of the Boston Area Chapter and its 300 Student Members. As a result of these efforts, the Chapter will be posting over 100 new positions on our website in the coming months!

Scholarship applications are due by November 1 for the next round of Chapter scholarships. Over its history, the Chapter has awarded scholarships to a whopping 50 percent of applicants. Take advantage of this great program and help pay for the cost of your education. Don't delay since a written reference is required - be sure to give your chosen reference time to write a glowing endorsement. Click here to learn more and complete your application on line.

Industry News In Brief

by Jillian Willard, Sanofi

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 Chapter Members.

Intarcia Closes $215 Million in Equity Financing

Intarcia Therapeutics announced the first closing of a major equity financing valued at $215 million. The funding was sought to aid in the potential approval and launch of ITCA 650 for Type 2 Diabetes late next year, and the progression of the company's pipeline programs in chronic diseases such as diabetes, obesity and auto-immune/inflammation. The Company expects a larger second close with additional top-tier investors in Q4.

Intarcia's technology platform, the Medici Drug Delivery System, is a proprietary subcutaneous delivery system that allows the drug within the pump to be released in a steady, consistent fashion at the distal end of the device. Each osmotic mini-pump is designed to hold an appropriate volume of either mono or combination therapy, to treat a patient for up to a full year and beyond. (Source: Intarcia Website, 15 September, 2016)

Merrimack to Reduce Headcount; CEO Resigns amid Restructure

Merrimack Pharmaceuticals has announced a major corporate restructuring. As part of this move, Merrimack is immediately implementing a 22 percent reduction in headcount and eliminating more than $200 million in expected costs over the next two years. The reduction in force was substantially completed on October 3 and is expected to be fully completed by December 3. In line with this restructuring, the Board of Directors has accepted the resignation of President and CEO Robert Mulroy, effective immediately. The reduction in personnel is not expected to impact the commercial team or the commercial launch and label expansion of Merrimack's product Onivyde. (Source: Merrimack Pharmaceuticals Website, 03 October, 2016)

Sanofi and Verily Life Sciences Launch Joint Venture in Diabetes

Sanofi and Verily Life Sciences (formerly Google Life Sciences) have announced the launch of Onduo, a joint venture created through Sanofi and Verily's diabetes-focused collaboration. The joint venture is based in Kendall Square in Cambridge. Onduo's mission is to develop solutions that combine devices, software, medicine, and professional care to enable improved disease management.

The company will leverage Verily's experience in miniaturized electronics, analytics, and consumer software development, and Sanofi's clinical expertise and experience in bringing treatments to people living with diabetes. Initially, Onduo will focus on the Type 2 diabetes community in developing solutions, ranging from encouraging improved medication management to improved habits and goals. (Source: Sanofi Website, 12 September, 2016)

Sunovion to Acquire Canadian-Based Cynapsus Therapeutics

Sunovion Pharmaceuticals and Cynapsus Therapeutics have announced that Sunovion will acquire Cynapsus for $40.50 per share in cash. The transaction has received unanimous s approval by the Board of Directors of both companies and values Cynapsus at approximately $624 million. Through this transaction, Sunovion would acquire Cynapsus' product candidate, APL-130277, which is designed to be a fast-acting, on-demand treatment option for managing OFF episodes associated with Parkinson's disease (PD). The companies expect to close the transaction following required securityholder, court and

regulatory approvals and satisfaction of certain other customary closing conditions. (Source: Sunovion Website, 31 August, 2016)

Biogen's Alzheimer's Treatment Granted FDA Fast Track Designation

Biogen has announced that aducanumab, its investigational treatment for early Alzheimer's disease (AD), was granted Fast Track designation by the FDA. The FDA's Fast Track program supports the development of new treatments for serious conditions with an unmet medical need such as Alzheimer's disease.

In addition, results from pre-clinical research and PRIME, the Phase 1b study of aducanumab, were published in Nature. The pre-clinical animal model and Phase 1b placebo-controlled study both demonstrate that aducanumab reduced amyloid-beta in the brain and the reduction was dose-dependent. Amyloid-beta plaque is associated with the development of AD and it is hypothesized that removing it may slow the clinical decline of people who have AD. In addition to the results observed on amyloid plaque reduction, exploratory results from the Phase 1b study also demonstrated dose- and time-dependent slowing of clinical decline.

