

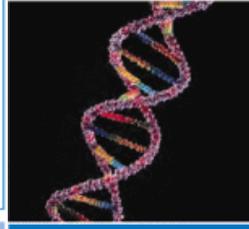


Connecting a World of  
Pharmaceutical Knowledge

Serving All of New England

# Boston Area Chapter

www.ispeboston.org



## NEWSLETTER

September 2015, Volume XXV, No. 5

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

Save page as PDF

Complete Facility Automation  
& Compliance Solutions for  
the Life Science Industry

**GxP Automation is now...**

Partnering for Success

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

978.710.3517  
www.GxPAutomation.com

### **President's Message: Incoming Chapter President H. Steven Kennedy Shares His Vision for the Chapter**



Dear Fellow Members,

It is with great pleasure that I welcome you to a new year with the ISPE Boston Area Chapter. It is hard to believe, but 25 years ago, a group of Boston area professionals got together to further and promote the interests of the then-fledgling biotech manufacturing industry. That group included such luminaries as Hank Moes, Myron Dittmer, Nancy Butcher and Richard Priester. They got together to talk about the challenges they were facing in developing these biomanufacturing facilities and share best practices. Then in 1992, after looking at various national organizations, they decided to throw their lot in with the International Society of Pharmaceutical Engineers and established the Chapter. Since our founding, we have grown to be the biggest Chapter in the Society with over 1700 members. Our events calendar has become the envy of all of the other Chapters and Affiliates. And our charitable endeavors continue

to grow.

This success comes after many years of vision by the leaders of our organization and the hard work of our volunteers. This past year we had 108 volunteers who gave their time and expertise in many different ways, from running educational events to manning the information booth at the Product Show. Our Chapter is successful because of the efforts of these volunteers and I was pleased to have been able to honor and thank them at our Summer Social and Volunteer Appreciation Night at Pier 6 in Charlestown on August 27th. It was a great night and I was especially delighted to be able to recognize out going Board Members Jillian Willard, James Stout and Tulsa Scott, as well as Past Presidents Dan Ramsey and Chris Opolski. Their efforts have helped strengthen the Chapter and ensure our success.

In this very special year, I encourage you to help out. As I write this, the new Board has just completed our strategic planning and we are taking steps to ensure the continued success of our organization for the next 25 years. This meeting plus the planning meetings in late July conducted by the Educational Programs Committee and the Student Development Committee have resulted in another full slate of events for the coming year.

We need your help to put these plans into action, so please consider joining the team and volunteer some of your time to work with one of our committees. Having been a member of most of our committees, I can tell you the work is rewarding and lots of fun.

And speaking of the new Board, please join me in congratulating your newly-elected Directors and Chapter Officers for the 2015-2016 term:

President	H. Steve Kennedy	Kennedy Strategic Consulting
Vice President	Jack Campion	The Hart Companies
Treasurer	John Spohn, CPIP	Hargrove Life Sciences
Secretary	Janet Tice	GMP Piping Inc.
Directors	Sean Burgess	Integrated Builders, Inc.
	Kevin Chronley	A/Z Corporation
	Eric Felz	Shire
	Michael Levesque	GE Healthcare
	Jared Marshall	Biogen
	Dan Rufo	IPM
	Darren Wolter	Pfizer

**KAYE**  
Advanced Validation System  
**Kaye Validator AVS**

NEW

Contact your local  
account manager  
today to schedule an  
on-site demo!

www.kaye-validator-avs.com

Kaye - A continuing  
History of Imagination,  
Quality and Compliance.

Turn the  
page to the  
next generation

**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

ISO 9001 CERTIFIED

10 Lomar Park  
Pepperell, MA 01463  
978.433.6279  
masy@masy.com  
www.masy.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  
www.gmppiping.com

Thank you for helping make  
Superior Controls

**CONTROL ENGINEERING**

2012  
**System Integrator**  
of the Year

**SUPERIOR CONTROLS**  
*Trusted Automation Excellence*

www.superiorcontrols.com

Immediate Past President Chris Opolski SPEC Process Engineering

As I noted, the Board has taken steps to ensure the long term health of our organization. First and foremost was the establishment of a Finance Committee to oversee the Chapter's finances and budgeting process. The most tangible outcome of this effort has been the creation of an investment policy to put our retained earnings to work for us. This continues our evolution into a decidedly professionally managed organization.

There are other changes happening as well. We are establishing an Industry Advisory Board. There will be more details on this in the coming months but we are excited about how this board could help provide direction on where the organization should go over the next 25 years. We are also looking to reinvigorate the Communications Committee this year. With the changes in technology, we are looking to revamp the website and take more advantage of social media platforms to service our membership. We are looking for help from Members with expertise in these areas.

One of the areas in which we have been trying to use technology to better serve our Members has been simulcasting our educational events beyond the greater Boston area. Admittedly, this effort at "live TV" has been met with mixed success but if we are going to serve our entire region - which runs from upstate New York to Massachusetts and from Connecticut to Maine - then we have to find a solution. We have established "hubs" outside of Boston where Members can gather to network and view rebroadcasts of our educational events. Current hubs are in Providence and Worcester but we envision additional hubs wherever there are Members interested in getting together. We will support hubs with funding and content - all that is needed is desire and a champion. Let us know if that champion is you.

The Educational Programs Committee has been busy and has programs planned through March of 2017. We are extremely excited that our first program of the season is our first joint program with the PDA New England Chapter. The topic is Process Validation and we've secured two excellent speakers who will help us decode and understand guidance documents on the topic produced by the FDA, ICH, PDA, ISPE and other industry sources. Don't miss out on this one-of-a-kind opportunity to meet, exchange ideas and network with a much larger industry cross section than usually participates at these programs.

Also, in early September, the Young Professionals hosted their annual Boston Harbor cruise. The YPs have planned three educational events and six networking social events for the next 12 months. But there is one of their upcoming events that I want to highlight as it was inspired by the needs of one of our own.

The YPs are fielding a team to participate in the National Kidney Foundation's Walk on October 25th. This is an inspiring community fundraiser that calls attention to the prevention of kidney disease and the need for organ donation. This year, the ISPE Boston Area Chapter and The New England Patriots Charitable Foundation are joining together to sponsor this team and we need your support. At this year's Product Show, you will have an opportunity to meet Patriot alumni Steve Grogan and Joe Andruzzi, the Patriots cheerleaders and see the Super Bowl trophy. For a donation of \$20, you can have your photograph taken with these champions. Your donation will be included in the funds raised by the team and donated to the National Kidney Foundation on the day of the walk. Help make a difference for millions of people and support our team.

I could not be more proud of the altruism that has become a measure of our organization. The Scholarship Committee, which oversees the Joel Goldenberg Memorial Scholarship Fund, awarded \$12,080 to nine worthy students in August. Proceeds from the Summer Golf Outing also go toward the fund each year. Our hope is that our new investment policy will generate returns that will allow us to increase the funding and enable us to help even more deserving students.

And with the way our Student Chapters are growing, we will need to. We now have 11 active Student Chapters - the most of any Chapter - with 232 student members and plan to add a few more Student Chapters this year. One of our primary missions is to help prepare the next generation of pharmaceutical engineers, as well our seasoned professionals, for careers in our ever-evolving industry. Hence the ever expanding programs and tools we offer our local Members to help them keep current on new developments.

The Society will be holding its Classroom Training in Boston October 19th through the 23rd. The Chapter will be holding a social event on October 20th to allow local members to network with the attendees, so keep an eye out for that. On November 8th through the 11th, the Society will hold its Annual Meeting in Philadelphia. If you plan to attend, the Chapter will hold a social event the evening of November 8th and you're invited. These parties are always a lot of fun and are on everyone's must-attend list.

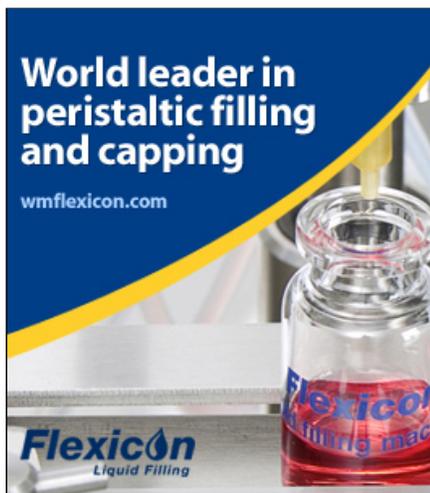
The week before the Annual Meeting, the Chapter will be hosting the Japan Affiliate as they make their way to the Annual Meeting. While here in Boston, they will be touring some of the area's newest, most innovative facilities and will join the Board for dinner and sake.

As you can see, our Social Committee has a lot of fun events planned. They are always looking for volunteers to help out with the golf outings, ski trip and other events throughout the year. And we are looking to expand those social events beyond the Boston area and seeking volunteers to help with that effort.

Having been a member of this great Chapter for 20 years, I am excited, proud, and honored to be President for our silver jubilee. It's going to be a great year and I look forward to seeing all of you soon at a Chapter event.

Warm Regards,

H. Steven Kennedy



## Chapter Bulletin Board

### Only a Handful of Product Show Booths Left – It's Now or Never!

This year's Product Show is shaping up to be the biggest and best to date. Read the following articles describing the many new attractions that will ensure attendance tops last year's 2500. Then register at <http://productshow.ispeboston.org/reserve-space/> or by contacting the Chapter office at 781.647.4773. And while you're at it, be sure to sign up for one (or more!) of the many new promotional and advertising opportunities available this year. See you at Gillette on October 7<sup>th</sup>!

