Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

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NEWSLETTER

September 2013, Volume XXIII, No. 5

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President's Message: New Board Members Working Together to Serve All of New England

Dear Boston Area Chapter Members,

It has been another incredible year for the Boston Area Chapter (BAC), and I want to thank you for allowing me to lead as President and serve this world class organization.

In case you haven't heard, the Boston Area and New England Chapters are once again united to serve the New England ISPE membership and industry as the "Boston Area Chapter: Serving all of New England." I'd like to welcome our new Members from the former New England Chapter - with your help we are now the largest ISPE Chapter and Affiliate in the world!

Please allow me to introduce our new Board of Directors, comprised of former New England and Boston Area Chapter Members. Their hard work and dedication has helped to develop the Chapter and continually expand the benefits provided to our membership:

President	Dan Ramsey	Commissioning Agents
Vice President	Chris Opolski	Alexion Pharmaceuticals
Treasurer	H. Steve Kennedy	Independent Consultant
Secretary	Janet Tice	GMP Piping
	Jack Campion	The Hart Companies
	Tom Choyce	Biogen Idec
	Dan Rufo	IPM
	Tulsa Scott	Commissioning Agents
	John Spohn, CPIP	Hargrove Life Sciences
	Jim Stout	Natrix Separations
	Jillian Willard	Genzyme
	Darren Wolter	Pfizer
Past President	Jay Zaino	GxP Automation
Past President	Kevin Chronley	A/Z

As a board, we have worked through the summer to develop a strategy for building upon our previous goals and accomplishments, and incorporating the expanded geography into our Chapter. Some of our major goals and strategies are outlined below:

GO Committee Our Chapter is now the largest in the world with over 1600 members spread throughout New England. The new Geographic Outreach (GO) Committee will look for ways to bring the Boston Area Chapter core services to the larger area now encompassed. The strategy for the integration of all geographic areas includes a focus on:

- Local education and social events Hosting an additional CPIP course location
- Outreach to Members and Student Chapters within new regions

Student Chapters Boston and the surrounding area are home to some of the greatest universities and research facilities globally. The BAC has actively engaged local students and educational institutions to develop Student Chapters. The students of today are the leaders of tomorrow and the BAC will continue to develop and support them, expanding upon and strengthening the existing Student Chapters. In this vein, we would like to welcome the University

of Rhode Island Student Chapter, which now falls within the expanded BAC, and the under formation Student Chapter at Mass Maritime Academy. Welcome aboard!

Young Professionals The BAC founded the original Young Professionals (YP) initiative. This movement has been promoted beyond New England and has become an ISPE International global initiative. Our BAC Young Professionals are planning a variety of entry level training sessions and social/networking opportunities created specifically to develop our newest Members. I encourage all people new to the life science industry to take advantage of our YP offerings.

Educational Programs Our BAC Educational Programs Committee (EPC) has received global attention due to the high caliber of our monthly educational programs. No other ISPE Chapter or Affiliate offers the same combination of excellent quality and regular frequency of events. The BAC continues to be committed to delivering high quality, cutting edge educational programs on topics requested by our membership, incorporating a variety of formats such as round table discussions, specialist panels, dual-track events combining entry level and advanced presentations on the same topic, and facility tours.

Giving Back We at the board understand that the key reason for the Boston Area Chapter's emergence as the standard for excellence and knowledge is our membership. It is your participation and your willingness to engage and share knowledge that has made our Chapter what it is today. In order to support our membership (both new and previous), we will continue to give back to them. Some of these initiatives include:

- **Joel Goldenberg Memorial Scholarship Program** – Awards of up to $2000 available for Student Members and children of Members.
- **Annual Product Show** – A free event that is internationally recognized as one of the preeminent single-day life science events in the world.
- **CPIP Study Groups** – Chapter CPIPs continue to share their knowledge and experience and grow the ranks of CPIPs locally - just one of the reasons the BAC has almost half the world's CPIPs!
- **Local COP's** – Many BAC Members play an active role within the International Communities of Practice. We are now looking for ways to leverage this knowledge and expertise at the local level by establishing local COPs for discussion of specific topics such as latest developments and best practices within specific knowledge areas.

As you can see from the sampling of items above, the BAC Board of Directors, committee chairs and volunteers are engaged in a multitude of initiatives to bring additional services to the Boston area - and now the entire New England area - life sciences industry and community. We welcome your participation and feedback on the benefits associated with ISPE BAC membership. And we need you to help spread the word to others so we can continue to grow and make our mark on the globe as a regional life sciences community that leads the industry in knowledge and innovation.

Thank you again for the opportunity to participate and help lead the way.

Sincerely,

Daniel Ramsey
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Chapter Scholarships Awarded

Congratulations to the latest winners of the Chapter's Joel Goldenberg Memorial Scholarship Program. This outstanding

group includes entering freshmen, undergraduates and students working toward advanced degrees.

Anatoly Tereschuk, UMass Amherst
Callie King, Worcester Polytechnic Institute
Noreen Rizvi, Northeastern University
Kathryn Gikas, Boston University
Lorraine Mathis, Tufts University
Samuel Musiak, UMass Lowell
John Busanovich, Boston College

This spring, more students than ever applied for scholarship awards of up to $2000 each, with a lifetime cap of $4000 per student. Awards are made twice each year, with applications due June 15 and November 15. For complete information about the program and to download an application, visit the Chapter website at www.ISPEBoston.org/Scholarship.

eNewsletter Advertising Space Now Available

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

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

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

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

Join This Fall's CPIP Study Group: You Won't Believe How Much You'll Learn!

Congratulations to our newest Boston Area Chapter CPIP: Jean Quong of Genzyme. Jean graduated from the CPIP study group recently completed this past spring. Jean joins the group of 29 CPIPs - a full 40 percent of the world's CPIP population - practicing their craft here in New England. We hope her success provides inspiration and motivation for her fellow spring study group graduates!

The Boston Area Chapter continues to lead the way by organizing and supporting two CPIP study groups annually. This fall, our program moves to the Pfizer site in Andover, giving ISPE Members who live or work north of Boston an opportunity to join the exclusive and prestigious CPIP ranks. Brian Hagopian, CPIP and Chapter Past President, will be one of the CPIPs leading the fall session.

There are still a few openings left for the fall study group. You won't believe how much you'll learn so sign up before it's too late. For more information on the CPIP program, please visit http://www.ispe-pcc.org. To sign up for the fall study group, contact the Chapter office at 781.647.4773 or office@ispeboston.org.

Student Members Now Attend Chapter Educational Programs at No Charge

The Chapter's Board of Directors has gone "all in" when it comes to providing pathways for students and young professionals to become actively involved with ISPE. In its latest effort to encourage a high level of participation by these industry leaders of the future, the Board voted to allow Student Members to attend Chapter educational and related events for free. An earlier vote enabled Young Professional Members to attend at a discounted rate: $20 for early registration and $30 after that date. Membership in the Boston Area Chapter truly does have its privileges!

Upcoming Chapter Events - Mark Your Calendar

Wednesday(s), September 11 - October 9, 2013
CPIP Study Group Introductory Session
Pfizer, 1 Burtt Rd, Andover, MA

The Boston Area Chapter is poised to help you attain this credential by sponsoring study groups. If you elect to pursue this credential on your own, you would need to invest over $2,500 to purchase the course materials. However, when you participate in an organized CPIP study group, ISPE has agreed to furnish these materials absolutely free! This saves you over $2,500 in course costs. The study group concept gives you the additional advantage of sharing ideas with other like-minded individuals seeking to advance their position in the industry. The study group concept has been pioneered in Boston and is being refined and improved with each successive offering. To date, this concept has been extremely successful and our study groups have a passing rate of about 90% on the certification exam. Last year, Boston Area Chapter study groups produced over 60% of the new CPIP's in the world.

Study group leaders have participated in one of the Chapter sponsored study groups, passed the exam, and helped to organize the flow of material, bringing all their practical experience to the session in order to make it easier for you to be successful. The upcoming fall study group will be led by Brian Hagopian, CPIP who attained the credential in 2012. Several other Boston Area CPIPs will also participate in this study group, sharing the valuable lessons they learned along the way.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=382

Thursday, September 19, 2013
Dual Track Seminar: CIP and SIP
Genzyme Framingham 68 New York Avenue, Framingham, MA 01701

TRACK 1: Round table discussion of Steam-in-Place and Clean-in-Place

The round table discussion will be a practical round table discussion of clean-in-place and steam-in-place concepts from design, development, and qualification. Different subjects will be posed to the panel but open to the audience to discuss. The program will be kept intimate in order to maximize the ability of the attendees to interact both with the panel but also with one another. Different topics surrounding cleaning and steam sterilization processes will be selected to engage the audience and panel around current industry issues. The purpose of this program is to not just scrape the surface of these subjects but to dig a little deeper by using the collective knowledge of the panel and attendees. Learn from others' successes and failures in this interactive forum.

