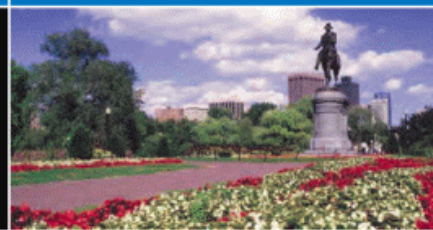
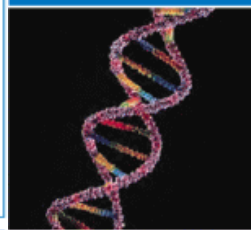




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NEWSLETTER

September 2016, Volume XXVI, No. 5

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President's Message: Providing Value to Members for a Quarter-Century

Esteemed Members,

Greetings at the dawn of the second quarter-century of the ISPE Boston Area Chapter. We remain the largest ISPE Chapter globally and present the most abundant and diverse offering of educational, networking, social and charitable opportunities of any ISPE Chapter or Affiliate. What a pleasure to be here in such a vibrant state and to be planning new and additional ways to deliver more services and content to a growing community of ISPE Members across our region.

This vibrancy comes from one source: our cadre of 154 dedicated volunteers. The 114 professionals and 40 students are organized into 11 standing committees that guide our operations, finances and philanthropic work, plan innovative and fun education and social events and oversee all aspects of Chapter activity throughout the year.

When unleashed on a challenge, these pharmaceutical professionals display commitment, productivity and verve that is a sight to behold. But even better, it is a joy to experience. There are countless stories of Boston volunteers that giving hours that never felt like work. I know that is what sold me and my fellow Members on ISPE's mission and supporting it through volunteerism.

One doesn't have to undertake a grand task to have fun volunteering with your colleagues. We will be making focused appeals for specific tasks or skills that should make it easier for members to engage without making a big commitment and devising more effective ways for would-be volunteers to find opportunities to make the difference they seek.

It is also the time to introduce the Chapter's Board of Directors. Please join me in congratulating your newly-elected Directors and Chapter Officers for the 2016-2017 term:

President

John Spohn, CPIP, Hargrove Life Sciences

Vice President

Jack Campion, The Hart Companies

Treasurer

Kevin Chronley, A/Z Corporation

Secretary

Janet Tice, GMP Piping

Directors

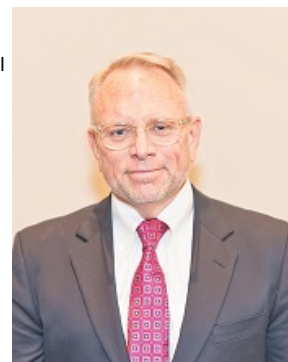
Sean Burgess, Integrated Builders
Eric Felz, Shire
Michael Levesque, GE Healthcare
Jared Marshall, Biogen
Dan Rufo, Industrial Process Management LLC
Mark Levanites, Sequence, Inc.
Samir Gondalia, Pfizer
Stacy Price, Shire
Russell Carr, PhD, University of New Hampshire

Immediate Past President

H. Steve Kennedy, Kennedy Strategic Consulting

It is fitting here to recognize two outgoing members of the Board: Darren Wolter of Pfizer and Past President Chris Opolski and publicly convey profound thanks for their years of service on behalf of the Chapter and the community of professionals we serve.

This new Chapter leadership wasted no time rolling up their sleeves. We just completed our two-day Strategic Planning Retreat, where we review with each committee what it has planned for the upcoming



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year and work together to forge across-the-board opportunities with a consistent level of excellence.

In preparation for strategic planning, we engaged professional assistance to review the way we plan, promote and execute the things we do for our Members. They sought feedback from surveys and interviews then used their expertise to deliver a report showing us we can do better - by offering more ways to access pharmaceutical knowledge, increase member and volunteer satisfaction and inform our membership, whether they are new or veteran, near or far. And so we shall.

A key recommendation is to focus our communications. Telling you all the good things we do, all at once, is not working well. So I will focus on a couple initiatives in each message in this space over the course of the year. Today it's the Product Show and the GO initiative.

We have a tremendous 25th Anniversary Product Show scheduled for October 5. Tom Struble and Jesse McLaughlin chair the Product Show Committee, a group of about 10 volunteers that works year round to ensure each Show builds on previous successes and is bigger and better than all that came before. The Committee has sustained such a trend for as long as I can remember and that is a tremendous accomplishment.

The Product Show has become a pivotal event for the Chapter and for the community of pharmaceutical professionals in the Boston Area. I urge you to take the time to look at the web pages and videos we send you that detail all the ways the Show can help your knowledge, practice and career, then attend! Or, get on board with this incredibly successful team as a volunteer and help plan next year's Show.

Access to our excellent educational events becomes more difficult for members the farther outside Boston they live or work. We responded by piloting the Geographic Outreach (GO) initiative to host in-person networking and interactive participation at "Hub" sites in Providence and Worcester to effectively triple the coverage area of our events.

This year we improved the presentation methods, expanded the system to four locations: Boston, Providence, Worcester and now Portsmouth and hosted the live program at several Hubs. But that is not the only way to get the educational content out to more Members in our region. We are investigating methods to provide the content using demand-based approaches so expect to hear more about this soon.

Leading such a talented and generous group of volunteers is at once humbling and a great honor. I look forward to a year of celebrating their accomplishments and service and to seeing you at our 25th Product Show on October 5th, our 25th Anniversary Gala in April, or at another event or volunteer meeting of the ISPE Boston Area Chapter.

With Kind Regards,



John Spohn, CPIP
President
ISPE Boston Area Chapter

Chapter Bulletin Board

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

Booths and tables are almost sold out - with only a few left. So register today to reserve your exhibitor space and join us October 5 at Gillette Stadium to help celebrate our 25th Anniversary Product Show.

The Boston Area Chapter Product Show is the largest one-day show serving the life sciences industry in the world. Highlights include:

- over 2500 professionals from major biopharma manufacturing sites in the northeast;
- senior decision makers from operations, engineering, sourcing and compliance;
- attendees with open projects they are sourcing for;
- opportunities to reconnect with current customers and prospect for new clients.

Not to mention exciting educational programs, plenary session and special events throughout the day. Plus our legendary After Party at Splitsville/Howl At The Moon in Patriots Place featuring Patriots Defensive End Rob Ninkovich.