### Chapter Awards Scholarships to 9 Area Students

The Chapter is proud to announce the winning applicants for the June 2015 Joel Goldenberg Memorial Scholarship awards. The Chapter accepts applications from graduating high school seniors, undergrad and grad students, and professionals currently working in the industry pursuing continuing education. Applicants must be members of the Boston Area Chapter and are eligible to receive up to \$8,000 in scholarship monies throughout their lifetime.

The easy-to-use online application requires information about the applicant's academic, extra-curricular and community service accomplishments, and their involvement with ISPE and the life sciences industry, as well as a written reference. For a look at the application, visit <https://scholarships.ispeboston.org/scholarships/>.

The scholarship program has application periods ending November 1st and June 1st. Winners from the June 2015 application period are:

Connor Brown	Assumption College	Biotechnology
John Busanovich	Boston College	Biology
Jennifer Langh	Northeastern University	Chemical Engineering
Kelsey Martin	UMass Lowell	Chemical engineering/biological engineering
Samuel Musiak	UMass Lowell	Chemical Engineering
Satyajeet Salvi	Hampshire College	Chemistry, Biology, Applied Mathematics
Nathaniel Swanson	UMass Lowell	Chemical Engineering
Peter Trearchis	Tufts University	Engineering Management
Matthew Woodard	University of Hartford	Computer Engineering

For more information about the Joel Goldenberg Memorial Scholarship Program, please visit <https://scholarships.ispeboston.org/scholarships/>, or contact the Chapter office at [office@ispeboston.org](mailto:office@ispeboston.org) or 781.647.4773. And don't forget, the next application deadline is November 1<sup>st</sup>.

### 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](mailto: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](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](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](mailto:office@ISPEBoston.org) and we'll be happy to help!

## Upcoming Chapter Events - Mark Your Calendar

Wednesday, September 16, 2015



Allegheny Bradford Corporation

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

**Chuck Ridenour - Regional Sales Manager**  
814-362-2590

[alleghenybradford.com](http://alleghenybradford.com)

CRB is a global provider of end-to-end solutions for life science and advanced technology companies. Our solutions deliver enhanced value, productivity and return on investment.



Bill McCarthy  
781.572.8759  
billmccarthy@crbusa.com  
www.crbusa.com

Consulting Design Construction Commissioning Qualification



**SEQUENCE**  
Quality and Compliance Services

- Validation
- Laboratory Compliance
- IT Quality Services
- Quality Program & Compliance
- Software Management
- Manufacturing Support

toll free 855.844.7171 phone 919.844.7171  
470 Atlantic Ave., 4th Floor Boston, MA 02210  
info@sequenceqcs.com

*Biotechnology Professional Development & Advancement*

Limited space, registering NOW for Winter 2014/2015

[www.uri.edu/prov/BPDA\\_BPM\\_seminars.html](http://www.uri.edu/prov/BPDA_BPM_seminars.html)

THINK BIG WE DO!



**PROPHARMA GROUP**

*Comprehensive Compliance Solutions*

- Validation • Quality Assurance
- Compliance • Program/Project Management

Visit [propharmagroup.com](http://propharmagroup.com) or contact us at 888.242.0559

## Previous Issues

[July 2015, Volume XXV... \(15\)](#)  
[May 2015, Volume XXV... \(12\)](#)  
[March 2015, Volume... \(12\)](#)  
[January 2015, Volume... \(13\)](#)  
[November 2014, Volume... \(13\)](#)  
[September 2014, Volume... \(17\)](#)  
[July 2014, Volume... \(13\)](#)  
[May 2014, Volume XXIV... \(13\)](#)  
[March 2014, Volume... \(13\)](#)  
[January 2014, Volume... \(11\)](#)  
[January 2014, Volume... \(0\)](#)  
[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... \(12\)](#)

## ISPE Process Validation Lifecycle Approach, A Return to Science

Hilton Boston/Woburn, Woburn, MA

### PROGRAM SUMMARY

Do we have a blockbuster September program for you! For the first time ever, the ISPE Boston Area Chapter and the PDA New England Chapter have pooled resources to present an incredibly strong educational event to kick off the program year! The topic is Process Validation and we've secured two excellent speakers who will help us decode and understand guidance documents written by the FDA, ICH, PDA, ISPE, and other industry sources on the topic. Don't miss out on this one of a kind opportunity to meet, exchange ideas, and network with a much larger industry cross section than usually participates at these programs. Be sure to sign up now to secure your spot before the event sells out! Register today!

Click below for full information and to register:

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=476](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=476)

Thursday, September 24, 2015

## ISPE RE-SHOWING: Process Validation Lifecycle Approach, A Return to Science

Crowne Plaza Hotel Providence - Warwick, Warwick, RI  
Worcester Polytechnic Institute - BETC, Worcester, MA

### PROGRAM SUMMARY

Attend a re-showing at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs will both feature a networking reception including appetizers.

Click below for full information and to register:

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=568](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=568)

Wednesday, October 7, 2015

## ISPE Annual Product Show and Educational Seminars

Gillette Stadium, Foxboro, MA

### EVENT INFORMATION

10:30 AM - 12:00 PM - Plenary Session with Keynote Address  
 12:00 PM - 6:30 PM - Exhibit Hall Open  
 6:30 PM - 9:30 PM - After-Party Networking Social

Register Today! Your FREE registration badge allows you to:

- Connect with experts from 375+ companies
- Get insights from educational sessions on the show floor
- Attend the plenary session and hear from keynote speakers John Bourmas, ISPE President & CEO, and Andy Skibo, Head of Global Biologics Operations & Global Engineering at MedImmune/AstraZeneca
- Visit Champions for Charity, where you meet Patriots alumni Steve Grogan and Joe Andruzzi and also contribute to a great cause
- Network and exchange ideas with peers at the After-Party at the new Optum Field Lounge and meet New England Patriot Malcolm Butler

And if you preregister now and attend the show, you are automatically entered into a drawing to win 2 tickets (courtesy of Superior Controls) to the New England Patriots versus New York Jets game on Sunday, October 25th, along with lodging and dinner on Saturday night at Patriot Place.

Click below for full information and to register:

<http://productshow.ispeboston.org/attendees/registration/>

Monday, October 19, 2015 - Friday, October 23, 2015

## ISPE Classroom Training

The Inn at Longwood Medical, Boston, MA

### PROGRAM SUMMARY

Learn how to improve manufacturing efficiency, maintain product quality and improve GMP compliance. Most courses leverage ISPE Guidance documents produced by pharmaceutical manufacturing industry professionals. These guides provide the practical, "real world" information needed to build on best practices to meet and exceed current regulatory requirements.

Click below for full information and to register:

[May 2012, Volume XXII... \(13\)](#)  
[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... \(10\)](#)

## Newsletter Archive

[http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=569](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=569)

**Sunday, October 25, 2015**

### **ISPE National Kidney Foundation Walk**

**Canal Park, Cambridge, MA**

#### **EVENT SUMMARY**

One in nine American adults has kidney disease and most don't know it. With the increase in diabetes and high blood pressure – two major kidney disease risk factors – kidney disease is on the rise. The National Kidney Foundation (NKF) Kidney Walk is an inspiring community fundraiser that calls attention to the prevention of kidney disease and the need for organ donation.

This year, the ISPE Boston Area Chapter and The New England Patriots Charitable Foundation are joining together to sponsor a team of our Young Professionals that will participate in the 2015 Boston Kidney Walk on October 25th and we need your support.

To help fundraise for the team or to participate in the walk by joining the ISPE team, "ISPE Nephronators", go to: [http://donate.kidney.org/site/TR/Walk/NewEngland?pg=entry&fr\\_id=7592](http://donate.kidney.org/site/TR/Walk/NewEngland?pg=entry&fr_id=7592). Or, contact the office at 781-647-4773 or [office@ISPEBoston.org](mailto:office@ISPEBoston.org).

**Click below for full information and to register:**

[http://donate.kidney.org/site/TR/Walk/NewEngland?pg=entry&fr\\_id=7592](http://donate.kidney.org/site/TR/Walk/NewEngland?pg=entry&fr_id=7592)

### **Sneak Preview of Upcoming Events**

**Tuesday, October 20, 2015**

ISPE Fall Social  
TBD, Boston, MA

**Sunday, November 8, 2015**

Chapter Social at the ISPE Annual Meeting  
Hard Rock Cafe, Philadelphia, PA

**Sunday, November 8, 2015 - Wednesday, November 11, 2015**

ISPE Annual Meeting  
Philadelphia Marriott Downtown, Philadelphia, PA

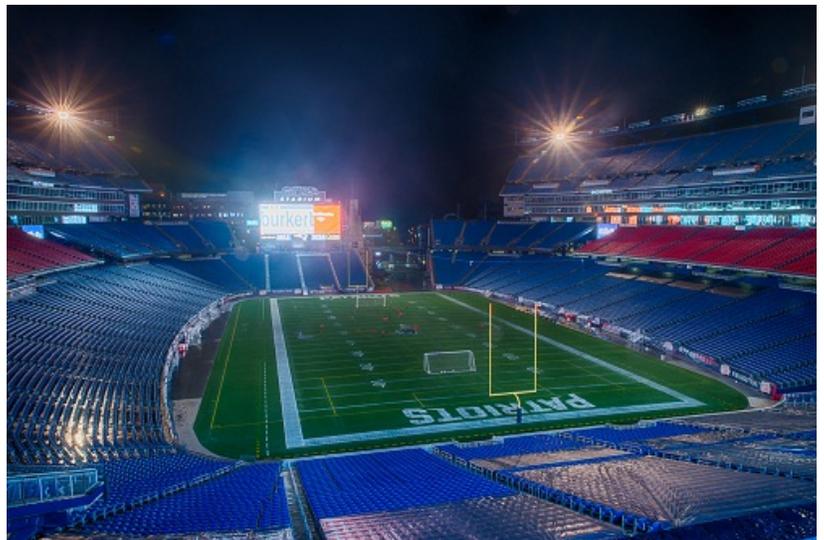
**Thursday, November 12, 2015**

ISPE Soft Skills: Death by Powerpoint  
Genzyme, Framingham, MA

### **Educational Programs, Vendor Exhibits, Career Fair & More – We've Got It All at the 2015 Product Show**

*by Mark Levanites, Sequence Quality and Compliance Services*

The 24th Annual ISPE Boston Area Chapter Product Show returns to Gillette Stadium in Foxborough on October 7, 2015 and what a Show we have in store. Whether you're a regular attendee or new to the Product Show we have stepped things up a notch this year and we know you'll be impressed. First things first...