TRACK 2: Seminar 101-Going back to school on cleaning and sterilization processes

Clean-in-Place and Steam-in-Place 101

Are the basics of cleaning and sterilizing of equipment baffling to you? Then this is the course for you. You will learn about AFo to Z Value. This intro session will give you the basics of CIP and SIP. If you are new to the industry or have not been exposed to cleaning or sterilization processes, this track will give you the basics to understand the critical aspects of these processes. Cleaning and steaming processes are subjects that come under intense regulatory scrutiny and are critical to pharmaceutical processing. Learn about these important topics from an industry expert.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=391

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

ISPE + is the theme for this year's Show. It means being greater than the sum of our parts. Be a part of the greater sum and join us at the 22nd Annual Product Show at Gillette Stadium in Foxborough, MA. With an expanded exhibition area

Previous Issues

+ education sessions + career fair + vendor show case + entertainment zone + after party + even more to be announced soon, this year's Show promises to be the best yet. Attendance and parking are free. Register today using the link below.

Exhibitor Booths are SOLD OUT!

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

Attendees, Register Here: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=324

Sneak Preview of Upcoming Events

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

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

Bigger and Better Product Show Returns to Gillette October 2 – Be There!

by H. Steven Kennedy, Independent Consultant

This year marks the 22nd edition of the ISPE Boston Area Chapter Product Show to be held at Gillette Stadium on October 2. This year's sold out show is shaping up to be even bigger and better than last year. This year the exhibit area has been doubled to accommodate an increase in the number of exhibitors – you'll find exhibitors and activities in clubhouses on both the east and west sides of the Stadium. For a brief overview of the day's activities, read on. And for complete details about the Product Show's many attractions, be sure to consult the articles that follow.


Gillette Stadium always provides a stunning backdrop for the Product Show

In addition to over 300 exhibitors and the many additional attractions and amenities available, this year's Product Show boasts a full slate of education and training events offered throughout the day. Educational programs start at 10:30am and 12noon; a career development panel discussion begins at 3:15pm and an overview of the Internship Challenge sponsored by the Massachusetts Life Sciences Center kicks off at 4:30pm. In addition, product demos will be held in the Vendor Showcase area on alternating stages throughout the day. And the winners of the Chapter's 2013 Student Poster Competition will be on hand to answer questions about their research. A show within a show, the annual Career Fair has many of the area's leading firms waiting to meet with you – so be sure to stop by and see what they have to offer.

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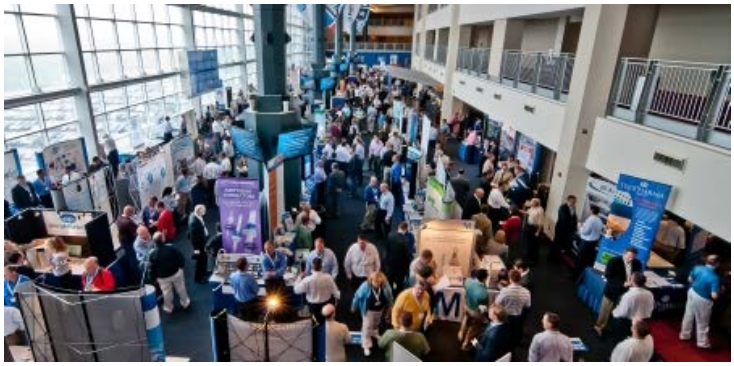

This year a record number of exhibitors will occupy both East and West Clubhouses

And don't miss the Plenary Session beginning at 1:30pm. You'll want to be there to hear Chapter President Dan Ramsey's update on the State of the Chapter and cheer the winners of special awards recognizing exceptional contributions by Chapter volunteers. To wrap up, you'll be treated to an insider's view of the state of the industry and its future, both locally and globally, by dynamic Keynote Speaker Robert Coughlin, President & CEO of MassBio. All in all, this will be a highlight of the Product Show you won't want to miss so be sure to leave time for it in your busy schedule!

Popular educational programs & workshops will take place throughout the day

Of course, it wouldn't be a Product Show without our many fun networking activities. So plan to take a break from checking out the hundreds of biotech and pharma vendor exhibits and have a special photo taken at our "green" screen. Or stop and be amazed by our wandering magician. Or grab a drink and rock out in the Entertainment Zone with one of the bands playing at Pharmapalooza. Or laugh and hang with some friends and co-workers while getting a once-in-a-lifetime portrait done by our digital caricaturist. Or take a chance to win an iPad – raffle winners will be announced throughout the day. And when the Show wraps up at 7:30pm, come join the crowd at the after party at Bar Louie for drinks, appetizers and networking and meet New England Patriot Stevan Ridley. Autographs are free!

Who will follow last year's Hank Moes Award winner Dick Priester?

The Product Show wouldn't be complete without our annual membership drive. So be sure to stop by the ISPE membership booth staffed by Chapter volunteers and take advantage of the generous Product Show membership discount for new members & renewals both. Better yet, bring a non-member colleague and sign them up!


Wind down at the After Party at Bar Louis & get a free Stevan Ridley autograph!

And best of all, the Chapter continues to offer this outstanding event free of charge, supported in full by our generous exhibitors. This includes free parking, free admission, free food and soft drinks, free educational seminars and free Stevan Ridley autographs. If you haven't attended in the past, please let us welcome you this year!

To those loyal ISPE Members who have attended year after year, thank you. You're the backbone of the Chapter. You built the foundation for this event's success over the past twenty-two years and we thank you for your contribution!

Click Here to View the Show Schedule

Hear from Industry Experts: Start Your Day at the Educational Program

by Mike Severino, Festo

The Boston Area Chapter is especially proud of the program of educational activities selected for this year's Product Show. In keeping with Chapter tradition, we have chosen engaging industry leaders presenting current topics of interest both locally and industry-wide. Two sessions run simultaneously during each of two time slots. The four sessions are a balance of emerging global standards, process trends and sound engineering principals, including Biotech 101, a back-to-basics intro to biotechnology specially designed for those new to the industry or looking for a refresher update.

This year's educational program topics include global standards, process trends & an intro to biotech

In a departure from prior years, the educational programs will be held on the far side of the stadium in the East Clubhouse. Be sure to register early at www.ISPEBoston.org/ProductShow to ensure a seat for the topics of your choice.

10:30 AM - 11:45 AM

• "This Old Plant" - Performing Projects and Manufacturing Operations Concurrently

Rick Kotosky, PE, Senior Process Engineer, Integrated Process Technologies, Inc.
John Spohn, CPIP, Senior Project Manager, Hargrove Life Sciences New England Operations

From simple tasks like adding a WFI drop to major process change or expansion, performing mechanical work in an operating GMP facility presents significant challenges. Under the best conditions, proper execution of engineering projects for GMP use is complex but retrofit projects in an operating plant add an additional layer of complexity, from the need to maintain production schedule and limit risk to product-in-process. This session will first examine some of the not-so-obvious ways that facility design can impact project design, then focus on operational considerations that constrain project execution and what planning techniques to offset those constraints.

• How Leaders are Harmonizing our Biopharm Industry Standards

There is a revolution within the biopharm industry, sharing best practices from around the globe to enhance standards to address emerging issues. The continuous process improvement nature of business combined with new technological discoveries requires a collaborative forum to advance these ideas. This collaborative effort leveraging industry focus groups provides interactions between organizations to respond to industry challenges.

The ability to leverage the ASME Bioprocessing Equipment (BPE) committee and its affiliations with other groups is a powerful tool to address manufacturing, R&D, and quality systems challenges. Through the adoption of these and similar standards, ISPE guidance documents provide an overview and examples of approaches to harmonize best practices.

In addition to the regular BPE committee meetings there are a number of additional affiliated groups addressing a wide range of topics with representation from the BPE, BPOG, and BPSA, to name a few. The BioPhorum Operations Group (BPOG) has 19 member companies with over 500 participants establishing best practices for a wide range of quality, engineering and organizational areas central to the challenge of mastering biotech drug substance operations. The Bio-Process Systems Alliance (BPSA) is an industry-led, corporate member trade association dedicated to encouraging and accelerating the adoption of single use manufacturing technologies used in the production of biopharmaceuticals and vaccines. Please join industry experts and a distinguished panel to learn more about these forums and to participate in an informative Q&A session.

Jay Ankers, Director of Technology, M+W Group
Frank J. Manning, Director of Sales, Biopharmaceutical Products, VNE Corporation

12:00 PM - 1:15 PM

• Single Use Technologies - Real Life Experiences

Excited about buying all of that nice, new disposable processing equipment for your biotech plant? Scared to death about how to implement it? Worried about what might happen after the new car smell is gone? Come to this one-of-a-kind panel discussion to hear top experts share their experiences with introducing single use technology into their biotech manufacturing processes. Far from a sales pitch, this discussion will prepare you to navigate through a risk-based application of this emerging technology.