Chapter Awards Nine Scholarships

The Chapter is pleased and excited to announce the winners from the June round of the Joel Goldenberg Memorial Scholarship Program. Congratulations to the following students on their achievements:

- Trevor Brown University of Rhode Island
- Prakalya Chandrasekar Tufts University
- Tyler Cole Northeastern University
- Leandro Cruz U Mass Lowell
- Jamie Freund Worcester Polytechnic Institute
- Erin Shaughnessey U Mass Lowell
- Ryan Sullivan U Mass Amherst
- Nathaniel Swanson U Mass Lowell
- Peter Trearchis Tufts University

The Scholarship Program has awarded over \$106,000 to 79 area students since its inception in 2011. The deadline for the upcoming round is November 1. Visit our website <https://scholarships.ispeboston.org/scholarships/> for more information.

New Member Wins Raffle for iPad Air



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The Chapter's Membership Committee held a raffle for an iPad for the months of June, July, and August 2016. The raffle coincided with the July membership drive at Sanofi (formerly Genzyme) in Framingham. Eligibility was based on new memberships and renewals completed between June 1st and August 31st.

Please join us in congratulating **Hunter Giles** on winning the drawing for an iPad Air 64 GB! Enjoy, Hunter and thank you for you for joining ISPE and the Boston Area Chapter!

eNewsletter Ad Space Expanding - Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping 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, September 15, 2016

ISPE Accidental Project Manager: Ok I'm in Charge, Now What?

Ainlyam Pharmaceuticals, Cambridge, MA

PROGRAM SUMMARY

Your assignment as a Project Manager is an indication that your project is complex enough to require a dedicated individual to lead/drive, organize and monitor a scope of work, budget, schedule and a number of other success criteria. While effective project management is a profession in its own right, there are techniques and best practices, other than active participation and team leadership, that project managers can learn in order to be more effective. Contrary to popular thinking, you don't need to become a schedule wizard or Microsoft Project guru. The secret lies in skills that can be honed, even when you've unexpectedly landed in a PM role. This presentation will focus on the key areas that are critical to project success and are often overlooked, the implications of overlooking them and the value in attentive project management.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=580

Sunday, September 18, 2016

ISPE Boston Area Chapter Social at the ISPE Annual Meeting

Max Lager's Wood Fired Grill & Brewery, Atlanta, GA

EVENT SUMMARY

Headed to the ISPE Annual Meeting in Atlanta, GA? Stop by for cocktails and hors d'oeuvres at Max Lager's for a great opportunity for networking, catching up with old friends, and striking up conversations with new colleagues. Max Lager's is conveniently located one block away from the Marriott Marquis! This event is for ISPE Boston Area Chapter members only and there is no cost to attend, though in order to provide a count to the venue, we ask that you pre-register.

To register:

Please email your RSVP to office@ISPEBoston.org or call the office at 781-647-4773 by **Friday, September 16th**. Walk-ins will be accepted onsite.

Thursday, September 22, 2016

ISPE RE-SHOWING Accidental Project Manager: Ok I'm in Charge, Now What?

Great Bay Community College, Portsmouth, NH
Worcester Polytechnic Institute - BETC, Worcester, MA
TBD, Providence, RI

Newsletter Archive

PROGRAM SUMMARY

Join us on September 22, 2016 at the WPI BETC at Gateway Park in Worcester, MA; Great Bay Community College in Portsmouth, NH; or TBA in Providence, RI for a re-showing of the program recorded at Alnylam Pharmaceuticals. A networking reception, including refreshments and appetizers, will be hosted before the presentation at each location.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=636

Wednesday, October 5, 2016

ISPE 25th Anniversary Product Show and Educational Seminars

Gillette Stadium, Foxboro, MA

EVENT INFORMATION

8:30 AM - 9:30 AM - Welcome Breakfast & Networking Coffee Hour
9:30 AM - 11:00 AM - Plenary Session with Keynote Address
11:00 AM - 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 Travis McCready, President & CEO of the Massachusetts Life Sciences Center, and the Honorable Richard E. Neal, House of Representatives, First District, Massachusetts
- Visit Champions for Charity, where you meet Patriots alumni Ronnie Lippett, Jermaine Wiggins, and Scott Zolak also contribute to a great cause
- Network with peers at the After-Party at Splitsville/Howl At The Moon right in Patriot Place! You can also enjoy dueling pianos and FREE bowling all night as well as meet New England Patriots defensive end Rob Ninkovich

And if you preregister now and attend the show, you are automatically entered into a drawing to win a Patriots game tickets package including lodging and dinner at Patriot Place (courtesy of Interphex, M+W Group, and Novatek International).

Click below for full information and to register:

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

Sunday, October 16, 2016

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.

Last year, the Chapter walking team became the #1 fundraising group in Boston and this year they are back to smash their record! But 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 our team page at <http://donate.kidney.org/goto/ISPE-Nephronators> or, contact the office at 781-647-4773 or office@ISPEBoston.org.

Click below for full information and to register:

<http://donate.kidney.org/goto/ISPE-Nephronators>

Monday, October 17, 2016 - Friday, October 20, 2016

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:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=631

Wednesday, October 19, 2016

ISPE Young Professionals Present Tips and Practices for Innovation Success

Tufts University Gordon Institute, Medford, MA

PROGRAM SUMMARY

This presentation will review drivers behind the growth of innovation and how leading companies innovate today. Behaviors that characterize and differentiate the great innovators of our time will be discussed, with emphasis on innovation best practices for the people, processes and philosophies within an organization. Tools and techniques that can be employed to assess the innovative environment within an organization will also be highlighted.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=675

Thursday, October 27, 2016

ISPE Oktoberfest Fall Social

Harpoon Brewery, Boston, MA

PROGRAM SUMMARY

Join your fellow ISPE colleagues this fall at the Harpoon Brewery on Northern Ave, South Boston for an evening of Beer, Pretzels, Brewery Tours and Laughs. There will be a 50/50 raffle with proceeds going to charity. So, put on your lederhosen, grab a pint and join us for OKTOBERFEST! (Lederhosen encouraged, but not required)