Gillette Stadium provides a spectacular backdrop for the Annual Product Show.

### Why Attend?

We show you the future and deliver everything you need to bring your ideas to life. You'll see the most advanced technologies for enhancing production from beginning to end from [375+ top-tier vendors and service providers](#). Keep reading for more reasons why you don't want to miss out. And for a video and additional highlights of why you should attend click [here](#).



Over 375 premier vendors will display their products and services at the 2015 Product Show.

### Register Now

[Register online now](#) prior to the Show and then attend the Show to be entered automatically into our raffle to win our grand prize of lodging, dinner for two at Davios, and two tickets to see the New England Patriots play the New York Jets on October 25th. You must pre-register and attend the Show to be eligible to win!

### Plenary Session

A highlight of the Product Show, our annual plenary session brings together all attendees to hear keynotes from some of the most inspiring thought leaders who influence our field and our future. This year's speakers include:

- H. Steven Kennedy, President, ISPE Boston Area Chapter
- John Bournas, President & CEO, ISPE
- Andrew Skibo, Head of Global Biologics Operations & Engineering, MedImmune/AstaZeneca

Click [here](#) to learn more about our speakers and topics.

### Educational Program

The Chapter's Educational Program Committee has been hard at work developing a cutting-edge innovative education program for this year's Show. They have come up with four relevant and timely topics - providing the know-how you need to advance your business. In each session, top thought leaders offer insights on issues essential to the industry and provide a wealth of information relevant to your business.



This year's new, larger venue for the educational sessions ensures everyone gets a seat, no matter how popular the topic.

This year's sessions are expected to draw large audiences and for the first time they will be held in the plenary session area in the Northeast Lounge on the main show floor. No more cramped

suites an elevator ride away! Plus they will occur sequentially throughout the afternoon of the Show and will be spaced 30 minutes apart. This location and schedule will allow attendees to participate in all four sessions while taking breaks to meet with and learn from exhibitors.

- Keeping Up with Single-Use: An Introduction to Single-Use Manufacturing Systems Including a Survey of Technology, New Developments, and Economic and Operational Issues
- Implementing Innovative Technologies
- Oral Solid Dosage Baseline Guide Preview
- Bioprocessing Intensification: Strategies for handling High-Titer Mammalian-Based Bioprocess Systems

For more detailed information regarding these sessions, including speakers and schedule, click [here](#) or refer to the following article.

#### **Innovation Stage**

Vendor Showcases on the Innovation Stage in the Southeast Lounge will give you a firsthand look at the latest breakthrough technologies and techniques that you can use in your business. These free, 20-minute presentations are listed below:

- Best Practices for Developing Single-Use TFF Steps for Biopharmaceuticals  
*Todd Kapp, Sales and Market Development Manager, Parker domnick hunter*
- The Path to Container Closure Integrity  
*Oliver Stauffer, Vice President/COO, PTI Inspection Systems*
- Point-of-Use WF/PPW Systems  
*Bill Frohlich, Head of Global Business Development, Exergy*
- Single-Use Powder Transfer Solutions  
*Jeff Salack, Eastern Regional Sales Manager, ILC Dover LP*
- Cleanability You Can See  
*Andy Obertanec, Product Sales Specialist, Jacoby-Tarbox® (A Clark-Reliance® Company)*
- How Operational Data Analytics Deliver Real Business Value  
*Karim Bibawi, Executive Vice President, Cimetrics, Inc.*
- Multi-Variate Flow Measurement and Control with Alicat Scientific  
*Christopher B. Hack, President, King Gage Engineering*

For more detailed information regarding the vendor showcases, including times, click [here](#).

#### **Career Fair**

Held in conjunction with the Product Show, the newly expanded Career Fair will feature Human Resources representatives and Talent Acquisition teams from 40 companies. These premier companies in the biopharmaceutical field are looking for qualified and experienced professionals like you to join them! So be sure to swing by and say hello. You might find the opportunity of a lifetime waiting for you. For a listing of hiring companies attending click [here](#).

Also, don't miss out on your chance to update that outdated and unprofessional selfie you've been sharing with potential employers or clients. Come visit our photographer and get a complimentary professional headshot. You can thank us later for assisting you in landing that dream position you've been looking for! Click [here](#) for some tips on how to look your best for that photo before you head to the Show.

#### **Champions for Charity Pavilion**

One in nine American adults has kidney disease and most don't know it. With the increase in diabetes and high blood pressure - two major kidney disease risk factors - kidney disease is on the rise. The National Kidney Foundation (NKF) Kidney Walk is an inspiring community fundraiser that calls attention to the prevention of kidney disease and the need for organ donation.

This year, the ISPE Boston Area Chapter and The New England Patriots Charitable Foundation are joining together to sponsor a team of ISPE Members and colleagues that will participate in the 2015 Boston Kidney Walk on October 25th. And we need your support. Stop by the Champions for Charity pavilion in the West Clubhouse for an opportunity to meet Patriots alumni Steve Grogan and Joe Andruzzi, the Patriots cheerleaders. For a donation of \$20, you can have your photograph taken with these champions. Your donation will be included in the funds raised by the team and donated to the National Kidney Foundation on the day of the walk. Help make a difference for millions of people and support our team!



Photos with the Patriots cheerleaders are a popular fund raiser at every Product Show.

#### **After Party**

What would the Product Show be without our famous After Party? This year we will be at the brand new Optum Field Lounge located in the South end zone so you don't have to leave Gillette Stadium to enjoy the fun. This new location has over 20,000 sf of space with a field level terrace, HD screens, media walls, and premium bars - the perfect place to wind down after the Product Show!



Last but by no means least, relax with fellow Product Show attendees at the After Party at Gillette's brand new Optum Field Lounge.

Our special guest this year will be the man who snatched victory from the jaws of defeat - New England Patriot Malcolm Butler. He will be signing autographs and posing for pictures. Make sure to thank him for bringing the Superbowl trophy back to New England! And as a special treat, our musical entertainment for the evening will be provided by beloved Boston icon - Keytar Bear! So come and enjoy the food and festivities after the Show. Doors open at 6:30 pm your Product Show name tag is required for entry so be sure to bring it withyou!



Patriot's player Malcolm Butler takes the place of last year's Chandler Jones, pictured here. Selfies, anyone?

#### **New Product Show Website and Mobile App**

Take some time and checkout all the new features of our new and improved [website](#) for additional details about this year's Product Show. And keep in mind that there is no longer a hard copy of the Show Guide. So if you want to know where to find that exhibitor you have to meet with or the time of that must-see Educational Session or where and when your favorite food is being served, then download the [2015 ISPE Boston Area Chapter mobile app](#) today. Available for both Apple and Droid devices, it is your personal guide to the show.

And last but not least, be a hero like Malcolm Butler and tell your colleagues and friends to register for the show. They will thank you later and buy you a drink at the After Party! Who knows? If they win the raffle, they might even bring you to the game! See you October 7th at Gillette!

#### **Follow Us on Twitter**

Remember to follow us on Twitter at @ISPEProductShow for updates of the day's action. Tweet us pictures of your booth for maximum exposure, as we will retweet during the event for all our followers to see. Please feel free to use #ISPEProductShow in all your social media posts as well so attendees and exhibitors alike can more easily find you!

### **Industry Experts Offer Insights at Product Show Educational Program**

*by Howard Sneider, CRB*

The Boston Area Chapter Educational Program Committee is proud to present our educational offerings for the 2015 Product Show. Each topic addresses challenges our industry is currently facing or may face in the near future. In each session, top thought leaders offer insights on issues essential to the industry and provide a wealth of information relevant to your business. The presentations are geared to enlighten and engage a wide range of industry professionals and will be enjoyed by those with novice to expert levels of experience.



Large and conveniently located on the exhibit level, the new venue will more comfortably accommodate the standing-room-only crowds of years past.

This year the four presentations will occur sequentially throughout the afternoon of the Show. All sessions are conveniently located in the Northeast Lounge in the East Clubhouse, on the same level as the exhibit areas. Presentations are 60 minutes in length and spaced 30 minutes apart. This location and schedule will allow attendees to participate in all four sessions while taking

breaks to meet with and learn from exhibitors. For more information about these sessions, please see below.