Aducanumab is currently being evaluated in two global Phase 3 studies, ENGAGE and EMERGE, which are designed to evaluate its safety and efficacy in slowing cognitive impairment and the progression of disability in people with early Alzheimer's disease. (Source: Biogen Website, 31 August and 01 September, 2016)

ImmunoGen Cuts Workforce by 17 Percent

Waltham based ImmunoGen, which produces therapies based on antibody-drug conjugates (ADCs) for the treatment of cancer, announced it will reduce its workforce by 17 percent and seek to partner its B-cell lymphoma programs. ImmunoGen will realize cost savings over the next two years in headcount, program, and support activities. These savings will include approximately $11 million per year relating to the elimination of 65 positions, primarily in Technical Operations and G&A functions. Going forward, the ImmunoGen expects to focus investment on initiatives including conducting the mirvetuximab soravtansine Phase 3 pivotal trial and accelerating the development of its IGN programs, IMGN779 and IMGN632 in cancer.

Based on its strong cash position and the savings generated from this strategic review, ImmunoGen expects to achieve its previously-stated goal of funding operations through the interim analysis of the mirvetuximab soravtansine pivotal trial and into mid-2018. As a result of the workforce reduction, ImmunoGen will record a one-time charge totaling approximately $3.5 million related to termination benefits and other related expenses. The majority of this charge is expected to be recorded in the quarter ending September 30, 2016.

In addition, the Company has prioritized its portfolio to focus on obtaining full marketing approval for lead program mirvetuximab soravtansine in cancers such as ovarian cancer, which will enter Phase 3 development next quarter and accelerating its earlier-stage portfolio containing IMGN779 and IMGN632.As part of this effort and the prioritization of its IGN programs, ImmunoGen will seek to monetize its non-core B-cell assets - IMGN529 and coltuximab ravtansine - through partnerships. (Source: Immunogen Website, 29 September, 2016)

Bayer and CRISPR Therapeutics Joint Venture Expands in Cambridge

Casebia Therapeutics, the joint venture founded by Bayer and CRISPR Therapeutics, started its operations in Cambridge. In December, 2015 Bayer and CRISPR Therapeutics agreed to create a joint venture (JV) to discover, develop and commercialize new therapeutics to cure blood disorders, blindness, and congenital heart disease. The two parties formally closed the transaction in the first quarter of 2016.

The joint venture has recently been incorporated as Casebia Therapeutics, a UK entity with its primary base of research operations in Cambridge. The name Casebia derives from the CRISPR-associated, or Cas, family of nuclease enzymes - key components of the breakthrough gene editing technology on which Casebia will base its therapeutic programs. Casebia has access to gene-editing technology from CRISPR Therapeutics in specific disease areas, as well as access to protein engineering expertise and relevant disease research through Bayer.

Casebia entered into a sublease agreement for approximately 33,000 sq ft of laboratory and office space that will host up to 80 employees and form its primary base of operations. The space is located at 610 Main Street North, a brand new, nine-story, MIT-owned building currently under construction in Kendall Square adjacent to the MIT campus. Casebia will be co-located with CRISPR Therapeutics and will enter the new location in early 2017.

Pfizer Contemplates Split, Decides to Remain One Company

Pfizer has announced that, after an extensive evaluation, the company's Board of Directors and Executive Leadership Team determined the company will maintain its current structure and will not pursue splitting Pfizer Innovative Health and Pfizer Essential Health into two, separate publicly-traded companies at this time. The two distinct businesses will remain separately managed, autonomous units within Pfizer,

The decision comes after a process that included evaluating the performance of each business within Pfizer, determining if each could compete as a stand-alone entity, assessing if trapped value existed in a combined entity and if any trapped value could be unlocked efficiently. (Source: Pfizer Website, 26 September, 2016)

AstraZeneca Sells Antibiotics Business to Pfizer

AstraZeneca has announced it has entered into an agreement with Pfizer to sell the commercialization and development rights to its late-stage small molecule antibiotics business in most markets outside the US. The portfolio comprises the approved antibiotics Merrem, Zinforo and Zavicefta, and ATM-AVI and CXL, which are in clinical development.