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=632

Sneak Preview of Upcoming Events

Thursday, November 10, 2016

ISPE Regulatory Symposium: Quality by Design and Regulatory Fundamentals

Northeastern University, Boston, MA (Live)

WPI BETC, Worcester, MA (Simulcast)

Redhook Ale Brewery, Portsmouth, NH (Simulcast)

TBD, Providence, RI (Simulcast)

Thursday, December 1, 2016

ISPE Young Professionals Social

TBD

Celebrate Our 25th Annual Product Show on October 5th

by Caren Jenkins, B&V Testing, with photos by Allistair Battson Photography

We are very excited to be celebrating the silver anniversary at the Annual ISPE Boston Area Chapter Product Show at Gillette Stadium in Foxborough on October 5, 2016. For a quarter century the Boston Area Chapter has been connecting professionals and organizations throughout the hub of life sciences in New England. The Product Show began as a small conference and has grown and morphed into the largest single-day show serving the life science industry. Whether you're a regular attendee or new to the Product Show, this year's event is not to be missed!



Over 375 exhibitors, multiple educational sessions and more bring thousands of industry professionals to Gillette every year...

Why Attend?

We show you the future and deliver everything you need to bring your ideas to life. You will experience the most advanced technologies for enhancing production from beginning to end from 375+ top-tier vendors and service providers. Plus a top-notch educational program, top-of-the-line food and drink throughout the day and our legendary After Party. And it's all free! For a video and additional highlights of why you should attend [click here](#).



...and did we mention the food?

Register Now to Win Pats Tickets

All attendees who register and attend the Product Show are entered into a raffle to win our grand prize of lodging, dinner for two at Davio's in Patriot Place and two tickets to a New England Patriots game. You must pre-register and attend the Product Show to be eligible to win! [Register online now](#).

Plenary Session & Ribbon Cutting Ceremony

Our Plenary Sessions are always a highlight of the Product Show and this year's will be no different. We will be kicking off the program with a networking breakfast leading into the plenary sessions where you will hear from our keynote speakers, some the most inspiring thought leaders who influence our industry today:

- Travis McCready, President and CEO of the Mass Life Sciences
- The Honorable Richard E. Neal, House of Representatives, First District, Massachusetts



The Plenary Session provides an exciting start to the day.

To celebrate our 25th anniversary, upon conclusion of the plenary session, Congressman Neal will cut the ribbon to officially mark the opening of the 25th Annual Product Show. Don't miss out on joining us as we reach this significant milestone. [Click here](#) to learn more about our plenary session speakers and topics.

Educational Programs

Plan to head to the Northeast Lounge in the East Clubhouse for this year's cutting-edge education program. Three time slots are provided for your convenience - and we promise, you'll still have lots of time left to walk the exhibit floor. In each session, top thought leaders offer insights on topics essential to the industry and provide a wealth of relevant information. This year, sessions cover improving the success of tech transfer, lifecycle process validation at CMOs, expansion/retrofit projects concurrent with GMP manufacturing, and a comparison of project delivery methods. Also included is "Biotech 101," an introduction to biotechnology perfect for students attending the Show as well as anyone new to biopharma. [Click here](#) to learn more about these exciting educational opportunities. And don't forget to [pre-register here](#) for the sessions of your choice so we can provide enough seats for everyone who wants to attend.



Hear from experts in the industry during cutting-edge educational sessions.

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 will take place at the times listed below:

- 1:00 to 1:30 pm - AutomaTech
- 1:30 to 2:00 pm - Kneat Solutions
- 2:00 to 2:30 pm - ClorDiSys Solutions
- 2:30 to 3:00 pm - Environmental Systems Corporation
- 3:00 to 3:30 pm - Harrington Pure / E&S Technologies
- 3:30 to 4:00 pm - AutomaTech
- 4:00 to 4:30 pm - Windshire Group

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

Career Fair

Back this year by popular demand, the Product Show Career Fair features human resources representatives and talent acquisition teams from 40 premier companies in the biopharmaceutical field. These companies are looking for qualified and experienced professionals like you, so be sure to swing by and say hello. You might find the opportunity of a lifetime waiting for you. For a list of hiring companies attending, [click here](#).



Over 40 hiring companies will be on hand to talk about job opportunities they have to offer.

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



Head to the Career Fair for a professional head shot - it's free!

Champions for Charity Event

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 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.



A donation to the Kidney Foundation qualifies you for a photo with Pats greats.

This year, the 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 2016 Boston Kidney Walk on Sunday October 16. And we need your support. Stop by the Champions for Charity pavilion in the West Clubhouse for an opportunity to meet Patriots alums Scott Zolak, Jermaine Wiggins and Ronnie Lippett, and the Patriots cheerleaders. For a \$20 donation, you can have your photograph taken with these champions and your donation will add to the funds raised by the team for the National Kidney Foundation on the day of the walk. Help make a difference for millions of people and support our team!

After-Party

And to celebrate another successful Product Show, this year's Silver Jubilee After-Party will take place at the Splitsville/Howl at the Moon in Patriot Place and will feature New England Patriot Defensive End Rob Ninkovich. Rob will be signing autographs and posing for pictures.



This year's After Party at Splitsville adds bowling to the popular mix of food, drink and camaraderie.

Splitsville is located within the Gillette Stadium retail complex and is walking distance from the Product Show floor. Free bowling on all 12 luxury lanes and free shoe rental will be available - be sure to bring rubber-soled shoes in case your shoe size sells out! There will also be Howl at the Moon's famous dueling pianos and delicious food, so join us at 6:30pm for the best After-Party ever! A Product Show name tag is required for entry, so make sure you register today!

Don't miss out: join us at Gillette on October 5 and help us celebrate our 25th year. We look forward to seeing you there! [Register online now.](#)

Join the YPs and Discover the Power of Social Media

by Shah Vaibhav and Christopher Ciampa, Thermo Fisher Scientific, with photos by Allistair Battson Photography

This year, the Young Professionals are trying something different during the YP Hour by offering a panel discussion on the role and emerging power of social media in the life science/biopharma sector. During the panel discussion, industry professionals will be on hand to review resumes and offer tips for success. And yummy hors d'oeuvres will be available throughout the hour, as well as high top tables for relaxing while you soak up the information.