In addition to these four sessions, there are two presentations designed especially for students (although young professionals and industry veterans could benefit from them as well and are welcome to attend). The first covers how to network at events like the Product Show and provides valuable insights on building your professional network and managing your career. The second introduces Quality Systems and why they are important to everyone working in the life sciences industry. For more information on these sessions, please see the following article on student-focused activities.

Sign up at <http://productshow.ispeboston.org/attendees/registration/> today to reserve your seat for the sessions below:

**12:30pm to 1:30pm | Keeping Up with Single-Use: An Introduction to Single-Use Manufacturing Systems, Including a Survey of Technology, New Developments, and Economic and Operational Issues**

This talk will present an overview of the state of the art in single-use manufacturing, including a survey of available technology and new developments. In addition, it will discuss quality aspects like vendor reliance and validation, economic pros and cons, and operational considerations for biopharmaceutical manufacturing in a single-use facility.

*Geoffrey Hodge, Bioprocess Technology Leader, Co-founder Xcellerex, Senior Vice President, UNUM Therapeutics*

**2:00pm to 3:00pm | Implementing Innovative Technologies**

Timing is everything. Everyone wants to be innovative, but deciding when, how, and who can be the difference between success and failure. Jorg Thommes, Biogen Senior Vice President of Operations Technology and Innovation, will share "Biogen's Approach to Biologics Manufacturing and the Role of Innovation in this Approach." James Hughes, Head of Engineering, Technical Services & EHS for AbbVie Bioresearch Centre, will discuss "Fostering an Innovative Culture in Technical Organizations and Building Strategic Value through Integration across Functions"

*Dr. Jorg Thommes, Senior Vice President of Operations Technology and Innovation, Biogen*  
*James Hughes, Head of Engineering EHS & Maintenance, Abbvie*

**3:30pm to 4:30pm | Oral Solid Dosage Baseline Guide Preview**

The ISPE Baseline Guides are internationally accepted guidance tools to aid in the development of solutions for new and renovated biopharma manufacturing facilities. The Oral Solid Dosage (or OSD) Baseline Guide Volume 3 rewrite, is currently being finalized and is under industry review. This talk will highlight some of the revisions included in the guide and will discuss the implications of these changes.

*Jack Chu, PE, Associate Director of Engineering, Merck*

**5:00pm to 6:00pm | Bioprocessing Intensification: Strategies for Handling High-Titer Mammalian-Based Bioprocess Systems**

This presentation will highlight the latest separation and purification technologies, processing methods and engineering strategies for handling increased productivity of high-titer harvests. Our speaker will discuss some of the scale-up challenges that accompany these technologies including ways of modifying process and facility design. An emphasis will be placed on strategies that operate within the footprint of facilities designed to handle lower-titer processes. The process optimizations discussed here may be applied to both high cell density mammalian cell harvest and high impurity process intermediate streams.

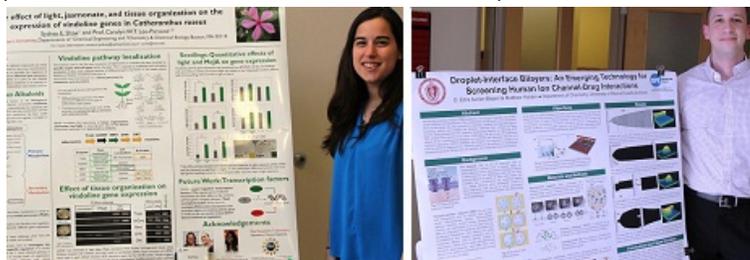
*Jonathan Romero Ph.D., Associate Director, Operations Technology and Innovation, Biogen*

**Product Show Draws Students with Special Activities & Free Buses**

*by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer*

The Annual Product Show at Gillette Stadium is one of the industry's premier events and it will be a magnet for students this year, with a brand new cluster of student-focused activities built into the program. To encourage students to attend, the Chapter will provide free bus transportation from several area campuses - watch your email for more detailed information.

Our first order of business for students is to help the winners of our Annual Student Poster Contest get ready for the international-level competition at the ISPE Annual Meeting in November. We've enlisted help from the Chapter's Board of Directors and several judges to help our students polish their presentations. Students will be showing off their posters and practicing their presentations in the VIP area at Gillette from 1:30 to 2:00pm.



[Help local winners prepare for the international-level Poster Competition at Annual Meeting.](#)

Next, we have two educational sessions specifically designed for students, although young professionals and industry veterans could benefit from and are welcome to attend these programs as well. The first program covers how to network at events like the Product Show and provides valuable insights on building your professional network and managing your career. The

second program introduces Quality Systems and why they are important to everyone working in the life sciences industry.

The Chapter will also be introducing its first-ever competition between Student Chapters with students selecting their topics and doing their initial research using the vast product resources and subject matter experts available at the Product Show.

Lastly, the Young Professionals Committee (YPC) is hosting a networking social from 5:00 to 6:00pm in the Southeast Lounge where students and young professionals can meet, mingle and network in a relaxed atmosphere. The YPC always does a great job with this event, so expect some surprises along with great food and camaraderie.



The Product Show provides many opportunities to relax with friends, old & new.

Of course, all of these student-focused activities are merely icing on the cake. With over 375 booths this year, the exhibit area will provide an education in the life sciences industry for students who walk the aisles to view the thousands of products and services on display. And the Career Fair will provide an introduction to many of the industry leaders currently hiring in the Boston Area. So mark your calendars and plan to attend the Product Show on October 7. You'll be glad you did!



The exhibit area offers a comprehensive introduction to the life sciences industry.

**1:30pm - 2:00 pm | Student Poster Presentations | West Clubhouse, South Red Level Landing**

Help the winners of the Annual Student Poster Contest polish their presentations in preparation for the international-level competition in November.

**2:00 pm - 3:00 pm | How to Network Successfully at the Product Show | West Clubhouse, South Red Level Landing**

Events like the Product Show are great places to meet professionals in the life sciences industry and excellent opportunities to build your network. Come to this session to learn how to make a strong first impression when meeting people and build your network.

**3:30pm - 4:30pm | Quality Systems - What Are They and How Can They Give Me an Edge? | West Clubhouse, South Red Level Landing**

Quality Systems are an essential part of the life sciences industry. This presentation will help you understand what Quality Systems are and why they exist. Come learn the industry lingo as well as the elements that make up a good Quality System from two recognized experts in the field.

**5:00pm - 6:00pm | Young Professionals Networking Hour | East Clubhouse, Southeast Lounge**

Whether you are in college, a recent graduate, or a working professional with a few years of

experience, the Young Professionals Networking Hour is a great way to relax and meet your peers after a day at the Product Show.

## **YPs Launch Champions for Charity and Networking Hour**

*by Peter Trearchis, Pfizer*

This year the Boston Area Chapter has put together another great Product Show at Gillette Stadium! With the keynote address, exhibits, vendor showcases, educational sessions, student development programs, networking opportunities and numerous other activities there is lots to see and do once again! Educational sessions this year range from single-use technology discussions to high titer processing strategies designed for industry professionals, and programs for students providing valuable information on networking and quality systems for those preparing for their entry into the workplace.



The Young Professionals Committee (YPC) has helped to plan two events at this year's Show: Champions for Charity and the Young Professionals Networking Hour. First a little background on Champions for Charity. The National Kidney Foundation (NKF) Boston Kidney Walk is a fundraiser promoting the prevention of kidney disease and the need for organ donation. This year, it is taking place on Sunday, October 25 and the Boston Area Chapter has joined with the New England Patriots Charitable Foundation to sponsor a team of ISPE Members and colleagues - the ISPE Nephronators - who will take part in the walk.

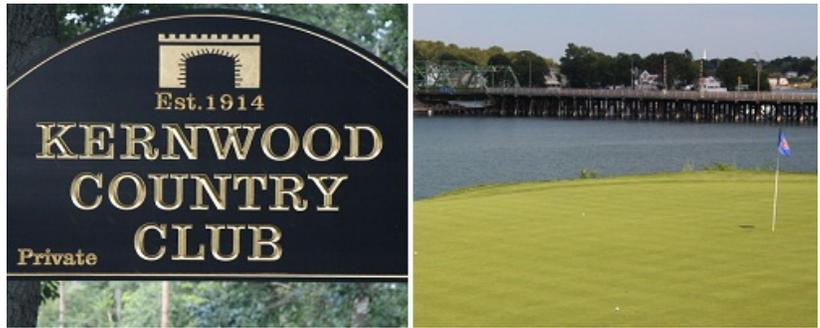
To support the team and help raise money for the NKF, visit the Champions for Charity pavilion in the West Clubhouse from 1:00 to 5:00pm. For a donation of \$20, you can have your photograph taken with Patriots alumni Steve Grogan and Joe Andruzzi, and the Pats cheerleaders! Your donation will be included in the funds raised by the team and donated to the NKF on the day of the walk. This is a great opportunity to give back to the community, which is part of the mission of the Boston Area Chapter. The Boston Kidney Walk is the largest walk of its kind in the country so be sure to stop by the Champions for Charity pavilion and contribute to this worthy cause!

On a lighter note, for those wanting to make connections with young colleagues around the industry and to see how we can assist you in learning more about the biotech community, please stop by the Young Professionals' Networking Hour sponsored by the YPC. Whether you're in college, a recent grad or a working professional with a few years' experience, the YPC is a great way to network, have fun, give back to ISPE and continue learning about the industry as you begin or progress in your career. The event will be held from 5:00 to 6:00pm in the Southeast Lounge with refreshments and the opportunity to win gift cards from a raffle drawing. Be sure to stop by and say hi!