Under the terms of the agreement, Pfizer will make an upfront payment to AstraZeneca of $550 million upon completion and a further unconditional payment of $175 million in January 2019 for the commercialization and development rights to the late-stage antibiotics business in all markets where AstraZeneca holds the rights. In addition, Pfizer will pay up to $250 million in commercial, manufacturing and regulatory milestones, up to $600 million in sales-related payments as well as recurring, double-digit

royalties on future sales of Zavicefta and ATM-AVI in certain markets. (Source: AstraZeneca Website, 24 August, 2016)

Alnylam Discontinues Revusiran Development

Alnylam Pharmaceuticals has announced that it has decided to discontinue development of revusiran, an investigational RNA interference (RNAi) therapeutic that was being developed for the treatment of hereditary ATTR amyloidosis with cardiomyopathy (hATTR-CM). The decision was made after the Data Monitoring Committee (DMC) reviewed unblinded data from the Phase 2 study and recommended to suspend dosing of revusiran in its Phase 3 study. The data review was requested by Alnylam after reports of new onset or worsening peripheral neuropathy were reported.

The DMC did not find conclusive evidence for a drug-related neuropathy signal in the trial, but informed Alnylam that the benefit-risk profile for revusiran no longer supported continued dosing. Alnylam subsequently reviewed unblinded trial data which revealed an imbalance of mortality in the revusiran arm as compared to placebo.

The decision to discontinue development of revusiran does not affect Alnylam's other investigation drug patisiran, which is currently in Phase 3 development for the treatment of hATTR amyloidosis with polyneuropathy (hATTR-PN), or any other investigational RNAi therapeutic program in development.

Based on a current assessment of the safety data across Alnylam's other program, there is no evidence of a drug-related neuropathy signal in over 800 treated subjects and patients with exposure of up to 34 months. This includes patisiran, which utilizes a lipid nanoparticle delivery formulation, and the seven other clinical programs in Alnylam's pipeline, which all use Enhanced Stabilization Chemistry (ESC) GalNAc delivery technology. ESC-GalNAc conjugates enable dose and exposure levels that are 12-30 times lower than revusiran, which uses Standard Template Chemistry (STC) GalNAc delivery technology. (Source: Alnylam Website, 05 October, 2016)

Moderna Closes $474 Million Equity Financing, Announces New Facility to be Built in Norwood and Receives Grant to Develop Zika Vaccine

Moderna Therapeutics, which specializes in developing messenger RNA (mRNA) therapies, announced it has raised $474 million in equity financing. With this financing completed, the company has $1.4 billion in cash on its balance sheet. Moderna also received a $125 million grant from Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS), to work on a Zika mRNA vaccine.

Moderna also plans to invest $110 million to build a new 200,000 square foot facility in Norwood that will be used to carry out all mRNA manufacturing activities. Moderna will begin initial build-out of the new facility in October 2016. The company plans to open the facility by early 2018.

The Norwood facility will host GMP manufacturing and quality control; fill/finish operations; the company's Personalized Cancer Vaccines unit; preclinical technical operations and testing; and general administrative functions to support these teams. At the facility's opening, the annual GMP manufacturing capacity will be 40 GMP mRNA lots and is expected to scale up to over 100 GMP mRNA clinical scale lots annually in the future.

Approximately 100 of Moderna's current 460 team members will move from the company's three existing locations in Cambridge to the Norwood facility. In addition, Moderna plans to hire more than 100 new employees for the Norwood site. (Source: Moderna Website, 07 and 21 September, 2016)

Pfizer Acquires Oncology Company Medivation for $14 Billion

Pfizer has announced the successful completion of its acquisition of Medivation. As of the tender offer expiration, 115,574,041 shares of Medivation common stock were validly tendered for $81.50 per share in cash, without interest, subject to any required withholding of taxes.

Following its acceptance of the tendered shares, Pfizer completed its acquisition of Medivation through the merger of its subsidiary Montreal with and into Medivation without a vote of Medivation's stockholders. As a result of the merger, Medivation became a wholly-owned subsidiary of Pfizer. Medivation common stock will cease to be traded on the NASDAQ Global Market. The total value of the tender offer is approximately $14 billion.

Medivation's portfolio includes Xtandi (enzalutamide), an androgen receptor inhibitor that blocks multiple steps in the androgen receptor signaling pathway within the tumor cell. Xtandi generated approximately $2.2 billion in worldwide net sales over the past four quarters, In addition, Medivation has a late-stage oncology pipeline, which includes two development-stage oncology programs, talazoparib for BRCA-mutated breast cancer and pidilizumab for B-cell lymphoma. (Source: Pfizer Website, 28 September, 2016)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights is a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies with the potential to impact the pharma, biotech and device industries, and related fields.

FDA Issues Draft Updated Recommendations on Submitting New 510(K) for Device Modifications

The FDA has issued draft updated recommendations to help manufacturers determine when they are required to notify the FDA about modifications made to certain medical devices already on the market, including a separate guidance applicable to software devices. The draft recommendations describe how manufacturers should consider the risk presented by the device modifications when determining if they should submit a new 510(k). When finalized, they will replace an earlier guidance issued in 1997.