Our panel will be led by Pietro Perrone, Chair of the ISPE Disposables Community of Practice (COP) Steering Committee. The panel will include folks with direct experience in the implementation of single use equipment at several top local biotechs such as Acceleron, Genzyme and Shire.

Pietro Perrone, PE, Single-Use Systems Engineer, EMD Millipore
Mauricio Barraza, Senior Manager of Facilities, Manufacturing Science & Technology, GMP Production & Fill Finish, Acceleron Pharma
Mark McElligott, Partner & Principal Process Engineer, PDS (Process Design Solutions)
Patrick Mullin, Validation Engineer, Genzyme

• Biotech 101: A Bird's Eye View of the Basics

New to the industry? Or seeking a refresher course on the basics? Learn the fundamentals of biotech during this informative session that will introduce basic concepts, review essential terminology and provide an overview of required processes. Attendees will gain knowledge of what's downstream, what's upstream, the required utility systems, and more, providing a clear understanding of key elements. Want a better understanding of the basics of biotech? This presentation is designed for you!

Lou Traglia, Senior Project Manager, Commissioning Agents Inc. (CAI)

Career Development Workshops Lure Students, Young Professionals & Job Seekers

Students and young professionals form a critically important group of Chapter Members - after all, they represent the industry leaders of the future. In light of this, the Chapter has been focusing resources on better serving the needs of this dynamic, upwardly mobile demographic with a robust range of activities designed just for them. Among these are two events taking place at this year's Product Show. The first is a panel discussion with tips for career success in the competitive life sciences marketplace; the second is an introduction to the Internship Challenge, a workforce development program designed to create hundreds of new, paid internship opportunities each year.

So if you're a student, young professional or job seeker. Or simply want to brush up your skills, be sure to register early at www.ISPEBoston.org/ProductShow to ensure a seat for the career development topics of your choice.

3:15 PM -4:15 PM

• What you should know about the Life Sciences Marketplace: Empowering You to Increase Your Value in the Workplace

Want to gain new opportunities within your current workplace? Need advice for making the right impression with a potential employer? Discerning employees know there's a need to go beyond working hard and hoping hiring managers recognize them for new openings or promotions. In the competitive world of life sciences, how do you honestly present yourself in a way that leads to career success?

Panel Moderator Nuno Goncalves of HireMinds LLC is responsible for connecting top talent with the best life sciences companies and working as a career consultant to the brightest scientists and engineering professionals in our industry.

Drawing upon a wealth of experience recruiting and developing biotech talent, our panelists will provide key insights for boosting personal success throughout the life cycle of a working professional and examine strategies for marketing yourself effectively.

Nuno Goncalves, Sr. Practice Director, Biotechnology & Pharmaceuticals, HireMinds LLC
Michael Pelletier, Site Manager Portsmouth, Lonza Biologics
George Kafes, Sr. Corporate Human Resources Recruiter, Biogen Idec
Sean Lamont, Sr. Manager, Automation Engineering, Biogen Idec
Carson Burrington, District Manager, Kelly Scientific Resources

4:30 PM - 5:30 PM

• The Massachusetts Life Sciences Center Internship Challenge

The Internship Challenge is a workforce development program administered and funded by the Massachusetts Life Sciences Center (MLSC) that is focused on enhancing the talent pipeline for Massachusetts life sciences companies. Consistent with the MLSC's role as a catalyst in growing the talent needed by the life sciences industry, the Internship Challenge is designed to create hundreds of new internship opportunities each year by enabling small businesses to hire paid interns. Students and recent grads looking for an internship in the life sciences industry submit an online application through the MLSC's website, while prospective host companies register with the MLSC to review applications and select candidates with the qualifications that are most suited to their needs. The MLSC will then reimburse eligible companies for intern stipends with a pay rate of up to $15 per hour, for a total reimbursement of up to $7,200 per intern.

Ryan H. Mudawar, Manager, Academic and Workforce Programs, MLSC

Career Fair Provides Showcase for New England's Leading Companies

by Alex McKinnon, RCM Technologies

This year, the Product Show Career Fair has expanded its space and will provide greater opportunities to area job seekers and hiring companies. For area job seekers, the Career Fair provides access to many of the top life science companies in New England and the ability to meet HR representatives and hiring managers face-to-face in a relaxed setting with beautiful Gillette Stadium as a backdrop. Prior participants have included Shire, Wyeth, Bristol-Myers Squibb, AstraZeneca, Biogen Idec, Abbott, Lonza, Pfizer, Genzyme, Vertex and more.

For hiring companies the Career Fair offers one of the largest one-day gatherings of biotechnology and pharmaceutical professionals in the Northeast. It gives hiring companies access to engineering, QA, validation, regulatory, clinical, manufacturing, project management and other life science professionals in a condensed amount of time and the ability for face-to-face contact on the spot. Gillette has plenty of space and offers a semi-private area for companies to conduct private conversations with potential candidates about open positions and career advancement.

In addition to the Career Fair, this year's Product Show includes two career development presentations. For more information about these exciting offerings, refer to the companion article above.

MassBio CEO to Shed Light on "State of the Biopharm Industry and its Future"

by Laurie Masiello, Masy Systems

The ISPE Boston Area Chapter is privileged to announce that Robert Coughlin, President and CEO of the Massachusetts Biotechnology Council (MassBio), will be the keynote speaker at this year's Product Show at Gillette Stadium on October 2. His address, discussing the current state of biopharm and what the future holds for the industry, will be the highlight of the Plenary Session beginning at 1:30pm in the West Clubhouse.

The mission of MassBio is to foster a positive environment that enables each biotechnology company to achieve its full potential in Massachusetts, making the state a world center for biotechnology. Bob is very familiar with all areas of the Massachusetts life sciences super cluster and is a passionate advocate for research and the biotechnology community.

Bob has spent his career in both the public and private sectors, most recently serving as Undersecretary of Economic Development within Governor Deval Patrick's administration. Prior to that, he was elected as State Representative to the 11th Norfolk district for three terms; both healthcare and economic development were his legislative priorities. In the world of business, Bob specialized in the environmental services industry and moved on to capital management and venture capital, holding senior executive positions in both fields. He is a graduate of the Massachusetts Maritime Academy where he majored in Marine Engineering, and is a Lieutenant in the United States Naval Reserve.

MassBio CEO Robert Coughlin will cover the biopharm industry - its current state and future prospects - during his keynote address

Bob has also been active in the community, serving on the boards of the Massachusetts Maritime Academy and Beth Israel Deaconess Hospital and acting as honorary chairman of the Great Strides Cystic Fibrosis Walk since 1996. In years past, he co-chaired the Children's Hospital Boston signature event, Champions for Children's. In 2011, the American Diabetes Association honored Bob with their Father of the Year Award. This past year, he served as the co-chair of the Schwartz Center Compassionate Healthcare Dinner.

Students and Young Professionals - There's Something Special Just for You!

by Sean Burgess, Integrated Builders with photos by Alastair Battson Photography

The Boston Area Chapter Young Professionals and Student Chapters have had a very successful year and are continuing to grow. At this year's Product Show there will be a great mix of educational and social activities for everyone to attend. In addition, there will be a series of offerings of special interest to our younger Members. These include this year's Student Poster Contest winners, a meeting of Student Chapter officers, a presentation by the Mass Life Sciences Center about their Internship Challenge Program, the announcement of the Joel Goldenberg Memorial Scholarship winners and, last but not least, a Social and Trivia Contest at the end of the afternoon to wrap up a great show!

Student Poster Competition In the Northeast Lounge of the East Clubhouse, this year's poster competition winners, Miglia Cornejo and Kassi Stein of Northeastern University in the Undergraduate Category and Dan Hickey of Northeastern University in the Graduate Category, will be on hand at the beginning of the Show to introduce their work. Not only will they be able to present their posters to the 300 companies and 2,000 local professionals in attendance, they will also get an expense paid trip to compete in the international poster competition held at the ISPE Annual Meeting! Next year it could be you!

Vendor exhibits provide a unique learning experience for students and young professionals

Student Chapter Officers Meeting This year for the first time, the Product Show will host a meeting of all of the Student Chapters' leaders in one of Gillette's luxury boxes. This meeting of the minds will allow the Student Chapters to share best practices, brainstorm about issues, plan joint events and come up with new ideas to grow and improve their programs. It will also be a great opportunity for our newer Student Chapters to work with veteran Members and long-standing Student Chapters.

Internship Challenge Program As part of the Product Show's Career Development offerings (see companion article above) Ryan Mudawar from the Mass Life Science Center (MLSC) will be speaking about their Internship Challenge Program. The program places students and recent grads in paid internships at Massachusetts companies, with the funding provided by the MLSC. Over 1,200 interns have been placed at over 340 companies in the past four years as part of the program. This will be an unparalleled opportunity for students, young professionals and eligible companies to

learn about the program and what it can do for them.