## **Summer Golf Outing Returns to Kernwood Country Club in August**

*by Jim Grunwald, Commissioning Agents, with photos by Brian Hagopian, Clear Water Consulting*

The Chapter's Summer Golf Outing on August 17th was a great success again this year with our host venue Kernwood Country Club in Salem, MA providing an amazing experience on this North Shore jewel. A full field was greeted with the course in tournament shape, amazing hospitality shown by the Kernwood staff, great food and camaraderie.



The views are always a distraction at exclusive Kernwood Country Club in Salem.

During the tournament, summer weather was in full force tempered by the afternoon sea breeze on the incoming tide. The competition was very keen and our winners were:

- **Winning Foursomes**
  - 1st - Reflex Lighting (Richard Trabucco, Jerry Nadeau, Joe Reilly, Joe Devlin)
  - 2nd - Interstate Electrical (Sal LaFauci, Tom Perry, Mike Walker, Jeff Walker)
  - 3rd - The Wilkinson Companies (Dan Paquette, Herbie Aikens, Geoff Wilkinson, Peter DeGennaro)
- **Longest Drive**
  - Arthur Weglewski
  - Magali Franceschini
- **Straightest Drive**
  - Bill Sayles
  - Magali Franceschini
- **Closest to the Pin**
  - Neal Corbett
  - Dianne Barrette

The Chapter would like to thank everyone who attended and made the tournament a success; and event volunteers Paul Sullivan, Jim Grunwald and Brian Hagopian, and our CAMI administrative staff for producing a great event.



Congratulations to the winning foursomes (top to bottom): 1st Place - Reflex Lighting; 2nd Place - Interstate Electrical; and 3rd Place - The Wilkinson Companies.

Lastly, we would like to extend a special thank you to all of our sponsors for making this event possible and for contributing to our Joel Goldenberg Memorial Scholarship Fund, now in its fifth year, the recipient of the event's proceeds. In addition to supporting the Scholarship Fund, the event's 50/50 raffle returned nearly \$800 for Children's Hospital, this year's chosen charity.



[Congratulations to double-winner Magali Franceschini of Shire.](#)

Many thanks to our event sponsors - your support is greatly appreciated:

- Albireo Energy
- A/Z Corporation
- Commissioning Agents
- Commodore Builders
- Cotter Brothers
- HDR
- Holloway America
- Interstate Electrical Services
- JC Cannistraro
- Middlesex Gases & Technology
- NorthEast Electrical Distributors
- North Star Contracting Group
- PIDC Construction
- RW Sullivan Engineering
- The Richmond Group
- Sentrol
- Shawmut Design & Construction
- Superior Controls
- The Wilkinson Companies

Hope to see everyone at next year's golf outings scheduled for May and August as well as at all of our upcoming summer and fall events! And if you're interested in volunteering on the Social Programs Committee please contact Dan Kenny at [dkenny@northeastengineering.com](mailto:dkenny@northeastengineering.com).

### **YP Planning Starts Strong**

*by Chris Ciampa, Thermo Fisher Scientific*

The Chapter's Young Professionals have been plenty busy since I last checked in. Planning for the remainder of 2015 and the upcoming year is in full swing and I assure you that many great opportunities will come out of the Young Professionals Committee! Among other initiatives, we are looking to partner up and collaborate more with our Student Chapters. There is also potential for a mentoring program that will be gearing up in the next few months. The purpose is to match interested mentors with mentees for a year-long partnership that will help mentees achieve their career objectives.

From a social media perspective, the YP LinkedIn page has been revamped and re-launched. This will be yet another way for news and updates to be pushed to our YP members. The name of the group is "ISPE Boston Area Chapter Young Professionals." Anyone is welcome to become a member of the group and we appreciate any feedback, ideas and comments you wish to disseminate through that group.

Our YP flagship event, the annual Boston Harbor cruise, took place this year on September 3. By the time you read this, the event will have taken place. As always, this was a great opportunity for new and returning members - both YPs and industry veterans - to enjoy an evening of socializing and networking in a beautiful Boston setting on a warm summer's night. And another great example of the energy and capabilities of the Chapter's YPs!

Calling all students, young professionals and members of the Boston Area Chapter: the Annual Product Show will take place at Gillette Stadium on Wednesday, October 7! By now you have

heard the many reasons to attend so I will focus on what is happening from the YP perspective. This year, the YPs have added a new focus with a charitable fund raising event planned for October 25 (see below for more information). There will be a booth at the Product Show promoting this effort and selling tickets. If you're interested in helping to man the booth, there are half-hour slots available between 1:00 and 3:00pm. Please let Jared or myself know or contact the Chapter office if you would like to help.

And as always, the YPs will sponsor a networking social at the Show - always a great opportunity to take a break from walking the exhibit floor and meet and mingle with students and young professionals. This year's event will be held from 5:00 to 6:00pm in the Southeast Lounge. Hope to see you there!

It has long been a tradition of the Boston Area Chapter to give back not only to its Members but also to the community. This year, the Chapter and the New England Patriots Charitable Foundation are joining together to sponsor a team of YPs that will participate in the 2015 Boston Kidney Walk on October 25 and we need your support. Our team is called the "ISPE Nephronators" based on the Terminator series (and, yes, I was a huge fan of Terminator Genisys - I will not include any spoilers for those who still haven't see the film but it definitely compliments the series well) and the prefix nephro, Greek for kidney. The event starts at 9:30am and takes place at Canal Park in Cambridge. If you are interested in donating, walking and/or volunteering, please don't hesitate to contact me at [christopher.ciampa@gmail.com](mailto:christopher.ciampa@gmail.com) or the Chapter office at 781-647-4773 or [office@ISPEBoston.org](mailto:office@ISPEBoston.org) - or stop by the booth at the Product Show.

Coming up on November 12 will be a dual-track educational program at Genzyme in Framingham with a focus on "soft" skills. The speakers and topics have not yet been confirmed, however possible topics for the introductory track include: making your first career change, conflict resolution, and technical writing. Dual-track programs are always great opportunities for students and YPs to network with other Members, so please stay tuned for more information.

As always, we want to hear from you! If you have any suggestions, or would like to attend one of the regularly scheduled YPC meetings, please don't hesitate to reach out to me ([christopher.ciampa@gmail.com](mailto:christopher.ciampa@gmail.com)) or Jared Marshall ([jaredbmarshall@gmail.com](mailto:jaredbmarshall@gmail.com)). Thank you for tuning in and I hope to see you soon!

### **Student Development Planning Pays Dividends**

*by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer*

The Chapter is really excited about the upcoming year as we strive for greater levels of involvement with each of our eleven Student Chapters. We're fresh off a summer strategic planning meeting where some great ideas were put forward to further support the Chapter's program to nurture deeper and deeper relationships with our Student Chapters. Thanks to the valuable input from our faculty advisors, we have some great plans for the upcoming fall semester including:

- Campus visits to promote the Chapter and the Product Show
- Buses for students to and from the Product Show
- New "school vs. school" competition kicking off at the Product Show
- Promotional video to show students the benefit of joining ISPE

We're working out the final details of the school vs. school competition and will unveil the program on campuses shortly. We're also actively seeking students, recent grads and long-time Chapter Members willing to be interviewed for our promotional video. Please contact the Chapter office at [office@ISPEBoston.org](mailto:office@ISPEBoston.org) or email me at [brian@clear-water-consulting.com](mailto:brian@clear-water-consulting.com) if you are interested.



**The Chapter's Annual Career Workshop is one of the many programs designed to help Student Members prepare for careers in the biopharm arena.**

We're also pleased and excited to announce the spring round of scholarship winners. Congratulations to the following students on their achievements and remember - the deadline for the upcoming round is November 1. Visit our website at <https://scholarships.ispeboston.org/scholarships/> for more information.

Connor Brown	Assumption College
John Busanovich	Boston College
Jennifer Langh	Northeastern University
Kelsey Martin	UMass Lowell
Samuel Musiak	UMass Lowell
Satyajeet Salvi	Hampshire College
Nathaniel Swanson	UMass Lowell
Peter Trearchis	Tufts University
Matthew Woodard	University of Hartford

And as always, there will be lots of exciting activities especially for students at the Annual Product Show on October 7 at Gillette Stadium, along with free buses for students to and from the event. For more information, visit the Product Show Preview section of the newsletter. Hope to see you on the 7th!

## 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.

### Lonza and Alexion Agree to Long-Term Agreement, Increased Production in Portsmouth

Lonza has announced the signing of a new long-term product supply agreement with Alexion. Lonza will construct a new suite as part of its Portsmouth, NH site; the new large-scale manufacturing line will be operational by the end of 2017. Lonza already manufactures Alexion products at multiple facilities as part of another existing manufacturing agreement. (Source: Lonza.com, 02 July, 2015)

### Danaher Will Split into Two Companies, Acquire Pall

Danaher Corporation has announced its intention to separate the company into two independent, publicly traded companies. The transaction will create:

- A science and technology company retaining the Danaher name. The company will include Danaher's existing Life Sciences & Diagnostics and Dental segments, and Water Quality and Product Identification platforms.
- An industrial company comprised of Danaher's Test & Measurement Instruments platform including Matco, Gilbarco Veeder-Root, Automation and Sensors, and its other specialty industrial businesses

The transaction is expected to occur through a tax-free separation. The Company is targeting to complete the separation around the end of calendar year 2016. In addition, Danaher will acquire Pall Corporation for \$127.20 per share in cash, or \$13.8 billion including assumed debt and net of acquired cash. The consideration represents approximately a 28 percent premium to Pall's common stock over the closing price of \$99.31 on May 11, 2015, the last trading day prior to initial media speculation around a possible transaction. The transaction is not subject to any financing conditions.