Do you know, in today's world, how much social media has deepened its roots in making a business successful? If statistics are to be believed, social media marketing has double the lead-to-close rate of traditional outbound marketing; and 84 percent of B2B marketers use social media in some form or another. It's a fact: social media is gaining tremendous ground in the life science/biopharma industry. But how much do you know about the ins and outs of social media and how to use it to enhance your career and professional life?



The YPs have created a panel of the best industry experts to provide you with information on social media and answer all your questions. They will introduce you to the role social media plays in patient advocacy, public relations strategy, brand awareness, marketing communication and more. In addition, experts will be on hand to review your resume and share some amazing social media tips to make your job search smarter and more efficient.

You can't even think for a second of missing such an important event. So make your way to the Vendor Showcase Area in the Southeast Lounge on the East side of the stadium and I'll see you there!

Special Attractions for Students at the Product Show

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

For the fourth year running, the Chapter is paving the way for the next generation of "best and brightest" life science professionals entering the work force by sending buses to all 13 of our Student Chapters to bring students to and from the Product Show at Gillette. Many students will be attending the Show to do research as part of their fall studies, so we encourage exhibitors and attendees to help students by answering their questions when they stop by looking for information.

There are two educational sessions geared to students, although young professionals and industry veterans are welcome to attend as well. The first, at 12:15pm, covers "How to Make the Most of Your Product Show Experience" which will provide valuable insights on meeting people, sharing information and navigating your way through this busy, world class event. The second is the Biotech 101 educational session being held from 3:30-5:00pm. For more information, [click here](#).



Special activities held throughout the day make the trip to Gillette worthwhile for the Chapter's Student Members.

Before heading back to campus, students and young professionals will have the opportunity to mingle at the Young Professionals Hour from 5-6pm. This year, a panel discussion on the uses of social media in the biopharma industry, resume reviews and light hors d'oeuvres await. The Young Professionals always do a great job with this event so plan on attending - and don't forget to bring a copy of your resume.

Of course, all of these 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 5. You'll be glad you did!

12:15pm - 1:00 pm | How to Make the Most of Your Product Show Experience | West Clubhouse, Southwest Red Level Suite Events like the Product Show are great places to meet professionals in the life sciences industry and establish connections that can help support career growth. Learn important tips on making a strong first impression when meeting people and getting the best from your Product Show experience.

3:30pm - 5:00pm | Biotech 101 | East Clubhouse, Northeast Lounge This presentation will highlight the historical development of the biotechnology field and the recent advances in bioprocessing and biomanufacturing as the result of this progress.

5:00pm - 6:00pm | Young Professionals Hour | Southeast Lounge, Vendor Showcase Area Whether you are a Student Member, a recent college grad, or a working professional with a few years' experience, plan to join the Young Professionals at 5pm. This year, a panel discussion on the uses of social media in the biopharma industry, resume reviews and light hors d'oeuvres await, so don't miss out!

Data Integrity Educational Program Reaches Members at Four Locations

by Brijesh Patel and Jimmy Hughes, Shire

The June educational program was held at the Crowne Plaza in Warwick, RI with live simulcasts in Worcester, MA at WPI, Medford at Tufts Gordon Institute and Portsmouth, NH at Redhook Ale Brewery. This was another first for the Chapter - a single educational program simultaneously presented at four locations in three New England states. Congratulations to the Educational Program and the GO (Geographic Outreach) Committees for working together to make it happen. The program focused on Data Integrity and the draft guidance recently published by the FDA and was a great success with over 75 attendees whose enthusiasm demonstrated broad interest in the topic.



Attendees in at all four locations shared food, drink and conversation prior to the presentations.

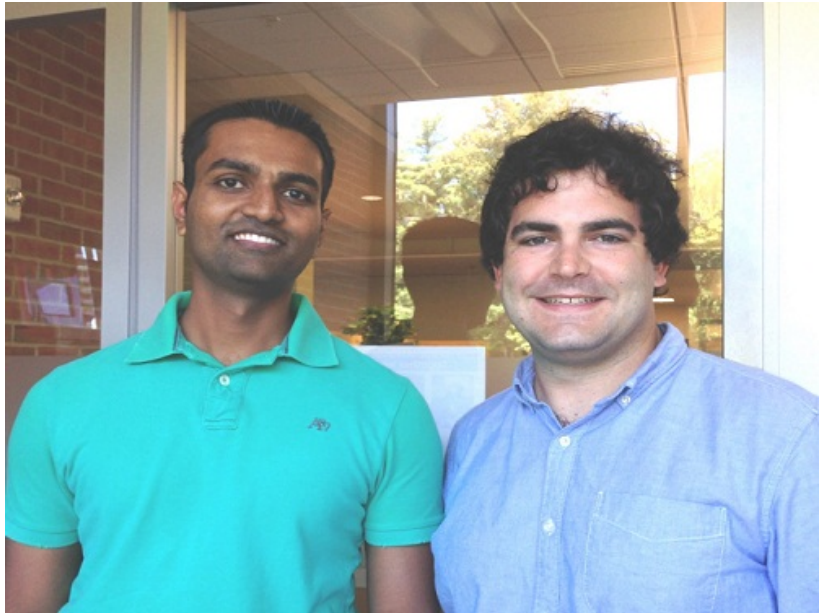
The event was kicked off with a great food, cold beer and a networking reception at the Crowne Plaza in Warwick where the live presentations took place. Similar gatherings were held at the simulcast locations in Worcester, Medford and Portsmouth. Meeting Manager and Chapter Vice President Jack Campion welcomed the crowd and introduced our speakers, Robert (Bob) Wherry of Paraxel International; and Heather Longden of Waters Corporation. Bob and Heather both gave excellent presentations covering several aspects of the topic including FDA's current focus, future trends and best practices, audit preparation and working with your software vendor.



Speakers Heather Longden and Bob Wherry

Bob works for Paraxel International as a Principal Consultant in the Strategic Compliance and Risk Management group with a focus on Data Integrity and Inspection Readiness. He gave audience members a glimpse into the draft guidance on data integrity recently published by the FDA and discussed data integrity challenges, best practices, the FDA's current focus and future trends in the field.