Access to industry leaders is a Product Show plus for young Chapter Members

Social and Trivia Contest Beginning at 5:45pm in the Southwest Lounge of the West Clubhouse, the Young Professionals will be hosting a Social and Trivia Contest for YPs and students. Before the trivia contest begins there will be a one-hour networking reception with appetizers, soft drinks and a cash bar where students can talk with the YPs about their experience with ISPE and learn about future opportunities and events. This will be a great opportunity to meet other people from different areas of the industry and get involved with the ISPE, all with a little friendly competition thrown in!

So if you're a YP or Student Member, there's something special just for you - in addition to the many exhibits, educational programs, product demos and the thrill of spending a day in the shadow of the New England Patriots at Gillette Stadium. Don't miss out!

Tufts Gordon Institute Hosts June Educational Program on Validation

by Chiderah Okoye, Rockwell Automation; Armen Nahabedian, Pfizer; and Brian Hagopian, CPIP, Clear Water Consulting

On Thursday, June 20 the Boston Area Chapter held its final educational program of the spring at the Tufts Gordon Institute in Medford. This program was another highly successful “dual track” program featuring concurrent introductory level and advanced level sessions. This program’s focus was on validation. The evening began with a gathering of attendees for a networking reception featuring a wide array of tasty appetizers. Carla Eberle and Nancy Buczko from the Tufts Gordon Institute welcomed attendees and gave a brief introduction to the Tufts Masters of Science in Engineering Management program, from which several ISPE members have benefitted. A myriad of different aspects of validation were then explored in both the introductory and advanced tracks.

At the introductory session, attendees listened intently as Rich Yeaton, President of East Coast Validation Services, and Jack Campion, Manager of Project Controls for Genzyme’s Allston Landing facility, provided attendees with their vast validation experience and presented a practical overview of key tenets of validation as well as some concrete recommendations to consider in order to comply with regulatory agency requirements.

During the advanced track, Peter Levy, Principal at PL Consulting, led attendees through some key aspects of the ISPE Process Validation Guide, while Dr. Lilong Huang, Senior Engineer in Global Automated Process Control at Biogen Idec, showed us how Biogen Idec used data generated from chromatography runs on the same process at different facilities to optimize performance and troubleshoot problems. During his presentation, Dr. Huang spoke of how Biogen Idec is advancing the state of the art by using Continuous Process Verification (CPV) as outlined in Stage 3 of the FDA Process Verification Guide to immediately adapt and change process operations to ensure optimum performance on a continuous basis. Adopting CPV posed some unique challenges and Dr. Huang was kind enough to share the lessons learned during this process with attendees.

The event catered to over 55 attendees, one of whom stated that the program’s dual focus was valuable in “building validation team work at [their] company” and many others expressed being impressed by the knowledge of the featured speakers and quality of the presentations.

Thanks again to our dual track speakers, the Tufts Gordon Institute, and the whole Boston Area Chapter session coordinators for helping put together this great June event!

Chapter Celebrates Summer with Bluegrass and Barbecue, Golf Outing & More

by Janet Tice, GMP Piping, photos by Patti Ascanio, Mangan Biopharm,

Each year during July and August, the Chapter takes a break from its rigorous schedule of monthly educational programs. The Educational Program Committee uses this hiatus to fine tune its educational offerings for the upcoming year and Chapter Members use it to enjoy the summer weather with a series of outdoor social and recreational activities, some traditional, some not so traditional.

In the first category, this year's Golf Outing - the 11th Annual, to be exact - took place on July 29th at the gorgeous Indian Pond Country Club in Kingston, MA. And this year, the weather gods smiled, providing participants with golf-perfect weather. Congratulations go to our winning foursomes and our six individual winners:

First Place (59)	**Second Place (59)**	**Second Place (62)**
George T. Wilkinson	**Skanska USA Building**	**SPS CleanTech**
Geoff Wilkinson, Jr.	Jim Maguire	Andy Martuscello
Dan Paquette	Brian Fugere	Ryan Burke
Herbie Aikens	Joe Devlin	Chris Corsetti
Paul Degnan	Glen De Noble	Bob Flynn

	Women	**Men**
Straightest Drive	Cheryl Huie	Brian Fugere
Closest to Pin	Tiffany Hubanks	Aiden O'Dwyer
Longest Drive	Suzie Stuhler	Herbie Aikens

Thank you to everyone who participated this year, with added thanks all the sponsoring companies who helped make this event another huge success for the Chapter: SciTech Builders, R.W. Sullivan Engineering, M+W Group, Middlesex Gases + Technologies, Superior Controls, George T. Wilkinson, Interstate Electrical Services, New England Controls, Siemens, The Richmond Group, POND Technical Sales, GxP Automation, RoviSys, RDK Engineers, Superior Controls, ICQ Corp, Mangan Biopharm, DECCO, Burkert Fluid Control Systems and DPS Biometics. We couldn't do it without your
support

Golf Outing raffle proceeds benefit the Joel Goldenberg Memorial Scholarship fund, so the event plays a crucial role in the Chapter's Member benefits. And rumor has it that plans are afoot to add a second Golf Outing during the 2014 season, so be sure to stay tuned!

In the second category, Bluegrass & Barbecue greeted Members at Tommy Doyle's in Kendall Square on June 26th with entertainment provided by The Four Legged Faithful. And not to be outdone, the Chapter's Young Professionals hosted their first-ever YP Volleyball Tournament at the Bunker Hill Community College playing fields on July 16th, smack in the middle of the summer's worst heat wave. All the better to enjoy a cool one at the nearby Warren Tavern after the competition!

Chapter Members gathered at Tommy Doyle's in Kendall Square for barbeque, blues & great company

So before you decide the Chapter is all work and no play, take another look at the photos above - I know you'll change

your mind!

Volleyball & Validation: YPs Mix Summer Fun with Education

Text by Dave Gallagher, GxP Automation

Hello fellow YPs! With summer coming to an end and fall quickly approaching, the Boston Area Chapter YPs hosted our last mid-summer event, the Young Professionals Volleyball Tournament at the Bunker Hill Community College fields. This was the first time we have hosted a volleyball tournament but it proved to be a great choice and venue. Even though we managed to have the event smack in the middle of the July heat wave, the turnout was still positive and there were many new faces in the crowd! Following the match, the group headed over to the Warren Tavern for drinks and networking. Thanks to Mike Comtois of RDK Engineers for organizing this event.

The YPs also took part in planning the Validation dual-track educational program which took place back in June at the Tufts Gordon Institute. The event consisted of an introductory track focusing on the key regulatory agencies and expectations of validation, as well as an overview of validation basics and why it is required from an agency, process and product life cycle perspective. The evening also included an advanced track, which plunged deeper into all aspects of process validation and highlighted its most advanced and practical applications. Dual-track events like this one are especially beneficial for our Young Professional and Student Members, as the introductory track gives an overview of the topic without diving deeper into specifics. Thanks to YP Chiderah Okoye for helping to organize this event.

As for future events, the Annual Boston Harbor Cruise is quickly approaching and will be held on Thursday, September 5. The Harbor Cruise is open to all ISPE members and is a good opportunity for young professionals to network and socialize with the Chapter's seasoned industry veterans. The boat leaves from 70 Rowes Wharf in Boston at 7pm sharp - so don't be late! There will be food aboard and a cash bar (no credit cards). Hope to see you there!

Student Development Efforts Accelerate as Fall Semester Gets Underway

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

Summer is often a quiet time for student-related activities but not this year when the Chapter and the Student Development Committee were both quite busy with warm weather activities and planning for the upcoming year.

Strategic Planning The Student Development Committee held its first annual strategic planning meeting on July 31 to organize activities for the upcoming year. Students, faculty advisors, and Boston Area Chapter industry advisors gathered to brainstorm, share ideas, and coordinate efforts for the upcoming academic year. All participants applauded the Chapter's willingness to organize monthly student events. Events will be posted on the Chapter Events Calendar once the dates are set, so check it out at http://www.ispeboston.org/eventcal/calendar.html .

Scholarship Update Congratulations to the latest winners of the Chapter's Joel Goldenberg Memorial Scholarships. These outstanding students include entering freshmen, undergrads and grad students working toward advanced degrees.

Anatoly Tereschuk, UMass Amherst
Callie King, Worcester Polytechnic Institute
Noreen Rizvi, Northeastern University
Kathryn Gikas, Boston University
Lorraine Mathis, Tufts University
Samuel Musiak, UMass Lowell
John Busanovich, Boston College

This spring, more students than ever applied for scholarship awards of up to $2000 each, with a lifetime cap of $4000 per student. Awards are made twice each year, with applications due June 15 and November 15. For complete information about the program and to download an application, visit the Chapter website at www.ISPEBoston.org/Scholarship.