Updates in the draft guidance recommendations include:

- Guiding principles, including recommendations for manufacturers to conduct a risk-based assessment in order to determine whether a modification could significantly affect the safety or effectiveness of the device.
- Updated sections and flow charts to provide more clarity to manufacturers on when they likely are required to submit a new 510(k) for labeling, materials, technology, engineering and performance changes.
- Examples of specific device changes that likely require a new 510(k) and ones that likely do not in order to help guide manufacturers during their own decision-making on whether to submit a new premarket notification.

The FDA drafted a separate guidance to address changes that are specific to software. This software draft guidance complements the general 510(k) modifications draft guidance. (Source: FDA Website , 05 August, 2016)

FDA Statement on Medical Device User Fee Agreement (MDUFA)

The FDA and representatives from the medical device industry and laboratory community have reached an agreement in principle on proposed recommendations for the fourth reauthorization of a medical device user fee program. Under the new draft agreement, the FDA would be authorized to collect $999.5 million in user fees plus adjustments for inflation over five years starting in October 2017. This funding would provide critical resources to the FDA medical device review program. Details of the draft agreement will be published for public comment in the coming weeks, and the final recommendations are scheduled to be delivered to Congress in January 2017.

"MDUFA IV is the result of more than a year of public input and negotiations with industry, laboratory, patient, and consumer representatives," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "This draft agreement represents a substantial investment in the future of the agency's medical device program and reflects the efforts the FDA has made to meet or exceed its performance goals and to help speed patient access to safe and effective medical devices. This funding will also improve the collection of real-world evidence from different sources across the medical device lifecycle, such as registries, electronic health records, and other digital sources." (Source: FDA Website, 22 August, 2016)

FDA Approves Erelzi, a Biosimilar to Amgen's Enbrel

The FDA has approved Erelzi, (etanercept-szzs) for multiple inflammatory diseases. Erelzi is a biosimilar to Enbrel (etanercept), which was originally licensed in 1998. The approval of Erelzi is based on review of evidence that included structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates Erelzi is biosimilar to Enbrel. Erelzi has been approved as a biosimilar, not as an interchangeable product.

Erelzi contains a Boxed Warning to alert health care professionals and patients about an increased risk of serious infections leading to hospitalization or death, including tuberculosis, invasive fungal infections (such as histoplasmosis) and others. The Boxed Warning also notes that lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor blockers, including etanercept products. The drug must be dispensed with a patient Medication Guide that describes important information about its uses and risks.

Erelzi is manufactured by Sandoz Inc., based in Princeton, New Jersey, at Novartis Pharma in Stein, Switzerland. Enbrel is manufactured by Amgen Inc., of Thousand Oaks, California. (Source: FDA Website, 30 August, 2016)

FDA Approves Sarepta's Exondys 51 - First Drug for Duchenne Muscular Dystrophy

The FDA has approved Exondys 51 (eteplirsen) injection, the first drug approved to treat patients with Duchenne muscular dystrophy (DMD). Exondys 51 is specifically indicated for patients who have a confirmed mutation of the dystrophin gene amenable to exon 51 skipping, which affects about 13 percent of the population with DMD.

DMD is a rare genetic disorder characterized by progressive muscle deterioration and weakness. It is the most common type of muscular dystrophy. DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. The first symptoms are usually seen between three and five years of age, and worsen over time. The disease often occurs in people without a known family history of the condition and primarily affects boys, but in rare cases it can affect girls. DMD occurs in about one out of every 3,600 male infants worldwide.

The manufacturer received a rare pediatric disease priority review voucher, which comes from a program intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. This is the seventh rare pediatric disease priority review voucher issued by the FDA since the program began.

Exondys 51 is made by Sarepta Therapeutics of Cambridge, Massachusetts. (Source: FDA Website, 19 September, 2016)

FDA Approves Amjevita, a Biosimilar to Abbvie's Humira

The FDA has approved Amjevita (adalimumab-atto) as a biosimilar to Humira (adalimumab) for multiple inflammatory diseases. Amjevita is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis in patients four years of age and older.

Like Humira, the labeling for Amjevita contains a Boxed Warning to alert health care professionals and patients about an increased risk of serious infections leading to hospitalization or death. The Boxed Warning also notes that lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor blockers, including adalimumab products. The drug must be dispensed with a patient Medication Guide that describes important information about its uses and risks.