Heather Longden, Senior Marketing Manager from Waters Corporation, interacts with regulatory bodies, industry groups and sales representatives across the globe. She talked about how to work with software vendors and what questions to pose before an audit. She also touched on computer systems validation, and some of the technical aspects of vendor testing and how to leverage it the right way. Heather concluded by addressing technical and procedural control and how to successfully manage a regulatory inspection.



Meeting Managers Brijesh Patel (l) and Jimmy Hughes (r)

Not only did Bob and Heather provide information that was simulcast to sites in four different cities, they were also able to receive questions from attendees no matter where they were located and provide answers in real-time. Thanks to our presenters, the EPC and GO Committees, and our simulcast site coordinators, Jared Marshall (Tufts), Jennalynn Culp-Yu (Portsmouth), and Dan Mardirosian, Kristin Marengo and Kristen Benoit (WPI), all of whom worked together on another successful first for the Chapter. And, last but not least, thank you to event sponsor Commissioning Agents for their continuing support for the Chapter's educational programs.

Summer Golf Outing Travels to Lake Winnepesaukee

by Jim Grunwald, DPS Engineering, with photos by Tom Coyner, E-Volve Systems

This past August 8, the Chapter took a different approach to our Annual Summer Golf Outing by searching for a course outside of greater Boston with the goal of providing a really unique experience in a world class setting. Golf Committee members found Lake Winnepesaukee Golf Club in September 2015 and were impressed with the course and its staff. The committee decided the venue would be a great draw despite the travel commitment and their bet paid off. The event, venue, weather and turnout were crazy good and the ISPE contingent made the most of their time at this wonderful venue. The travel commitment was a small price to pay for such an exceptional day.



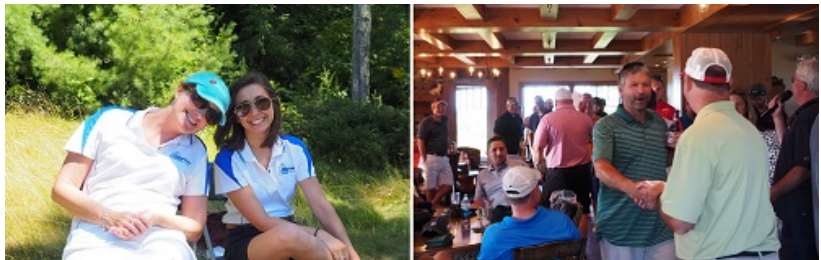
Congratulations to this year's winners:

- Foursomes
 - First: Tim Crowley, Peter DeGennaro, Justin Tucker, Geoff Wilkinson
 - Second: Rod Cole, Kristin Dangelo, Eileen Heffernan, Shaun McCormack
 - Third: Newman Flanagan, Dan Ramsey, Paul Sullivan, David Surette
- Longest Drive
 - Kathy Melia
 - Steve Robak

- Straightest Drive
 - Eileen Heffernan
 - Rich Trabucco
- Closest to the Pin
 - Dianne Barrette
 - Rob Melchionda



The Chapter would like to thank our many sponsors whose support made this event possible: AHA Engineers, A/Z Corporation, Albireo Energy, Boston Analytical, Commissioning Agents, Commodore Builders, DPR Construction, DPS Engineering, J. Calnan & Associates, JENSEN HUGHES, PIDC Construction, Paradigm Construction, R.W. Sullivan Engineering, Reflex Lighting, Sentrol, Structure Tone, Superior Controls, TRIA, UltraFiltronic, and ValSource.



The Chapter would also like to thank everyone who attended, with special thanks to those whose efforts helped make the event a success: the staff at Lake Winnepesaukee Golf Club; the Golf Committee of Paul Sullivan, Tim Crowley and Jim Grunwald; and Erin Young and the Chapter's admin staff at CAMI.

And not only was a fine time had by all but our sponsoring companies, participants and guests all contributed to the Boston Area Chapter as a portion of the proceeds from the event go to the Chapter's Joel Goldenberg Scholarship Program.

Student Chapters Gearing Up for the Year Ahead

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

The Chapter is really excited about the upcoming year as we strive for greater levels of involvement with each of our 13 Student Chapters. We're fresh off an excellent strategic planning meeting where student leaders, faculty and staff, and ISPE volunteers helped to generate some great ideas to further support the Chapter's efforts to nurture deeper relationships and increased involvement with our Student Chapters. Thanks to this valuable input, we have some great plans for the upcoming year including:

- Campus visits to promote ISPE on campuses
- Bussing students to and from the Product Show
- Promotional video encouraging companies to post their open positions on the Chapter website
- Periodic conference calls to share Student Chapter best practices

We're also pleased and excited to announce the scholarship winners from the spring applicants. Congratulations to the following students on their achievements:

- Trevor Brown, University of Rhode Island
- Prakalya Chandrasekar, Tufts University
- Tyler Cole, Northeastern University
- Leandro Cruz, U Mass Lowell
- Jamie Freund, Worcester Polytechnic Institute
- Erin Shaughnessey, U Mass Lowell
- Ryan Sullivan, U Mass Amherst
- Nathaniel Swanson, U Mass Lowell

- Peter Trearchis, Tufts University

And for those of you attending the Product Show on October 5 (and we know you're planning to be there), our Student Members will be there in force. Take a minute to welcome them and make them feel at home - after all, they're our future Chapter Members!

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 our readers.

Vertex and Moderna to Collaborate in mRNA Therapeutic for Cystic Fibrosis

Vertex Pharmaceuticals and Moderna Therapeutics announced the two companies have entered into an exclusive research collaboration and licensing agreement aimed at the discovery and development of messenger Ribonucleic Acid (mRNA) Therapeutics™ for the treatment of cystic fibrosis (CF). The three-year collaboration will focus on the use of mRNA therapies to treat the underlying cause of CF by enabling cells in the lungs to produce functional copies of the cystic fibrosis transmembrane conductance regulator (CFTR) protein, which is known to be defective in people with CF. Through the collaboration, the companies will explore the potential utilization of pulmonary mRNA delivery.

Under the terms of the collaboration, Vertex and Moderna will conduct exclusive research, development and commercialization activities to advance the mRNA Therapeutics. Moderna will lead discovery efforts, leveraging its platform technology along with Vertex's scientific experience in CF biology and the functional understanding of CFTR, as well as the company's proprietary assay platform that utilizes human bronchial epithelial (HBE) cells of multiple different CF gene mutations from people with CF. Vertex will lead all preclinical, development and commercialization activities associated with the advancement of mRNA Therapeutics that result from this collaboration and will fund all expenses related to the collaboration.