Upon completion of the transaction, Pall will operate as a subsidiary in Danaher's portfolio and will maintain its brand. The transaction was approved by Pall Shareholders on July 28 and is subject to customary closing conditions. It is expected to close by the end of 2015. (Source: news.pall.com, 12 May, 2015 and 29 July, 2015; Danaher.com, 13 May, 2015)

### Biogen Second Quarter Revenues Increase, Company Decreases Earnings Outlook

Biogen reported second quarter 2015 results, including revenues of \$2.6 billion, a 7 percent increase compared to the second quarter of 2014. Non-GAAP diluted earnings per share (EPS) for the second quarter of 2015 were \$4.22, an increase of 21 percent over the second quarter of 2014. The company also decreased its projected 2015 earnings outlook. Revenue growth is now expected to be approximately 6 to 8 percent compared to 2014, a decrease from prior guidance of 14 to 16 percent. The decrease is based largely on revised expectations for the growth of Tecfidera. (Source: Media.biogen.com, 24 July 2015 and 29 January, 2015)

### Genzyme Acquires Thyroid Cancer Drug from AstraZeneca

Genzyme has entered into a definitive agreement with AstraZeneca to acquire Caprelsa (vandetanib), a rare disease therapy indicated for the treatment of symptomatic or progressive medullary thyroid carcinoma in patients with unresectable locally advanced or metastatic disease. Caprelsa is an oral kinase inhibitor treatment and is currently available in 28 countries. Caprelsa is also in Phase III development for differentiated thyroid carcinoma, with the study expected to finish in the second half of 2015.

Under the terms of the agreement, Genzyme will pay AstraZeneca up to \$300 million, including an upfront payment of \$165 million to acquire the global rights to sell and further develop Caprelsa, and further development and sales milestone payments of up to \$135 million. The

transaction does not include the transfer of any AstraZeneca employees or facilities.

The transaction is subject to closing conditions, including the receipt of antitrust clearance from the US Federal Trade Commission. The transaction is expected to complete in the second half of 2015. (Source: News.genzyme.com, 27 July, 2015)

### **Cholesterol Treatment Competition Heats Up with Approvals for Amgen's Repatha in Europe and Sanofi/Regeneron's Praluent in US**

On July 21, the European Commission (EC) granted marketing authorization for Amgen's Repatha (evolocumab), the first proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor to be approved in the world, for the treatment of patients with uncontrolled cholesterol who require additional intensive low-density lipoprotein cholesterol (LDL-C) reduction. Repatha is a human monoclonal antibody that inhibits PCSK9, a protein that reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood. Elevated LDL-C is an abnormality of cholesterol and/or fats in the blood, and is recognized as a major risk factor for cardiovascular disease (CVD).

Approval from the EC grants a centralized marketing authorization with unified labeling in the 28 countries that are members of the EU. Norway, Iceland and Liechtenstein, as members of the European Economic Area (EEA), will take corresponding decisions on the basis of the decision of the EC.

Following the EC decision, the FDA approved Sanofi/Regeneron's own PCSK9 Inhibitor Praluent (alirocumab), on July 24. The European Medicine Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has also adopted a positive opinion for the marketing authorization of Praluent, recommending its approval for use in certain adult patients with hypercholesterolemia. The European Commission (EC) is expected to make a final decision on the Marketing Authorization Application for Praluent in the European Union in September 2015. (Source: Amgen.com, 21 July, 2015)

### **Teva Withdraws Mylan Offer, Will Acquire Allergan Generics for \$40.5 Billion**

Teva Pharmaceuticals has announced that it has withdrawn its cash and stock proposal to acquire all of the outstanding ordinary shares of Mylan. The company does not intend to continue to pursue a transaction with Mylan at this time. Teva also announced that it has signed a definitive agreement with Allergan to acquire Allergan Generics in a transaction valued at \$40.5 billion. Upon closing, Allergan will receive \$33.75 billion in cash and shares of Teva valued at \$6.75 billion, representing an estimated under 10 percent ownership stake in Teva. The transaction was unanimously approved by the Boards of Directors of Teva and Allergan and is expected to close in the first quarter of 2016. (Source: Tevapharma.com 27 July, 2015)

### **Regeneron and Sanofi Launch New Immuno-Oncology Collaboration**

Regeneron and Sanofi have entered into a new collaboration to discover, develop and commercialize new antibody cancer treatments in the field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor currently in Phase 1 testing and plan to initiate clinical trials in 2016 with new therapeutic candidates based on ongoing preclinical programs.

Sanofi will make an upfront payment to Regeneron of \$640 million, and the companies will invest \$1 billion for discovery through proof of concept (POC) development (usually a Phase 2a study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25 percent by Regeneron (\$250 million) and 75 percent by Sanofi (\$750 million). The companies have also committed to equally fund an additional \$650 million (or \$325 million per company) for development of REGN2810, a PD-1 inhibitor.

In addition, Sanofi will pay Regeneron a one-time milestone of \$375 million in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product exceed, in the aggregate, \$2 billion in any consecutive 12-month period. Finally, the two companies have agreed to reallocate \$75 million (over three years) for immuno-oncology antibodies from Sanofi's \$160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

The new agreement covers both monoclonal antibodies and new bi-specific antibodies, a variation of standard antibody therapeutics in which two distinct targets within the body can be bound by the same molecule, usually the cancer cell and an immune cell. Regeneron has developed a novel and flexible manufacturing platform that enables efficient production of bispecific antibodies that are otherwise similar to natural antibodies. Beyond PD-1, other programs in preclinical development include antibodies to lymphocyte-activation gene 3 (LAG3), glucocorticoid-induced tumor-necrosis-factor-receptor-related protein (GITR) and a programmed death ligand (PD-L1) inhibitor. Finally, the collaboration is advancing bi-specific antibodies that target hematologic and solid cancers, either as monotherapies or in combination regimens with other immune modulating treatments. (Source: regeneron.com, 28 July, 2015)

### **Baxalta Drug Granted FDA Priority Review, Company Rejects Offer from Shire**

Baxalta launched on July 1, 2015 following separation from Baxter International. While still headquartered in Northern Illinois, its new Global Innovation and R&D Center is located in Cambridge, MA. Baxalta employs 16,000 employees worldwide.

A week prior to the official separation, Baxalta got some good news on its collaboration with Merrimack Pharmaceuticals on MM-398 for treatment of patients with metastatic adenocarcinoma of the pancreas. The New Drug Application (NDA) for MM-398 was granted priority review by the FDA. The agency has set a goal of October 24, 2015 to take action under the Prescription Drug User Fee Act (PDUFA).

In August, Shire confirmed that it made a private proposal to Baxalta on July 10, 2015 to combine the companies in an all-stock transaction in which Baxalta shareholders would receive, for each Baxalta share, 0.1687 Shire ADRs. The proposal implied a value of \$45.23 per Baxalta share and represented a premium of 36 percent over Baxalta's stock price as of August 3, 2015.

Baxalta's Board of Directors reviewed the proposal and unanimously determined that it was not in the best interests of Baxalta or its shareholders. Baxalta's Chairman of the Board of Directors stated the offer undervalues Baxalta and a merger would be disruptive at such an early stage of Baxalta's existence. (Source: baxalta.com, 04 August 2015; shire.com 04 August 2015, 01 July 2015, 25 June 2015)

### **Shire Acquires Privately Held Foresight Biotherapeutics**

Shire announced that it has acquired New York-based, privately held Foresight Biotherapeutics for \$300 million. With the acquisition, Shire acquires the global rights to FST-100 topical ophthalmic drops, a therapy in late-stage development for the treatment of infectious conjunctivitis, an ocular surface condition commonly referred to as pink eye.

Currently no therapy exists to resolve both clinical signs and symptoms and eradicate adenovirus, which is the most common cause of viral conjunctivitis. Approximately 50 percent of infectious conjunctivitis cases have a viral etiology, and 65 to 90 percent of these are caused by adenovirus. Viral conjunctivitis is highly infectious and transmissible, causing lost work and school days as well as increased healthcare costs and risks from unnecessary antibiotic prescriptions. There are 5.9 million cases of infectious conjunctivitis annually in the United States and approximately 5.4 million cases in the EU annually.

If approved by regulatory agencies, FST-100 has the potential to become the first agent to treat both viral and bacterial conjunctivitis. This is important as it is frequently difficult to ascertain the etiology of the condition based on clinical presentation. (Source: shire.com, 03August 2015)

### **ConforMIS Goes Public, Stock Price Increases from \$15 to \$24 in First Days of Trading**

NASDAQ trading began for Bedford-based ConforMIS on July 1. The Initial Public Offering closed on July 7. ConforMIS is a medical technology company that uses its proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped to fit each patient's unique anatomy. ConforMIS offers a broad line of customized knee implants designed to restore the natural shape of a patient's knee.