Welcome to the University of Rhode Island Student Chapter One of the many benefits of our merger with the New England Chapter is the addition of the University of Rhode Island to our roster of Student Chapters. URI has its own biotech-based curriculum which has been developed, marketed, and primarily taught by Dr. Ed Bozzi, who we are fortunate to have as the Student Chapter academic advisor. Please join me in extending a warm welcome Ed and the URI Student Chapter! Chapter volunteers from the Student Development committee will be meeting with the incoming freshman class in September to share our plans for the year.

Massachusetts Maritime Academy Adds Student Chapter It's about to become official, so let me extend a warm welcome to our newest Student Chapter at Massachusetts Maritime Academy (MMA). There is excitement in the air as momentum builds. Many thanks to George Howe, our faculty advisor at MMA, for his efforts in helping to get the Chapter organized. And a special thank you to Jonathan Michael "JM" Beane, a student at MMA and an ISPE Student Member. JM attended the April educational program at WPI and expressed interest in starting a Student Chapter at MMA. JM did the initial legwork, made the appropriate introductions and, coupled with the efforts of MMA alumni Dan

Ramsey, Rob DeCoste and Mike Cheney, helped the Chapter hold a very successful alumni panel discussion at MMA that led to the formation of the new Student Chapter. It is efforts like these by committed volunteers that give the Boston Area Chapter its strength and leadership position in the industry! Thanks JM!

Students at Mass Maritime Academy attended a recent presentation by MMA alumni & Chapter leaders Dan Ramsey, Rob DeCoste and Mike Cheney.

Lots of Student Events This Year The Chapter has a full slate of activities planned for the fall and spring semesters, with the following events already planned for students:

- **September 19 Introduction to CIP/SIP** with introductory track free to ISPE Student Members.
- **October 2 Product Show at Gillette Stadium.** ISPE will provide round trip bus transportation from each Student Chapter campus. This year's show will be packed with opportunities for students to learn and network with young professionals and industry leaders in a casual environment.
- **November student-centered educational program and plant tour at Genzyme** in Framingham.
- **February Career Fair** to prepare students to make the right first impression during interviews for internships, co-ops and fulltime employment.
- **March plant tour**
- **April 17 Student Poster Contest and dual-track educational program** at WPI.

Calling All Poster Contestants We want to bring your attention to the last bullet point, the Boston Area Chapter Student Poster Contest. Do you have a research project you want to share? Would you like an opportunity to showcase your work and network with industry leaders? Start planning now and participate in our spring Student Poster Contest, which will be held April 17 at WPI in conjunction with our monthly educational program. Graduate and undergraduate category winners will receive an expense paid trip to the ISPE Annual Meeting to compete in the International Student Poster competition. This past year, Northeastern swept the Chapter competition, making it two years running! Congratulation to Northeastern! But now it's time for our other Student Chapters to step up! Visit our website at www.ISPEBoston.org or contact the Chapter office for details.

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

Industry News In Brief

by Janet Tice, GMP Piping

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

Sunovion Announces FDA Approval of Latuda for Bipolar Depression

Sunovion Pharmaceuticals announced that the FDA has approved two new indications for the use of Latuda (lurasidone HCl) as 1) monotherapy and 2) adjunctive therapy with either lithium or valproate, both to treat adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression). Bipolar disorder, a mental illness characterized by debilitating mood swings, affects approximately 10.4 million American adults and is among the top 10 leading causes of disability in the United States. Bipolar depression refers to the depressive phase of bipolar disorder.

"These two approvals represent a significant milestone not only for Sunovion and DSP, but for the millions of Americans who are living with bipolar disorder and struggling to manage the symptoms of bipolar depression," said Masayo Tada, Representative Director, President and Chief Executive Officer of Dainippon Sumitomo Pharma Co., Ltd. "We look forward to building on the strong foundation started in the United States to bring LATUDA to other markets around the world. In addition, we are preparing for Phase 3 clinical trials for bipolar I disorder (bipolar depression) in Japan, an important market for us, where Phase 3 clinical trials for schizophrenia are already underway. This is part of Sunovion and DSP's ongoing commitment to researching, developing and commercializing new treatments for people with mental illness." (Source: Sunovion Pharmaceuticals Website, 28 June, 2013)

EnVivo Announces Appointment of Deborah Dunsire as President & CEO

EnVivo Pharmaceuticals, a Watertown-based company dedicated to developing a broad range of novel therapies for central nervous system (CNS) diseases, has announced the appointment of Deborah Dunsire, M.D., as president and chief executive officer. She also joins the company's board of directors.

Dr. Dunsire served as president and chief executive officer of Millennium Pharmaceuticals, Inc., now Millennium: The Takeda Oncology Company, from 2005 to 2013. During that period, she transformed the company into a biotechnology industry leader by focusing R&D, driving the development pipeline, fostering a culture of employee engagement and increasing the commercial mindset across the organization to enhance the commercial success of marketed products. The company was acquired by Takeda Pharmaceutical Company Limited in 2008 for $8.8 billion – one of the largest biotech acquisitions at that time – and became Millennium: The Takeda Oncology Company. Dr. Dunsire was the first woman appointed to Takeda's board of directors.

"CNS diseases, including Alzheimer's disease and schizophrenia, take a devastating toll on patients, families and the health care system," said Dr. Dunsire. "EnVivo's late-stage lead product candidate and broad pipeline of promising clinical programs present a unique and compelling opportunity to develop new therapies with the potential to make a dramatic impact on patients' lives. I am looking forward to working with the EnVivo team to purpose-build a biopharmaceutical company focused on transforming the CNS treatment landscape."

Prior to leading Millennium, Dr. Dunsire led the Novartis U.S. Oncology Business, playing a critical role in the broad development and successful launch of a number of products. Over 10 years, she increased the North American oncology revenues from $50 million to more than $2.2 billion. She served on the U.S. Pharmaceutical Executive Committee at Novartis. (Source: EnVivo Website, 11 July, 2013)

J & J Reports Strong Second-Quarter Results

Johnson & Johnson announced sales of $17.9 billion for the second quarter of 2013, an increase of 8.5% as compared to the second quarter of 2012. Worldwide Pharmaceutical sales of $7.0 billion for the second quarter represented an increase of 11.7% versus the prior year.

Primary contributors to operational sales growth were Remicade (infliximab) and Simponi (golimumab), biologics approved for the treatment of a number of immune-mediated inflammatory diseases; Stelara (ustekinumab), a biologic approved for the treatment of moderate to severe plaque psoriasis; Invega Sustenna/Xeplion (paliperidone palmitate), a once-monthly, long-acting, injectable atypical antipsychotic for the acute and maintenance treatment of schizophrenia in adults; Velcade (bortezomib), a treatment for multiple myeloma; Prezista (darunavir), a treatment for HIV; and sales of recently launched products.

The strong sales results of recently launched products included Zytiga (abiraterone acetate), an oral, once-daily medication for use in combination with prednisone for the treatment of metastatic, castration-resistant prostate cancer; Xarelto (rivaroxaban), an oral anticoagulant; and Incivo (telaprevir), a direct acting antiviral protease inhibitor, for the treatment of genotype-1 chronic hepatitis C virus.

During the quarter, the FDA approved Simponi (golimumab) for the treatment of moderately to severely active ulcerative colitis in adult patients who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine. Additionally, the FDA granted Breakthrough Therapy Designation for daratumumab for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD. Daratumumab is an investigational human CD38 monoclonal antibody licensed from Genmab A/S.

Also during the quarter, the Committee for Medical Products for Human Use of The European Medicines Agency granted a positive opinion on two variations relating to the use of Velcade (bortezomib). In addition, the European Commission approved a new twice daily (BID) dosing of Incivo (telaprevir), a direct acting antiviral protease inhibitor, in combination with pegylated-interferon and ribavirin for naive and previous treatment experienced patients.

A definitive agreement was signed in June to acquire Aragon Pharmaceuticals, Inc., a privately-held, pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers. The acquisition includes Aragon's androgen receptor antagonist program. Aragon's lead product candidate is a second generation androgen receptor signaling inhibitor, ARN-509, in Phase 2 development for castration resistant prostate cancer. (Source: J&J Website, 16 July, 2013)

Ironwood Pharmaceuticals Provides Second Quarter 2013 Investor Update

Cambridge-based Ironwood Pharmaceuticals provided an update on its second quarter 2013 and recent business activities. According to Peter Hecht, chief executive officer of Ironwood:

The past six months have been a transformative period at Ironwood, thanks to the dedication and hard work of our team," said "The Linzess launch is strong and tracking well across all leading indicators, and we and Forest are working closely together to drive all aspects of the launch. At the same time, together with Forest we are making progress in our efforts to maximize the commercial and clinical success of Linzess by exploring ways to strengthen the existing label and seeking regulatory approval for Linzess in additional populations and indications. During the second quarter, Almirall launched Constella in key European countries, and we continue to advance linaclotide in territories around the world along with our partners. We also continued to make progress with our other pipeline programs. We look forward

to advancing our key value drivers and managing investments across our portfolio to maximize per share value for our fellow shareholders.