Vertex will pay Moderna \$20 million in cash as part of its upfront commitment to the collaboration. Vertex will also make a \$20 million investment in Moderna which will provide Vertex with an ownership stake in Moderna. Vertex will also pay Moderna future development and regulatory milestones of up to \$275 million, including \$220 million in approval and reimbursement milestones, as well as tiered royalty payments on future sales. (Source: Vertex Website, 06 July, 2016)

MilliporeSigma Starts Construction on \$115 Million Campus in Burlington

MilliporeSigma announced plans to build a new campus in Burlington, Massachusetts that will serve as a major hub for the North American life science business of Merck KGaA, Darmstadt, Germany. The 280,000 ft² facility at 400 Wheeler Road will include a customer collaboration laboratory and training center as well as office space. The center will be one of nine worldwide. Other locations will include Brazil, China, France, India, Singapore and South Korea.

The new center in Burlington will replace the lab at the company's Billerica facility. MilliporeSigma's 850 full-time Billerica-based employees will relocate to the new campus when construction is complete in the second half of 2017. The \$115 million five-story, single tenant building near Route 3 and Route 128 will be LEED certified. The project includes an opportunity to expand an additional 70,000 square feet. (Source: EMD Group Website, 19 July, 2016)

Jounce Therapeutics to Collaborate with Celgene in Cancer Therapeutic

Cambridge-based Jounce Therapeutics announced a collaboration with Celgene Corporation focused on developing and commercializing immuno-oncology treatments for patients with cancer. The collaboration includes options on Jounce's lead product candidate, JTX-2011, and up to four early-stage programs to be selected from a defined pool of B cell, T regulatory cell and tumor-associated macrophage targets and an additional option to equally share a checkpoint immuno-oncology program. Post option exercise, Jounce will lead global development and U.S. commercialization for JTX-2011 and one additional collaboration program.

Under the terms of the collaboration, Jounce will receive an upfront payment of \$225 million and a \$36 million equity investment from Celgene. Jounce will also receive regulatory, development, and net sales milestone payments and tiered royalties on exU.S. sales. Aggregate payments for development, regulatory and commercial milestones could potentially be \$2.3 billion in total across all programs reaching commercialization. Celgene has the option to opt-in at defined stages of development across the programs. Following any opt-in, Celgene and Jounce will share U.S. profits and losses on all programs. (Source: Jounce Website, 19 July, 2016)

Pfizer Wins Assets of BIND Therapeutics with \$40 Million Auction Bid

BIND Therapeutics announced that Pfizer prevailed at a bankruptcy auction to purchase substantially all of BIND's assets. The winning bid of \$40 million, subject to U.S. Bankruptcy Court approval for which a hearing is scheduled to take place on July 27, 2016, was selected as the highest and best bid. NanoCarrier was selected as the back-up bidder.

BIND initiated voluntary Chapter 11 bankruptcy protection on May 1, 2016 and conducted a sale of assets, pursuant to Section 363 of the Bankruptcy Code, during an auction held on July 25 and 26, 2016. BIND Therapeutics is a biotechnology company developing targeted therapeutics, primarily for the treatment of cancer. BIND'S product candidates are based on proprietary polymeric nanoparticles called Accurin®, which are engineered to target specific cells and tissues in the body at sites of disease. (Source: BIND Website, 26 July, 2016)

Momenta Discontinues Phase 2 Trial of Pancreatic Cancer Drug

Momenta Pharmaceuticals, a biotechnology company specializing in the characterization and engineering of complex drugs, announced that it has discontinued further accrual in its Phase 2 trial evaluating necuparanib in combination with Abraxane® and gemcitabine in patients with advanced metastatic pancreatic cancer.

The decision to discontinue enrollment into the study was based on the recommendation from the independent Data Safety Monitoring Board (DSMB) following a planned interim futility analysis conducted once 57 deaths (50 percent of the target number of 114 events required for trial completion) had occurred. Data were assessed from 120 randomized patients as of July 20, 2016. While no new safety signals were observed and the toxicity profile was considered manageable, the DSMB determined that necuparanib in combination with Abraxane and gemcitabine did not show a sufficient level of efficacy to warrant continued enrollment. Additionally, no new toxicities were observed that necessitate immediate discontinuation of study drug in patients currently active on protocol. The DSMB also recommended that the company consider unblinding the data to provide more information to determine how best to address ongoing patients.

Necuparanib (M402) is an oncology drug candidate engineered to have a broad range of effects on tumor cells. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these products has been limited by their anticoagulant activity. Momenta engineered necuparanib from unfractionated heparin to have significantly reduced anticoagulant activity while preserving relevant antitumor properties associated with heparins. (Source: Momenta Pharmaceuticals Website, 04 August, 2016)

Merck and Moderna Ink Second Collaboration Agreement

Merck, known as MSD outside the United States and Canada, and Moderna Therapeutics announced a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines.

Moderna and Merck will develop personalized cancer vaccines that utilize Moderna's mRNA vaccine technology to encode a patient's specific neoantigens, unique mutations present in that specific patient's tumor. When injected into a patient, the vaccine will be designed to elicit a specific immune response that will recognize and destroy cancer cells. The companies believe that the mRNA-based personalized cancer vaccines' ability to specifically activate an individual patient's immune system has the potential to be synergistic with checkpoint inhibitor therapies, including Merck's anti-PD-1 therapy, Keytruda® (pembrolizumab). In addition, Moderna has developed a rapid cycle time, small-batch manufacturing technique that will allow the company to supply vaccines tailored to individual patients within weeks.

Under the terms of the agreement, Merck will make an upfront cash payment to Moderna of \$200 million, which Moderna will use to lead all research and development efforts through proof of concept. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's Keytruda. Moderna will also utilize the upfront payment to fund a portion of the build-out of a GMP manufacturing facility in suburban Boston for the purpose of personalized cancer vaccine manufacturing.