The company offered 10,350,000 shares of common stock at a public offering price of \$15 per share, before underwriting discounts, including 1,350,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the public offering price, less the underwriting discount. The stock price closed at over \$24 on July 6. (Source: conformis.com, 07 July 2015)

### **Biogen to Build New Facility in Switzerland**

Biogen has signed a preliminary contract with the Swiss canton of Solothurn. The company plans to invest one billion Swiss francs in the town of Luterbach to build a new production plant employing up to 400 people. The company would start hiring a new workforce for the facility in 2019. (Source: www.so.ch, 30 June 2015)

**Bristol-Myers Squibb Expands R&D in Cambridge, Will Close Wallingford, CT and Waltham Sites**

Bristol-Myers Squibb Company announced plans to open a new research site in Cambridge in addition to the ongoing expansion of the company's R&D Discovery site in the San Francisco Bay Area. The new facility in Cambridge, which will be located at 100 Binney Street in Kendall Square, is expected to open in 2018. The ongoing site expansion in the San Francisco Bay Area adds 61,000 square feet of laboratory and office space and is expected to be completed in 2016. This decision does not impact the company's marketed products in virology.

In Cambridge, BMS scientists will focus on the company's ongoing discovery efforts in genetically defined diseases, molecular discovery technologies and discovery platform chemistry. In addition to relocating up to 200 employees from its Wallingford, CT and Waltham sites, and a limited number from its central New Jersey locations, the company expects to recruit scientists from the Cambridge area. As part of this transition, the Waltham site is expected to close in early 2018. The existing site in Wallingford will also close in early 2018 with up to 500 employees relocating to a new location in Connecticut. (Source: news.bms.com, 25 June, 2015)

### **Vertex and Parion Sciences to Collaborate on Cystic Fibrosis and Other Pulmonary Diseases**

Vertex Pharmaceuticals and Parion Sciences announced that the companies will collaborate to develop investigational epithelial sodium channel (ENaC) inhibitors for the potential treatment of cystic fibrosis (CF) and other pulmonary diseases. Under the agreement, Vertex gains worldwide development and commercial rights to Parion's investigational ENaC inhibitors, including P-

1037 and P-1055, for CF and other pulmonary diseases. P-1037 is currently being evaluated in an exploratory Phase 2a study in people with CF, regardless of genotype.

Vertex and Parion plan to begin an additional Phase 2a study that adds P-1037 to treatment with the investigational combination of lumacaftor and ivacaftor for people with CF who have two copies of the F508del mutation. Parion will receive an \$80 million up-front payment from Vertex with the potential to receive additional development and regulatory milestone payments and tiered royalties related to P-1037 and P-1055 in CF and other pulmonary diseases.

Cystic fibrosis is a rare genetic disease that is caused by defective or missing cystic fibrosis transmembrane conductance regulatory (CFTR) proteins resulting from mutations in the CFTR gene. The defective or missing CFTR proteins result in poor flow of salt and water into and out of the cell in a number of organs, including the lungs. The defective CFTR protein that causes CF is also believed to increase the function of ENaC, which may contribute to dehydration of the cell surface of lungs in people with CF. In CF, the poor flow of salt and water in cells prevents cilia on the surface of the cell from beating properly, which leads to a buildup of abnormally thick, sticky mucus that can cause chronic lung infections and progressive lung damage, eventually leading to death.

Beyond CF, Vertex and Parion plan to conduct additional Phase 2a studies of P-1037 across multiple other pulmonary diseases where the disease results in defective hydration of the cell surfaces in the lung. These diseases include Chronic Obstructive Pulmonary Disease (COPD), Non-CF Bronchiectasis (NCFB) and Primary Ciliary Dyskinesia (PCD). Parion will conduct Phase 2a development in these diseases and retains an option to participate in co-development and co-commercialization activities related to one of these non-CF pulmonary diseases. (Source: investors.vrtx.com, 04 June, 2015)

### **Teva and Lexington-based Microchips Biotech Announce Partnership**

Teva Pharmaceuticals and Microchips Biotech have announced that they have entered into a partnership in which the companies will explore ways to apply Microchips Biotech's implantable drug delivery device to Teva's portfolio of products with the goal of enhancing results for patients on chronic drug therapies. Microchips Biotech's electronic device is made up of microchip arrays that can store hundreds of therapeutic doses of drug for periods ranging from months to years and releases each dose at precise times. The device can be programmed to release drug on a pre-determined schedule and will have wireless control features.

Under the terms of the agreement Teva will make a \$35 million upfront payment to Microchips Biotech in the form of an equity investment and technology access fee. The partnership has an initial focus on one selected disease area, but will provide Teva with the option to later expand the program into several additional therapeutic areas and sensing applications that are proprietary to Teva. As programs advance, Microchips Biotech will receive development and commercial milestone payments and royalties on future product sales.

Microchips Biotech will also receive funding to develop products for any future additional indications Teva may develop, and Teva will be responsible for Phase II and Phase III clinical development and regulatory filings.

The microchip-based implant is a self-contained hermetically-sealed drug delivery device that is easy to implant and remove by a physician. The implant has been clinically validated in human studies delivering parathyroid hormone in osteoporosis patients. The microchip-based technology was originally developed at MIT by researchers Robert Langer, Ph.D. and Michael J. Cima, Ph.D. (Source: microchipsbiotech.com, 18 June, 2015)

### **Sanofi Reorganizes, Genzyme Will Get New Name, Products**

Sanofi announced plans to reorganize its business with the creation of five Global Business Units:

- General Medicines & Emerging Markets will be led by Peter Guenter and will consist of Sanofi's Established Products, Generics, Consumer Healthcare, and all pharmaceutical businesses in Emerging Markets.
- Specialty Care, to be called Sanofi Genzyme, will be led by David Meeker and will consist of Sanofi's medicines in Rare Diseases, Multiple Sclerosis, Oncology and immunology, including two, investigational biologics currently under Sanofi organizations
- Diabetes & Cardiovascular will be led by Pascale Witz and will consist of Sanofi's Diabetes Care medicines as well as Cardiovascular, which includes Praluent (alirocumab), which is currently under review by the European Medicines Agency (EMA) and recently approved by the FDA
- Sanofi Pasteur, a current Global Business Unit
- Meril, a current Global Business Unit

This new structure will be implemented beginning in January 2016. The composition of the Executive Committee remains unchanged. The leadership roles are effective January 1, 2016. (Source: en.sanofi.com, 15 July, 2015)

## **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 New Antiplatelet Drug Used During Heart Procedure**

The FDA has approved Kengreal (cangrelor), an intravenous antiplatelet drug manufactured by The Medicines Company based in Parsippany, New Jersey. Kengreal prevents formation of harmful blood clots in the coronary arteries, the blood vessels that supply blood to the heart. It is approved for adult patients undergoing percutaneous coronary intervention (PCI), a procedure used to open a blocked or narrowed coronary artery to improve blood flow to the heart muscle.

According to the Centers for Disease Control and Prevention, PCI is performed on approximately 500,000 people in the US each year. The coronary arteries are opened by inflating a balloon at the site of the narrowing, usually followed by placement of a small mesh tube, called a stent, to keep the artery open. By preventing platelets from accumulating, Kengreal reduces the risk of serious clotting complications related to the procedure, including heart attack and clotting of the stent (stent thrombosis). (Source: FDA Website, 22 June, 2015)

## **Vertex Wins FDA Approval for Orkambi for Treatment of Cystic Fibrosis**

The U.S. Food and Drug Administration today approved the first drug for cystic fibrosis directed at treating the cause of the disease in people who have two copies of a specific mutation. Orkambi (lumacaftor 200 mg/ivacaftor 125 mg) is now approved to treat cystic fibrosis (CF) in patients 12 years and older, who have the F508del mutation, which causes the production of an abnormal protein that disrupts how water and chloride are transported in the body. Having two copies of this mutation (one inherited from each parent) is the leading cause of CF.

Orkambi received FDA's breakthrough therapy designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies. The FDA also reviewed Orkambi under the priority review program. A priority review is conducted over six months, or less, instead of the standard 10 months, and is employed for drugs that may offer significant improvement in safety or effectiveness in treatment over available therapy in a serious disease or condition.

In addition, the FDA granted Orkambi orphan drug designation because it treats cystic fibrosis, a rare disease. Orphan drug designation provides financial incentives, like clinical trial tax credits, user fee waivers, and eligibility for market exclusivity to promote rare disease drug development.

CF is a serious genetic disorder that results in the formation of thick mucus that builds up in the lungs, digestive tract and other parts of the body leading to severe respiratory and digestive problems, as well as other complications such as infections and diabetes.

CF, which affects about 30,000 people in the United States, is the most common fatal genetic disease in Caucasians. The F508del mutation is the most common cause of CF. People who have two copies of the F508del mutation, one inherited from each parent, account for approximately half of the CF population in the U.S. (Source: FDA Website, 2 July, 2015)

## **FDA Approves New Drug from Novartis to Treat Heart Failure**

The FDA has approved Entresto (sacubitril/valsartan) tablets for the treatment of heart failure. Entresto is manufactured by Novartis, based in East Hanover, New Jersey. The drug has been shown to reduce the rate of cardiovascular death and hospitalization related to heart failure.

Heart failure is a common condition affecting about 5.1 million people in the United States. It is a condition in which the heart can't pump enough blood to meet the body's needs. Heart failure generally worsens over time as the heart's pumping action grows weaker. The leading causes of heart failure are diseases that damage the heart, such as heart attacks and high blood pressure. (Source: FDA Website, 07 July, 2015)

## **FDA Approves AstraZeneca's First-Line Treatment for a Type of Metastatic Lung Cancer**

The FDA has approved Iressa (gefitinib) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors harbor specific types of epidermal growth factor receptor (EGFR) gene mutations, as detected by an FDA-approved test.