Amjevita is manufactured by Amgen, Inc., of Thousand Oaks, California. Humira was approved in December 2002 and is manufactured by AbbVie Inc. of North Chicago, Illinois. (Source: FDA Website, 23

September, 2016)

FDA Approves Expanded Indications for Novartis Drug Ilaris

The FDA has approved three new indications for Ilaris (canakinumab). The new indications are for rare and serious auto-inflammatory diseases in adult and pediatric patients. All three syndromes are hereditary diseases that are characterized by periodic attacks of fever and inflammation, as well as severe muscle pain. There are no previously approved therapies for these conditions. Ilaris was previously approved for another periodic fever syndrome called Cryopyrin-Associated Periodic Syndromes (CAPS) and for active systemic juvenile idiopathic arthritis.

Ilaris is manufactured and distributed by Novartis Pharmaceuticals Corporation, of East Hanover, New Jersey. (Source: FDA Website, 23 September, 2016)

FDA Approves Orkambi for Use in Children with Cystic Fibrosis

Vertex Pharmaceuticals has announced that the FDA approved Orkambi (lumacaftor/ivacaftor) for use in children with cystic fibrosis (CF) ages 6 through 11 who have two copies of the F508del mutation. People with this mutation represent the largest population of those with CF, a rare, life-threatening disease. Orkambi is the first and only medicine to treat the underlying cause of CF for people with this mutation. It was previously approved by the FDA for use in people ages 12 and older with two copies of the F508del mutation. With today's approval, approximately 11,000 people with CF are eligible for treatment with Orkambi in the United States.

Vertex plans to submit a Marketing Authorization Application (MAA) variation in the European Union in the first half of 2017 for children ages 6 through 11 who have two copies of the F508del mutation.

Cystic fibrosis is a rare, life-threatening genetic disease affecting approximately 75,000 people in North America, Europe and Australia. Vertex initiated its CF research program in 2000 as part of a collaboration with CFFT, the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation. Orkambi (lumacaftor/ivacaftor) was discovered by Vertex as part of this collaboration. (Source: Vertex Website, 28 September, 2016)

Astrazeneca and Lilly Receive Fast Track Designation for Investigational Treatment for Early Alzheimer's Disease

AstraZeneca and Eli Lilly and Company (Lilly) received FDA Fast Track designation for the development program in Alzheimer's disease for AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in Phase III clinical trial. The FDA's Fast Track program is designed to expedite the development and review of new therapies to treat serious conditions and tackle key unmet medical needs.

Alzheimer's disease is a fatal illness and is the most common form of dementia, accounting for 60 to 80 percent of cases. There are currently an estimated 46 million people living with dementia worldwide, and this number is expected to exceed than 74 million in 2030 and 131 million in 2050. Only 50 percent of people with dementia ever receive a formal diagnosis, and Alzheimer's disease continues to be one of the most significant health challenges facing the world. The total estimated worldwide cost of dementia in 2015 was $818 billion. By 2018, dementia will become a trillion dollar disease, rising to $2 trillion by 2030. (Source: AstraZeneca Website, 22 August, 2016)