Following human proof of concept studies, Merck has the right to elect to make an additional undisclosed payment to Moderna. If exercised, the two companies will then equally share cost and profits under a worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the U.S. The agreement entails exclusivity around combinations with Keytruda. Moderna and Merck will each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents.

Merck and Moderna have an existing collaboration and license agreement focused on the discovery and development of mRNA-based infectious disease vaccines and passive immunity treatments. Moderna is also advancing its own pipeline of infectious disease vaccine candidates and currently has two phase 1 studies underway in Europe and the U.S. (Source: Moderna Website, 29 June, 2016)

Biogen to End Manufacturing in Cambridge

Biogen stated it will close or divest its manufacturing facility in Kendall Square during its July Q2 Earnings Conference. Originally opened in 1989, Biogen's Cambridge facility is the longest running in their manufacturing network. It is also its smallest. The site was first licensed for the production of Avonex in 1996 and has been supplying Avonex since. More recently, the facility obtained licenses for commercial production of Eloctate and Plegridy. (Source: Biogen Website, 21 July, 2016)

Biogen to Spin Off New Hemophilia-Focused Company, Named Bioverativ

Biogen announced that Bioverativ will be the name of the standalone, publicly-traded global biotechnology company that it expects to launch in early 2017. Bioverativ will be focused on the discovery, research, development and commercialization of treatments for hemophilia and other blood disorders. Following completion of the spin-off, Bioverativ plans to trade under the symbol BIVV on the NASDAQ Stock Market.

Bioverativ will continue commercialization of Eloctate® and Alprolix®, indicated for the treatment of hemophilia A and B, respectively, under Biogen's existing collaboration agreement with Swedish Orphan Biovitrum AB. After the spin-off, Bioverativ expects to continue development of Eloctate and Alprolix, including conducting studies to explore the potential benefits of Fc fusion technology on long-term joint health, immunogenicity and immune tolerance induction in hemophilia patients who develop inhibitors. (Source: Biogen Website, 09 August, 2016)

Zafgen Suspends Obesity Drug Program, Reduces Workforce

Boston-based Zafgen, a biopharmaceutical company working on treatments for obesity and complex metabolic disorders, announced that it is suspending further development of its drug beloranib and refocusing its resources on development of a differentiated second-generation MetAP2 inhibitor, ZGN-1061, in severe and complicated obesity.

The beloranib Investigational New Drug (IND) application was placed on full clinical hold in December 2015 by the FDA. To address the clinical hold, Zafgen recently held a Type A meeting with the FDA to discuss the clinical and preclinical data for beloranib as well as a proposed risk mitigation strategy for

beloranib in Prader-Willi syndrome (PWS). Based on the outcome of that meeting, Zafgen has determined that the obstacles, costs and development timelines to obtain marketing approval for beloranib are too great to justify additional investment in the program, particularly given the promising emerging profile of ZGN-1061.

ZGN-1061, like beloranib, is a fumagillin-class MetAP2 inhibitor that was discovered by Zafgen's researchers as part of a multi-year campaign to identify novel compounds that avoided limiting preclinical safety concerns observed with beloranib, including teratogenicity and effects on testicular function. The compound has similar efficacy, potency, and range of activity in animal models of obesity as beloranib, but displays a reduced potential to impact thrombosis.

Zafgen is currently screening patients to initiate a Phase 1 clinical trial evaluating ZGN-1061 for safety, tolerability, and weight loss efficacy over four weeks of treatment, and currently expects Phase 1 clinical data by the end of the first quarter of 2017. Based on the clinical data demonstrating beloranib's significant effect on body weight and glycemic control in patients with severe obesity complicated by type 2 diabetes, Zafgen plans to focus later-stage development of ZGN-1061 in severe and complicated obesity.

The company plans to reduce its workforce by approximately 34 percent, to a total of 31 employees, by December 2016. Zafgen expects the restructuring to result in approximately \$4.8 million in reduced annualized workforce expenses once the plan is fully implemented. The Company also expects to incur a non-recurring charge of approximately \$2.4 million in the third quarter of 2016 related to the restructuring. In addition, both Patrick Loustau, President, and Alicia Secor, Chief Commercial Officer, will be leaving the Company to pursue other opportunities. Zafgen ended June 30, 2016 with approximately \$150.5 million in cash and cash equivalents and now expects to end 2016 with greater than \$125 million. (Source: Zafgen Website, 09 August, 2016)

Pfizer Breaks Ground On New Facility in Andover

Pfizer broke ground for its new biologics clinical manufacturing facility in Andover, Massachusetts. The company will spend more than \$200 million in development of the 175,000 sq.ft. state-of-the-art facility. The new 5-story building is expected to be operational by January 2019. Approximately 75 new employees will be hired to support clinical manufacturing. In addition to the Andover campus, Massachusetts is home to Pfizer's Research and Development hub in Cambridge. Pfizer has approximately 2,000 employees based in Massachusetts.

Pfizer's Andover campus currently includes 7 buildings which house laboratories, clinical and commercial manufacturing suites, and support areas. It also includes a multiproduct manufacturing facility. The new clinical manufacturing facility is designed with 5 independent manufacturing suites. (Source: Pfizer Website, 16 June, 2016)

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 Gilead's Epclusa for Treatment of Chronic Hepatitis C

The FDA has approved Epclusa, manufactured by California-based Gilead Sciences, to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis (advanced liver disease). For patients with moderate to severe cirrhosis (decompensated cirrhosis), Epclusa is approved for use in combination with the drug ribavirin. Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. There are at least six distinct HCV genotypes, or strains, which are genetically distinct groups of the virus. Knowing the genotype helps inform treatment recommendations and the duration of treatment. Approximately 75 percent of Americans with HCV have genotype 1; 20-25 percent have genotypes 2 or 3; and a small number of patients are infected with genotypes 4, 5 or 6. According to the Centers for Disease Control and Prevention, HCV infection becomes chronic in approximately 75 to 85 percent of cases. Patients who suffer from chronic HCV infection over many years may have complications, such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections, liver cancer and death.

Epclusa 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, 28 June, 2016)

FDA Issues Draft Guidances on Next Generation Genomic Sequencing-Based Tests

In support of the President's Precision Medicine Initiative, the FDA has issued two draft guidances that, when finalized, will provide a flexible and streamlined approach to the oversight of tests that detect medically important differences in a person's genomic makeup.