Ironwood and Forest continue to explore additional development opportunities to strengthen the clinical profile of Linzess within its indicated population and to expand the product label for broader patient populations and indications, as well as to explore the potential for linaclotide-based combination products. The companies expect to initiate U.S. clinical trials in the pediatric population, as well as for the potential treatment of adult patients suffering from opioid-induced constipation, in the first half of 2014.

In addition to exploring additional linaclotide development opportunities, Ironwood is leveraging its pioneering understanding of linaclotide's pharmacology and mechanism of action, guanylate cyclase-C (GC-C) agonists, cyclic GMP, and symptomatic diseases to advance other programs in its pipeline, which include early development candidates and discovery research efforts focused on gastrointestinal disease, central nervous system disorders, allergic conditions and cardiovascular disease. (Source: Ironwood Pharmaceuticals Website, 23 July, 2013)

Acetylon and Celgene Announce Collaboration, Option for Celgene to Acquire Acetylon

Boston-based Acetylon Pharmaceuticals has announced a strategic collaboration and option agreement with Celgene Corporation which supports the development of Acetylon's portfolio of oral, selective HDAC inhibitors in oncology, hematology, immunology, and neurologic disease indications. The agreement includes an exclusive option for the future acquisition of Acetylon by Celgene.

The collaboration will focus on the continued clinical advancement of Acetylon's lead candidate, ACY-1215, an oral first-in-class selective HDAC6 inhibitor being developed for hematological malignancies, ACY-738 for neurological diseases, an HDAC1/2 inhibitor, and a yet unnamed project, spanning cancer and non-cancer disease indications.

Under the terms of the agreement, Acetylon will receive a $100 million upfront cash payment. In return, Celgene receives an exclusive option to acquire Acetylon at a cash purchase price that will be within a defined value range and based upon future independent valuations of Acetylon. Acetylon will retain control of its drug development programs during the option period.

"Celgene has been an enthusiastic investor and supporter of Acetylon's mission since completing its equity investment in our company early last year," said Walter C. Ogier, President and Chief Executive Officer and co-founder of Acetylon. "We are excited to be able to work with Celgene under the expanded framework of this new development and option agreement. The $100 million in up-front, non-dilutive funding should enable us to aggressively advance our drug pipeline and create substantial value for our patients and investors."

According to its website, Acetylon Pharmaceuticals is a leader in the development of novel small molecule drugs targeting epigenetic mechanisms for the enhancement of therapeutic outcomes in cancer and other critical human diseases. The Company's epigenetic drug discovery platform has yielded a proprietary portfolio of optimized, orally-administered Class I and Class II histone deacetylase (HDAC) selective compounds. Alteration of HDAC regulation through selective HDAC inhibition is thought to be applicable to a broad range of diseases including cancer, sickle cell disease and beta-thalassemia, and autoimmune and neurodegenerative diseases. Acetylon's lead drug candidate, ACY-1215, is a selective HDAC6 inhibitor currently in Phase 1b clinical development for the treatment of multiple myeloma. Acetylon's scientific founders are affiliated with the Harvard University, the Dana-Farber Cancer Institute, the Massachusetts General Hospital, and Harvard Medical School. (Source: Acetylon Pharmaceuticals Website, 29 July, 2013)

Pfizer Reorganizes Business Units

Pfizer has announced plans to move forward to internally separate its commercial operations into three business segments, two of which will include Innovative business lines and a third which will include the Value business line. Each of the three segments will include developed markets and emerging markets. The changes will be implemented in January 2014 in countries that do not require a consultation with works councils or unions, and will be implemented in countries that require consultation after the successful conclusion of those processes. Beginning with the first-quarter 2014 financial results, the company will provide financial transparency for each of these three business segments, which will include a 2014 baseline management view of profit and loss for each segment.

One of the Innovative business segments will be led by Geno Germano, Group President, Innovative Products Group. It will generally include products across multiple therapeutic areas that are expected to have market exclusivity beyond 2015. The therapeutic areas include Inflammation and Immunology, CV/Metabolic, Neuroscience and Pain, Rare Diseases and Women's /Men's Health. The other Innovative business segment will include Vaccines, Oncology and Consumer Healthcare and will be led by Amy Schulman, Group President, Vaccines, Oncology and Consumer Healthcare. Each of these businesses will operate as a separate global business and require distinct specialization in terms of the science, talent, and market approach required to deliver value to consumers and patients.

The Value business segment will be led by John Young, Group President, Value Products Group. This group will include products that generate strong, consistent cash flow, and will be positioned to provide patients access to effective, lower-cost, high-value treatments. In addition to products that have lost market exclusivity, it will generally include mature, patent-protected products that are expected to lose exclusivity through 2015 in most major markets, biosimilars and current and future established products collaborations, such as our existing partnerships with Mylan in Japan, Teuto in Brazil and Hisun in China. (Source: Pfizer Website, 29 July, 2013)

Cubist to Acquire Two Drug Makers

Cubist Pharmaceuticals is set to acquire drug makers Trius Therapeutics and Optimer Pharmaceuticals in separate deals worth up to $1.6 billion. The transactions have been approved by the Boards of Directors of the three companies.

Trius brings to Cubist a highly complementary, late-stage antibiotic candidate, tedizolid phosphate (TR-701), as well as several pre-clinical antibiotic programs. Tedizolid phosphate is an IV and orally administered second generation oxazolidinone in development for the potential treatment of certain Gram-positive infections, including methicillin-resistant Staphylococcus aureus (MRSA).

Trius has partnered with Bayer Pharma AG for the development and commercialization of tedizolid phosphate outside of the U.S., Canada and the European Union. It is currently expected that a New Drug Application for tedizolid phosphate seeking approval for an indication in ABSSSI will be submitted to the FDA during the second half of 2013 and a Marketing Authorization Application will be submitted to the European Medicines Agency in the first half of 2014.

Optimer received FDA approval in May 2011 for Dificid, the first antibacterial drug approved in more than 25 years to treat Clostridium difficile-associated diarrhea (CDAD) in adults 18 years of age or older. The CDAD market is large, with over 700,000 cases annually in the U.S. alone and a high recurrence rate at 20-30%. Hospital stays related to CDAD increased four-fold from 1993 to 2009 and, according to the CDC, the disease is estimated to be responsible for approximately 14,000 deaths per year in the U.S.

Dificid was launched in the U.S. in July 2011. In April 2011, Cubist and Optimer entered into a two-year agreement under which Cubist has been co-promoting Dificid to physicians, hospitals, and other healthcare institutions in the U.S. Concurrently with the merger agreement, the companies have agreed to extend the co-promotion agreement for up to one year. (Source: Cubist Pharmaceuticals Website, 30 July, 2013)

Amgen To Acquire Onyx Pharmaceuticals for $10.4 Billion

Amgen and Onyx Pharmaceuticals have announced that their Boards of Directors have unanimously approved a transaction under which Amgen will acquire all of the outstanding shares of Onyx for $125 per share in cash. The purchase price is $10.4 billion, or $9.7 billion net of estimated Onyx cash. Amgen expects to close the transaction at the beginning of the fourth quarter, subject to the satisfaction of customary closing conditions, including the receipt of regulatory clearance.

Onyx Pharmaceuticals is a global biopharmaceutical company engaged in the development and commercialization of innovative cancer therapies. Onyx has an important and growing multiple myeloma franchise, with Kyprolis (carfilzomib) for Injection already approved in the United States. In addition, Onyx has three partnered oncology assets: Nexavar (sorafenib) tablets (an Onyx and Bayer HealthCare Pharmaceuticals compound), Stivarga (regorafenib) tablets (a Bayer compound), and palbociclib (a Pfizer compound). Onyx also has multiple oncology compounds in various stages of clinical development.

Onyx holds global rights to Kyprolis, excluding Japan. Kyprolis has an orphan drug designation in the U.S. with exclusivity until July 2019, and patents in the U.S. which extend until at least 2025. Amgen will benefit from the global rights to Onyx's innovative oncology portfolio and pipeline. Amgen intends to leverage its oncology capabilities and experience to support Onyx's clinical development programs and maximize Kyprolis' potential in the U.S. and the rest of the world.

The acquisition of Onyx also adds to Amgen's robust late-stage pipeline. This pipeline includes nine innovative products for which registration-enabling data are anticipated by 2016. Four of these are innovative, first-in class oncology products. Onyx's pipeline complements Amgen's growing oncology portfolio.