Iressa is a kinase inhibitor that blocks proteins that promote the development of cancerous cells with certain EGFR mutations. It is intended for the treatment of patients whose tumors express the most common types of EGFR mutations in NSCLC (exon 19 deletions or exon 21 L858R substitution gene mutations). The theascreen EGFR RGQ PCR Kit was approved as a companion diagnostic test to identify patients with tumors having the EGFR gene mutations in order to determine which patients would be appropriate for treatment with Iressa.

The FDA granted Iressa orphan product designation for the treatment of EGFR mutation-positive metastatic NSCLC. Orphan product designation is given to drugs intended to treat rare diseases, which provides financial incentives - like tax credits, user fee waivers, and eligibility for market exclusivity - to promote their development.

Iressa is marketed by Wilmington, Delaware-based AstraZeneca Pharmaceuticals. The theascreen EGR RGQ PCR Kit is manufactured by QIAGEN Manchester Ltd., based in the United Kingdom. (Source: FDA Website, 13 July, 2015)

## **FDA Approves Abbvie's Technivie for Chronic Hepatitis C Genotype 4**

The FDA has approved Technivie (ombitasvir, paritaprevir and ritonavir) for use in combination with ribavirin for the treatment of hepatitis C virus (HCV) genotype 4 infections in patients without scarring and poor liver function (cirrhosis). Technivie in combination with ribavirin is the first drug that has demonstrated safety and efficacy to treat genotype 4 HCV infections without the need for co-administration of interferon, an FDA-approved drug also used to treat HCV infection. The three drugs included in Technivie are also included in Viekira Pak, previously approved for the treatment of HCV genotype 1 infection. Technivie and Viekira Pak are marketed by AbbVie Inc. based in North Chicago, Illinois.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take several years. According to the Centers for Disease Control and Prevention, approximately 2.7 million Americans are infected with HCV, of which genotype 4 is one of the least common.

Technivie carries a warning alerting patients and health care providers that elevations of liver enzymes to greater than five times the upper limit of normal occurred in approximately 1 percent of clinical trial participants. The elevations occurred more frequently in females taking contraceptives containing ethinyl estradiol. Contraceptives containing ethinyl estradiol must be discontinued prior to starting Technivie. Hepatic laboratory testing should be performed during the first four weeks of starting treatment, and as clinically indicated thereafter. (Source: FDA Website, 24 July, 2015)

### **FDA Approves BMS' Daklinza for Chronic Hepatitis C Genotype 3**

The FDA has approved Daklinza (daclatasvir) for use with sofosbuvir to treat hepatitis C virus (HCV) genotype 3 infections. Daklinza is the first drug that has demonstrated safety and efficacy to treat genotype 3 HCV infections without the need for co-administration of interferon or ribavirin, two FDA-approved drugs also used to treat HCV infection. Daklinza is marketed by Bristol-Myers Squibb, based in Princeton, New Jersey.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take several years. According to the Centers for Disease Control and Prevention, approximately 2.7 million Americans are infected with HCV of which, approximately 10 percent are genotype 3.

Daklinza carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone is co-administered with sofosbuvir in combination with another HCV direct-acting antiviral, including Daklinza. Co-administration of amiodarone with Daklinza in combination with sofosbuvir is not recommended.

Daklinza was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness. (Source: FDA Website, 24 July, 2015)

### **FDA Approves Novartis' Odomzo for Most Common Form of Advanced Skin Cancer**

The FDA has approved Odomzo (sonidegib) to treat patients with locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or who are not candidates for surgery or radiation therapy. Odomzo is marketed by East Hanover, New Jersey-based Novartis Pharmaceuticals Corporation.

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. Basal cell carcinoma starts in the top layer of the skin (called the epidermis) and usually develops in areas that have been regularly exposed to the sun and other forms of ultraviolet radiation. According to the National Cancer Institute, the number of new cases of non-melanoma skin cancer appears to be increasing every year. Locally advanced basal cell skin cancer refers to basal cancers that have not spread to other parts of the body, but cannot be curatively treated with local treatments, specifically surgery and radiation.

Odomzo is a pill taken once a day. It works by inhibiting a molecular pathway, called the Hedgehog pathway, which is active in basal cell cancers. By suppressing this pathway, Odomzo may stop or reduce the growth of cancerous lesions.

Odomzo carries a Boxed Warning alerting healthcare professionals that Odomzo may cause death or severe birth defects in a developing fetus when administered to a pregnant woman. Pregnancy status should be verified prior to the start of Odomzo treatment, and both male and female patients should be warned about these risks and advised to use effective contraception. (Source: FDA Website, 24 July, 2015)

### **FDA Approves Praluent to Treat Certain Patients with High Cholesterol**

The FDA has approved Praluent (alirocumab) injection, the first cholesterol-lowering treatment approved in a new class of drugs known as proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. Praluent is approved for use in addition to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or patients with clinical atherosclerotic cardiovascular disease such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

HeFH is an inherited condition that causes high levels of low-density lipoprotein (LDL) cholesterol. A high level of LDL cholesterol (known as "bad" cholesterol) in the blood is linked to cardiovascular disease. Heart disease is the number one cause of death for Americans, both

men and women. According to the Centers for Disease Control and Prevention, about 610,000 people die of heart disease in the United States every year - that equals one in every four deaths.

Praluent is an antibody that targets a specific protein, called PCSK9, which works by reducing the number of receptors on the liver that remove LDL cholesterol from the blood. By blocking PCSK9's ability to work, more receptors are available to get rid of LDL cholesterol from the blood and, as a result, lower LDL cholesterol levels.

Praluent is marketed by Sanofi-Aventis U.S., based in Bridgewater, New Jersey, and Regeneron Pharmaceuticals, based in Tarrytown, New York. (Source: FDA Website, 24 July, 2015)

## **New Members**

**Fauzia Amuda**, Umass Lowell

**Daniel Balentine**, Lantheus Medical Imaging

**Stephen E. Brodeur**

**Paul Buraczynski**

**Tamara Byrne**, Umetrics Inc, An MKS Company

**Linda Carney**, Vertex Pharmaceuticals

**Deanna Cavallaro**, Barry Wehmiller Design Group

**Christopher W. Chappel**, Pfizer

**Stanley Chung**, Northeastern University

**Eric Cobane**, Shire

**John De La Parra**, Northeastern University

**Michael DeGirolamo**, Azzur Group

**Nicholas Demitrack**

**Mark Denning**

**Alexandrea Dustin, BS**

**Michael Farrell**, Alnylam Pharmaceuticals

**Katherine Galindo**

**Tyler D. Gilpatrick**

**Steven Glover**, CRB

**Charles R. Grant, BA**, Lantheus Medical Imaging

**Malcolm M. Hutchinson**, Carr Co Ltd

**Mina Jung**, DPS Engineering

**Kimberly Kitch, AS**

**Evangelos Kustubardis**, Azzur Group

**Kip Kyprianou**

**Angela Langford**, DPS Engineering

**James Leverone**

**Charles Maher, MBA, MA, BS, BA**, Commissioning Agents Inc

**Zainab Mamuwala**

**Erik McWilliams**, Genzyme

**Robert Melchionda, BS, MS**

**Pegah N. Abadian**, Northeastern University

**Kelly O'Hare**, Lantheus Medical Imaging

**Gaurang J. Patel**, DPS Engineering

**Trey Peck**

**Kelly Quesada**, Shire

**Joe Reale, BS, MS**, Genzyme

**Kyle Roberts**, CAI

**Jarrod Rodominick**, Genzyme

**Nicholas Ryan Sapack**

**Marissa Schaffer**

**William J. Schlageter, PE**, DPS Engineering

**Vaibhav K. Shah**, University of Massachusetts

**Dr. Sonja A. Sharpe, PhD**, GlaxoSmithKline

**Tim Sowell**, ASTRO PAK Corporation

**Doug Staruk**, TESARO, Inc.

**Ming Sun**

**Brian Timmins, B.S.**, Sanofi Pasteur Biologics

**Whitney Withington**, ImmunoGen Inc

## **Member Anniversaries**

### **Over Twenty Years**

- Robert T. Clark, Perrigo Company PLC (21 years)
- Michael J. James, Northeast Water Services (21 years)
- Stephen R. Potter, Baxter (23 years)
- Paul E. Rowe (22 years)
- Lawrence W. Weiner, Biogen Idec (23 years)
- Jeffrey L. Werner (22 years)

### **Twenty Years**

- Gary J. Mills, Momenta Pharmaceuticals Inc

### **Fifteen Years**

- Arthur Kyle Kennedy, Mylan Technologies, Inc

### **Ten Years**

- Catherine Hall
- Edward Kozloski, Decco Inc
- Jorge A. Torres-Gonzales, Biopharma Consulting JAD Group

### **Five Years**

- David R. Bartorelli, Organogenesis Inc.
- Daniel Post
- Mark Schores, Siemens Industry, Inc.
- Jason Theberge, Commodore Builders
- Kim R. Tooker, CRC Consulting

« 1 2 33 »

Chapter Manager: Amy Poole, CAMI - Tel: 1.781.647.4773 and E-mail: [office@ispeboston.org](mailto:office@ispeboston.org)