The powerful new technology, known as next generation sequencing (NGS), can scan a person's DNA to detect genomic variations that may determine whether a person has or is at risk of disease or may help to inform treatment decisions. While current regulatory approaches are appropriate for conventional diagnostics that measure a limited number of substances associated with a disease or condition, such as blood glucose or cholesterol levels, the new sequencing technologies can examine millions of DNA variants at a time, and thus require a flexible approach to oversight that is adapted to the novel nature of these tests.

The field of genetic and genomic testing is dynamic, and the agency understands that there is a need to encourage innovation while assuring that NGS-based tests provide accurate and useful results. When the guidances are finalized, adherence to them will offer appropriate flexible and adaptive regulatory oversight of these tests, while allowing for variations in development and validation and accommodating the rapid evolution of NGS technologies.

The first draft guidance, titled "Use of Standards in FDA's Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases" provides recommendations for designing, developing and validating NGS-based tests for rare hereditary diseases, and addresses the potential for using FDA-recognized standards to demonstrate analytical validity, which is how well a test predicts the presence or absence of a particular genomic change.

The second draft guidance, titled "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics" describes an approach wherein test developers may rely on clinical evidence from FDA-recognized public genome databases to support clinical claims for their tests and provide assurance of accurate clinical interpretation of genomic test results - an easier path for marketing clearance or approval.

This adaptive approach to regulating NGS-based tests is part of the FDA's engagement in the Precision Medicine Initiative (PMI). The PMI, launched by the White House in early 2015, is an innovative approach to developing a new kind of health care that takes into account individual differences in people's genes, environments and lifestyles. The FDA's role in the PMI is foundational: to create regulatory processes that encourage advances in genomic testing while assuring that NGS-based tests are safe and effective. The FDA has been working with experts in the genomics community to conceptualize this flexible approach that strikes the important balance between safeguarding public health and promoting innovation.

The FDA encourages public comments on the draft guidances during the 90-day comment period. (Source: FDA Website, 06 July, 2016)

FDA Approves Sanofi-Aventis Drug Adlyxin to Treat Type 2 Diabetes

The FDA has approved Adlyxin (lixisenatide), manufactured by New Jersey-based Sanofi-Aventis, a once-daily injection to improve glycemic control (blood sugar levels), along with diet and exercise, in adults with type 2 diabetes.

Type 2 diabetes affects more than 29 million people and accounts for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage. Adlyxin is a glucagon-like peptide-1 (GLP-1) receptor agonist, a hormone that helps normalize blood sugar levels. The FDA is requiring two post-marketing studies for Adlyxin. (Source: FDA Website, 28 July, 2016)

New Members

Michael David Ashman, PE, CRB - Medford, MA

Daniel Barbin, University of Massachusetts-Lowell

Julia Bushell, Worcester Polytechnic Institute

Paulo Careiro, Denison Pharmaceuticals

Chesley Chen, Safety Partners, Inc.

Peter M. Cottrell, Shire

David Craig, BINDER Inc.

Dr. Nima Farrokhsiar, New England Controls Inc

William D. Fischer, Rockwell Automation

Larry Forgue

Hunter S. Giles, DPS

Lance Goodreau, B.S., New England Biolabs

Dr. Carsten Haber, HNP Mikrosysteme

Brian Howard, Core Informatics

Rajarajan Jagadesan, Shire

Thomas W. Joyner, AHA Consulting Engineers

Raj Kewalramani, Kala Pharmaceuticals

Raffe Khazadian, TRIA

Eoin Kiely, Zenith Technologies

Katrina Kiely, UMass Amherst

Brian Krisak, Integrated Solutions Sales Manager

Andrew Lapointe, Shire Pharmaceuticals

George Liang, UMass Lowell

Edward Charles MacRae, Albireo Energy

Katelyn Malavenda, B.S., Lonza

Theresa McCarthy, Pfizer - Andover

Philip Michel, Ultrafiltronics

James Miller, Genzyme- Allston Landing, MA

Patrick Norton

Seann O'Connell, Boston Institute of Biotechnology
Richard Pampuro, Genzyme
Kartavya Patel, Genzyme
Rupangi Patel, Biogen Idec
Maggie Pax, Thermo Fisher Scientific
Mark Piscatelli, Biogen Idec
Victor Proops, Commodore Builders
Raymond Paul Protano, BS, MBA, Genzyme
Riju Saini, PhD, SNC-Lavalin Project Services, Inc
Zachary Stufflebeam, Stantec Consulting Services Inc
Kristin Sullivan, BS, MS, Pfizer Inc
Terry Swindle, The Clorox Company
Julie Tareco, The Cardinal Group
Jeffrey Tuzzio, Avista Pharma Solutions
Nancy Waggoner, BS, JD, MS, Northeastern University
Michelle Wasserman, Lonza Biologics Inc
Craig Wells, BSME, BSCE, Steel-Pro, Incorporated
Charmian Wu, Sanofi

Member Anniversaries

Over Twenty Years

- Robert T. Clark, Perrigo Company PLC (22 years)
- Edwin L. Harmon, III, LSNE (25 years)
- Michael J. James, Northeast Water Services (22 years)
- Stephen R. Potter (24 years)
- Paul E. Rowe (23 years)
- Lawrence W. Weiner, Biogen - Cambridge, MA (24 years)
- Jeffrey L. Werner, BA, MS, Retired (23 years)

Fifteen Years

- Steven A. Finco, Commissioning Agents

Ten Years

- Christopher Brown, Lantheus Medical Imaging
- Mallory Duquesne, Consultant
- Delayn S. Haynes, Pfizer Inc
- Mike Kubick, Perfex Corp
- Sharlene Lugo, Sunovion Pharmaceuticals
- Stephen E. O'Brien, Genzyme
- James E. Taylor, SLC Consulting LLC

Five Years

- Dr. Maurizio V. Cattaneo, CPIP, BioVolutions
- Anthony Copas, DPS, Inc.
- Leslie L. Doyle
- Christine Mosholder, Fort Point Project Management
- Glen Potvin, Quintiles Consulting
- Christopher B. Sears, Blend Therapeutics
- Robert J.A. Wilson, AIA, DPS Engineering

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