In addition to accelerating Amgen's revenue growth, the acquisition of Onyx is expected to be accretive to Amgen's adjusted net income in 2015. (Source: Amgen Website, 25 August, 2013)

Astrazeneca Strengthens Cancer Therapy Portfolio with Acquisition of Amplimmune

AstraZeneca today announced that MedImmune, its global biologics research and development arm, has entered into a definitive agreement to acquire Amplimmune, a privately-held, Maryland-based biologics company focused on developing novel therapeutics in cancer immunology.

The acquisition will bolster MedImmune’s oncology pipeline by obtaining multiple early-stage assets for its immune-mediated cancer therapy (IMT-C) portfolio, including AMP-514, an anti-programmed cell death 1 (PD-1) monoclonal antibody (mAb). AMP-514 is currently in late-stage pre-clinical development with the aim of an investigational new drug (IND) filing before the end of 2013.

Other Amplimmune assets include multiple preclinical molecules targeting the B7 pathways. MedImmune’s oncology research is focused on IMT-C, a promising therapeutic approach that may lead to durable and prolonged response rates across a range of cancer types. IMT-Cs are being designed to empower the immune system to counteract the tactics employed by cancer cells to avoid detection and attack the body.

Under the terms of the agreement, MedImmune will acquire 100 per cent of Amplimmune’s shares for an initial consideration of $225 million and deferred consideration of up to $275 million based on reaching predetermined development milestones.

MedImmune, with its clinical stage programmes – tremelimumab, anti-OX40 mAb and MEDI-4736 (anti-PD-L1 mAb) - and a robust pre-clinical pipeline, is building one of the most comprehensive programmes in IMT-C. The acquisition of the Amplimmune technology and pipeline significantly strengthens the AstraZeneca and MedImmune portfolio, enabling

the pursuit of the most effective data-driven combinations of IMT-C molecules as well as combinations with highly targeted small molecules. Because of the complexity of cancer biology, combination therapies have the potential to be one of the most effective ways of treating this disease.

The proposed transaction is subject to customary regulatory approvals and is expected to close in the third quarter of 2013. (Source: AstraZeneca Website, 26 August, 2013)

Lonza to Cut 200 In Hopkinton, Phase Out Plant

The parent group of Lonza Biologics will lay off most of its approximately 300 workers at its Hopkinton plant this year and gradually reduce operations there as part of cost reductions by the Switzerland-based pharmaceutical supplier. Lonza said the reduction of roughly 200 employees at the South Street facility will take place gradually over the next several months. In an email response to questions, Lonza spokeswoman Melanie Disa said final staff-reduction plans are not complete yet.

The announcement came as the company announced financial results for the first half of the year. A statement from Lonza said the company will consolidate future microbial biologics work – which the Hopkinton site performs - in its largest plant in Visp, Switzerland. The company said it will honor all its obligations to existing customers served by the Hopkinton facility.

In recent years, Disa added, the Hopkinton plant has manufactured several commercial products and additional products for customers at various stages of clinical supply; it has also executed several research and development projects for customers around the world. (Source: Rick Saia, Worcester Business Journal, 26 July, 2013)

Mass Life Sciences Center, Consortium Announce Research Funding

The Massachusetts Life Sciences Center (MLSC) and the Massachusetts Neuroscience Consortium announced the first round of awards to fund research on neurological diseases since the consortium launched in 2012. The consortium, which includes Marlborough-based Sunovion Pharmaceuticals, Abbvie and Biogen Idec, which have operations in Worcester, as well as EMD Serono, Merck, Janssen Research and Development LLC, and Pfizer, reviewed applications from researchers at Massachusetts academic and research institutions and selected seven projects to receive a total of $1.75 million in funding, MLSC said.

The winning applicants include researchers from Boston University School of Medicine, Massachusetts General Hospital, the Massachusetts Alzheimer Disease Research Center, Brigham and Women's Hospital, Boston Children's Hospital, and the Massachusetts Institute of Technology.

Researchers will each receive $250,000 to study neurological diseases, including Alzheimer's disease, Multiple Sclerosis, neuropathic pain and Parkinson's disease. Each consortium member will act as a liaison to a corresponding project. Sunovion will fund Multiple Sclerosis research at Brigham and Women's; AbbVie will fund neuropathic pain research at Boston Children's Hospital and Biogen Idec will fund Alzheimer's research at Boston University School of Medicine.

"We are excited that the first solicitation yielded such a positive response from the state's academic and research institutions. We look forward to seeing the results of this research, and the impact it will have on patients suffering from the effects of Alzheimer's disease, Multiple Sclerosis, neuropathic pain and Parkinson's disease," MLSC President Susan Windham-Bannister said in a statement. (Source: Emily Micucci, Worcester Business Journal, 12 July, 2013)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

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

FDA Approves Amgen's Xgeva to Treat Giant Cell Tumor of Bone

The FDA expanded the approved use of Xgeva (denosumab) to treat adults and some adolescents with giant cell tumor of the bone (GCTB), a rare and usually non-cancerous tumor. GCTB generally occurs in adults between the ages of 20 and 40 years. In most cases, GCTB does not spread to other parts of the body but destroys normal bone as it grows, causing pain, limited range of motion and bone fractures. Rarely, GCTB can transform into a cancerous tumor and spread to the lungs.

Xgeva is a monoclonal antibody that binds to RANKL, a protein essential for maintenance of healthy bone. RANKL is also present in GCTB. Xgeva is intended for patients whose GCTB cannot be surgically removed or when surgery is likely to result in severe morbidity, such as loss of limbs or joint removal. It should only be used in adolescents whose bones have matured.

The FDA reviewed Xgeva under its priority review program, which provides for an expedited review of drugs. Xgeva was granted orphan product designation because it is intended to treat a rare disease or condition.

Xgeva was approved in 2010 to prevent fractures when cancer has spread to the bones. It is marketed by Amgen, based in Thousand Oaks, CA. (Source: FDA Website, 13 June, 2013)

FDA Approves First Genotyping Test for Patients with Hepatitis C Virus

The FDA has approved a test that identifies the genotype of hepatitis C virus (HCV) that a patient is carrying. The Abbott RealTime HCV Genotype II, manufactured by Abbott Molecular in Des Plaines, IL, can differentiate genotypes 1, 1a, 1b, 2, 3, 4, and 5,using a sample of an infected patient's blood plasma or serum and will aid health care professionals in determining the appropriate approach to treatment. Because the various HCV genotypes respond differently to available drug therapies, knowing the type of HCV a person is infected with can result in better patient outcomes.

HCV is transmitted through blood and other bodily fluids. Injection drug users who share needles are at the highest risk for HCV infection. Health care workers stuck by needles that have been used on HCV-infected patients and children born to HCV-infected mothers are also at risk.

The Abbott RealTime HCV Genotype II is approved for individuals known to be chronically infected with HCV. It is not approved for use as a diagnostic test or as a screening test for the presence of HCV genetic material in blood, blood products or tissue donors. It has not been evaluated in newborns or pediatric patients, or in patients with compromised immune systems, such as people with AIDS. (Source: FDA Website, 20 June, 2013)

FDA Obtains Waiver from European Commission to Facilitate Exports to Europe

The FDA has announced that the U.S. is now a "listed" country with the European Commission (EC). This means U.S. companies need not obtain an export certificate from the FDA before shipping certain pharmaceutical products to Europe. Without the waiver, all U.S. companies shipping active pharmaceutical ingredients (APIs) to Europe after July 1, 2013 would have had to first submit documentation from the FDA that the product was manufactured in accordance with Europe's good manufacturing practices.

To avoid that burden for companies, the FDA filed a formal "listing request" with the EC in January 2013 that the FDA's good manufacturing practices be considered at least equivalent to those in Europe. The EC has now approved that request following a comprehensive audit of the FDA's regulatory and inspectional oversight of APIs. The audit took place from May 13-20, 2013.

Europe's requirement for the import of APIs falls under its Falsified Medicines Directive, enacted in 2011 in response to the challenges posed in keeping the pharmaceutical supply chain safe at a time when products are increasingly sourced from around the world.

Protecting consumers around the globe from falsified medicines is an enormous and complex undertaking that requires international cooperation. Over the past several years, the FDA has been transforming from a domestically-focused agency to a proactive, global public health agency in order to carry out its mission more effectively in a world where trade, and product safety and quality, have no borders. (Source: FDA Website, 21 June, 2013)

FDA Approves Vibativ for Hospitalized Patients with Bacterial Pneumonia

The FDA expanded the approved use of the antibiotic Vibativ (telavancin) to treat patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by Staphylococcus aureus. Vibativ should be used for the treatment of HABP/VABP only when alternative treatments are not suitable.

Bacterial pneumonia is a lung infection that can be caused by many different types of bacteria. Vibativ is approved only to treat S. aureus, not other bacteria that cause pneumonia. HABP/VABP, also known as nosocomial pneumonia, is a particularly serious lung infection because patients in the hospital and especially those on ventilators are often already very sick and usually cannot fight the infection.