New Members

Jaclyn Andrews, Shire

Jennifer Bairam, URI

Nicholas A. Baird, University of New Hampshire

Cenk Baskaraca, Biogen Idec

Jason Keith Beneker, Amgen Inc

Matthew Berman, DPS Engineering

Josiane Bongo, University of Massachussetts

David Bouffard, IPS

Peter Breed, Lantheus Medical Imaging

Wesley Brubaker, B.S, Stantec Consulting Services Inc

Thi Ngoc Bui, BS, University of Massachusetts Amherst

Katherine Cano, Middlesex Community College

Paulo J. Carreiro, B.S., M.B.A., Denison Pharmaceuticals

Kalli Catcott, Northeastern University

Caroline Victoria Cater, Pfizer

Albert Chap, University of Massachusetts Lowell

Steven Chen, University of Massachusetts Lowell

Darryl Coombs, Cianbro Corporation

Joseph Cote, BACH, Pfizer

Peter M. Cottrell, Shire

Drea DeMarco, Genzyme Biosurgery

Ivy Dutta, Northeastern University

Jeeson Easo, DPS

Alexander Elpidio Teles, Middlesex Community College

Gillian Emerson, Meredith College

Dr. Nima Farrokhsiar, New England Controls Inc

Samuel Field, CrossPoint Engineering

Zach Foster, Alnylam Pharmaceuticals

Timothy French, Monarch Instrument

Bonnie Gauss, B.S. ChE, Barry-Wehmiller Design Group

James Giordani, ImmunoGen Inc

Matt Groff, Shire

Susan Guerette, Shire

Vincent Guido

Derek Hargrove, University of Connecticut

Alison Hebert

Martin Heffler, Test-Rep Associates, Inc

Inneke Herwono, Middlesex Community College

Rick Hill, DPS Engineering

Raheeq Hossain

Guodong Hui, Sanofi

Shahid Hussain, MCPHS University Boston

Kirk Johnson, DPS Engineering

Thomas W. Joyner, AHA Consulting Engineers

Tyler J. Kaleta, DPS Engineer

Daniel Kallin, University of Massachusetts

Katrina Kiely, UMass Amherst

Kent Koeman, TTE Laboratories Inc

Ravi Krishna, MBA, Sequence Inc

Sanjeev Kumar, Vertex Pharmaceuticals

Michael Lamb, Process Design Solutions, LLC

John C. Lang, Middlesex Community College

Randy Lavigne, BSChE, Sanofi/Genzyme

Shaun LeBlanc, Rescop

Scott Lessard, DPS Engineering

Vincent Li, University of Massachusetts Lowell

George Liang, UMass Lowell

Todd Marchefka, Hygeniks, Inc

Kaci Markewicz

Celeste B. Marsan, Worcester Polytechnic Institute

Adam McCabe, DPS Engineering

Theresa McCarthy, Pfizer

John F. McGrath, DPS Engineering

Patrick McKelvey, DPS Engineering

Brendan McKeogh, B.S.

Chris Megahey, M+W Group

Philip Michel, Ultrafiltronics

Peter Mitchell, NNE Pharmaplan

Abraham Moniri, CED Corporation

Esther Namala, Middlesex Community College

Daniel Nelligan, Alares LLC

Bobby Nerbonne, DPS Engineering

Logan Nichols, Worcester Polytechnic Institute

Christina Pan

Jigar Parikh, Sanofi

Marybeth Park, DPS BioMetics Inc

Rupangi Patel, Biogen Idec

Jeisa Pelet, PhD, Alnylam Pharmaceuticals

Matt Peranelli, Middlesex Community College

Emmett Pierro, University of Massachusetts Lowell

Phillippine M. Pin, Middlesex Community College

Ilana Pinkus, DPS Engineering

Laura Ploude, Genzyme

Stephen Prescott, Moderna Therapeutics

Vannak Pril, Sanofi (Genzyme)

Ismarie E. Ramirez Zamora, BS, MS, Barry-Wehmiller Design Group

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Cazim Saracaevic, Shire

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Marisa Sposato

Zachary Stufflebeam, Stantec Consulting Services Inc

Timothy W. Sullivan, University of Massachusetts

Huyen Tran, University of Massachusetts Lowell

Matthew J. Turner, Seres Therapeutics

Anthony Valle, Merck & Co Inc

Derek VanDyke, University of Massachusetts Lowell

Julie M. Wadja, Lafayette College

Hugh Wight, Allena Pharmaceuticals

Nathan Wilson, Cianbro Corporation

Serena Zhou, Momenta Pharmaceuticals

Member Anniversaries

Over Twenty Years

- James R. Dube, Alexion Pharmaceuticals (23 years)
- Thomas G. Larkin, Amgen Inc (23 years)
- Pasquale M. Sacco, Shire HGT (26 years)

Twenty Years

- Charles H. Brown, II, MS, Retired
- Robert M. Stern, Genzyme Corporation

Fifteen Years

- Michael R. Allard, NewAge Industries/Advantapure
- Michael J. Carr, PE, DPS BioMetics Inc
- Peter T. Fox, CAI
- George A. Lombardo, Lizardos Engineering PC

- Ralph K. Manning
- Yuthea Sar, Commissioning Agents, Inc.

Ten Years

- Jonathan D. Davis, Associates of Cape Cod, Inc
- Jared B. Marshall, Biogen
- Sarvang Mishra, Merck - Kgaa
- Herbert Ordonez, Sanofi Pasteur Biologics
- James C. Spavins

Five Years

- Mark Broadley, Citra Labs, LLC.
- Matthew A. Fessenden, Process Design Solutions, LLC
- Michael Hansen, DPS
- Brian P. Kennedy, Sanofi
- Dr. Jakub Mocny, CPIP, Superior Controls
- Sinead Rainville, AstraZeneca

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