During clinical trials, more patients with pre-existing kidney problems treated with Vibativ died compared to those treated with vancomycin. Vibativ can also cause new or worsening kidney problems in patients. This information has been added to Vibativ's Boxed Warning.

Vibativ was approved in 2009 to treat complicated skin and skin structure infections. It is marketed by Theravance, based in San Francisco, CA. (Source: FDA Website, 21 June, 2013)

FDA Approves First Recombinant Coagulation Factor IX to Prevent Bleeding Episodes

The FDA has approved Rixubis [Coagulation Factor IX (Recombinant)] for use in people with hemophilia B who are 16 years of age and older. Rixubis, manufactured by Baxter Healthcare, is indicated for the control and prevention of bleeding episodes, perioperative (period extending from the time of hospitalization for surgery to the time of discharge) management, and routine use to prevent or reduce the frequency of bleeding episodes (prophylaxis).

Rixubis is a purified protein produced by recombinant DNA technology. It does not contain human or animal proteins. It is supplied in single-use vials of freeze-dried powder and is administered by intravenous injection after reconstitution with sterile water for injection. When used for the routine prevention of bleeding episodes, it is administered twice weekly. (Source: FDA Website, 27 June, 2013)

FDA Approves First Non-Hormonal Treatment for Hot Flashes

The FDA has approved Brisdelle (paroxetine) to treat moderate to severe hot flashes (vasomotor symptoms) associated with menopause. Brisdelle, which contains the selective serotonin reuptake inhibitor paroxetine mesylate, is currently the only non-hormonal treatment for hot flashes approved by the FDA. There are a variety of FDA-approved treatments for hot flashes, but all contain either estrogen alone or estrogen plus a progestin.

Hot flashes associated with menopause occur in up to 75 percent of women and can persist for up to five years, or even longer in some women. Hot flashes are not life-threatening, but the symptoms can be very bothersome, causing discomfort and disruption of sleep.

All medications that are approved for treating depression, including Paxil and Pexeva, have a Boxed Warning about an increased risk of suicide in children and young adults. Because Brisdelle contains the same active ingredient as Paxil and Pexeva, a Boxed Warning about suicidality is included in the Brisdelle label.

Additional labeled warnings include a possible reduction in the effectiveness of tamoxifen if both medications are used together, an increased risk of bleeding, and a risk of developing serotonin syndrome (signs and symptoms can include confusion, rapid heart rate, and high blood pressure).

Brisdelle and Pexeva are marketed by Noven Therapeutics, LLC, based in Miami, FL; Paxil is marketed by GlaxoSmithKline, based in Philadelphia, PA. (Source: FDA Website, 28 June, 2013)

FDA Approves New Treatment for Late-Stage Lung Cancer; Companion Test Also Approved

The U.S. Food and Drug Administration today approved Gilotrif (afatinib) for patients with late stage (metastatic) non-small cell lung cancer (NSCLC) whose tumors express specific types of epidermal growth factor receptor (EGFR) gene mutations, as detected by an FDA-approved test.

Lung cancer is the leading cause of cancer-related death among men and women. According to the National Cancer Institute, an estimated 228,190 Americans will be diagnosed with lung cancer, and 159,480 will die from the disease this year. About 85 percent of lung cancers are NSCLC, making it the most common type of lung cancer. EGFR gene mutations are present in about 10 percent of NSCLC, with the majority of these gene mutations expressing EGFR exon 19 deletions or exon 21 L858R substitution.

Gilotrif is a tyrosine kinase inhibitor that blocks proteins that promote the development of cancerous cells. It is intended for patients whose tumors express the EGFR exon 19 deletions or exon 21 L858R substitution gene mutations. Gilotrif is being approved concurrently with the therascreen EGFR RGQ PCR Kit, a companion diagnostic that helps determine if a patient's lung cancer cells express the EGFR mutations.

"Today's approvals further illustrate how a greater understanding of the underlying molecular pathways of a disease can lead to the development of targeted treatments," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Gilotrif is the second drug approved this year for patients with untreated metastatic NSCLC whose tumors have the EGFR exon 19 deletions or exon 21 L858R substitution mutations."

In May, the FDA approved Tarceva (erlotinib) for first-line treatment of patients with NSCLC. Tarceva's new indication was approved concurrently with the cobas EGFR Mutation Test, a companion diagnostic to identify patients with tumors having the EGFR gene mutations.

"The approval of companion diagnostic tests and drugs are important developments in oncology, as they help us bring safe and effective treatments to patients who need them," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

The FDA's approval of the therascreen EGFR RGQ PCR Kit is based on data from the clinical study used to support Gilotrif's approval. Tumor samples from NSCLC participants in the clinical trial helped to validate the test's use for detecting EGFR mutations in this patient population.

The FDA reviewed Gilotrif under its priority review program, which provides an expedited review for drugs that may provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products.

Gilotrif is marketed by Boehringer Ingelheim Pharmaceuticals based in Ridgefield, CT. The therascreen EGFR RGQ PCR Kit is manufactured by QIAGEN Manchester Ltd., based in the United Kingdom. The cobas EGFR Mutation Test is manufactured by the Roche Molecular Systems in Pleasanton, CA and Tarceva is co-marketed by California-based Genentech and OSI Pharmaceuticals of Farmingdale, NY. (Source: FDA Website, 12 July, 2013)

FDA Permits Marketing of First Test for Simultaneous Detection of TB Bacteria and Antibiotic Resistance

The FDA allowed marketing of the Xpert MTB/RIF Assay, manufactured and marketed by Cepheid of Sunnyvale, CA, the first FDA-reviewed test that can simultaneously detect bacteria that cause tuberculosis (TB) and determine if the bacteria contain genetic markers that makes them resistant to rifampin, an important antibiotic for the treatment of TB.

The new test is less complex to perform than other previous FDA-cleared tests for the detection of TB bacteria. Test results, including the detection of TB bacteria and whether the bacteria are drug resistant, are available in approximately two hours. Traditional methods to detect drug resistant TB usually require one to three months.

TB is caused by bacteria that belong to a group known as Mycobacterium tuberculosis complex, which usually attacks

the lungs. Not everyone infected with M. tuberculosis develops active TB, and only people with active TB can spread the bacteria to other people. Those with weakened immune systems are at a much higher risk for developing TB once infected with the bacteria, and TB can be fatal if left untreated. TB is a leading killer worldwide of people with HIV. (Source: FDA Website, 25 July, 2013)

FDA Approves First Rapid Diagnostic Test for HIV-1 Antigen and HIV-1/2 Antibodies

The FDA approved the first rapid Human Immunodeficiency Virus (HIV) test for the simultaneous detection of HIV-1 p24 antigen as well as antibodies to both HIV-1 and HIV-2 in human serum, plasma, and venous or fingerstick whole blood specimens. Approved for use as an aid in the diagnosis of HIV-1 and HIV-2 infection, the Alere Determine HIV-1/2 Ag/Ab Combo test is also the first FDA-approved test that independently distinguishes results for HIV-1 p24 antigen and HIV antibodies in a single test.

The test can be used by trained professionals in outreach settings to identify HIV-infected individuals who might not be able to be tested in traditional health care settings. The test does not distinguish between antibodies to HIV-1 and HIV-2, and is not intended to be used for screening of blood donors.

Detection of HIV-1 antigen permits earlier detection of HIV-1 infection than is possible by testing for HIV-1 antibodies alone. The test can distinguish acute HIV-1 infection from established HIV-1 infection when the blood specimen is positive for HIV-1 p24 antigen but is negative for HIV-1 and HIV-2 antibodies.

The Alere Determine HIV-1/2 Ag/Ab Combo test is manufactured by Orgenics, Ltd. (an Alere, Inc. company) of Yavne, Israel. (Source: FDA Website, 08 August, 2013)

FDA Approves New Drug to Treat HIV Infection

The FDA has approved Tivicay (dolutegravir), a new drug to treat HIV-1 infection. Tivicay is an integrase strand transfer inhibitor that interferes with one of the enzymes necessary for HIV to multiply. It is a pill taken daily in combination with other antiretroviral drugs.

Tivicay is approved for use in a broad population of HIV-infected patients. It can be used to treat HIV-infected adults who have never taken HIV therapy (treatment-naïve) and HIV-infected adults who have previously taken HIV therapy (treatment-experienced), including those who have been treated with other integrase strand transfer inhibitors. Tivicay is also approved for children ages 12 years and older weighing at least 40 kilograms (kg) who are treatment-naïve or treatment-experienced but have not previously taken other integrase strand transfer inhibitors.

Tivicay is marketed by ViiV Healthcare and manufactured by GlaxoSmithKline, both based in Research Triangle Park, NC. Isentress is marketed by Merck based in Whitehouse Station, NJ and Atripla is marketed Gilead based in San Francisco, CA. (Source: FDA Website, 12 August, 2013)

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