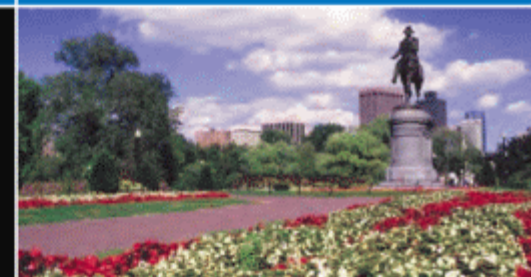
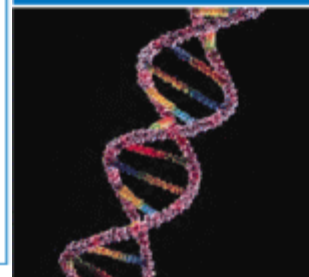




Boston Area Chapter

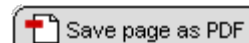
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NEWSLETTER

September 2011, Volume XXI, No. 5

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President's Message: Looking Ahead to Another Exciting Year of Chapter Activities...



Dear ISPE Boston Area Chapter Members,

I am excited, proud, honored, and humbled - all at the same time - to be president of this truly great Chapter of ISPE for the upcoming year! It's going to be a fantastic year, and we've already hit the ground running.

I would like to begin by introducing you to this year's Board of Directors while officially thanking each and every director for participating in this exciting and vibrant volunteer organization for the upcoming year.

President	Brian Hagopian	Clear Water Consulting
Vice President	Jay Zaino	GxP Automation
Treasurer	Chris Opolski	Alexion Pharmaceuticals
Secretary	Janet Tice	GMP Piping
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	Dan Ramsey	Commissioning Agents
	Dan Rufo	IPM
	Mark Sitcoske	High Purity New England
	Bob Urbanowski	Invensys
Past President	Jim Grunwald	SciTech Builders

Just look at the horsepower on this Board! They represent a microcosm of the life sciences industry in Boston. Many board Members do double duty and are involved with one or more of the Chapter committees listed below.



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- Product Show Committee
- Educational Program Committee
- Membership Services Committee
- Social Committee
- Communications Committee
- Young Professionals Committee
- Student Chapter Committee

These committees are the real workhorses of the Chapter, being responsible for "getting things done" throughout the year. We have excellent teams in place on each committee, but we can always use new ideas, and I want to take a minute to actively solicit your participation. If you can see your way to giving an hour a year to ISPE, we'd really appreciate your input and help. Diversity brings strength and, with your help, we can become an even stronger organization. Check our website for opportunities (www.ispeboston.org) or email our business office (office@ispeboston.org) and consider donating a little bit of your time to ISPE. Trust me, it's really rewarding and it gives you visibility with over 1,200 professionals in the Boston area.

An example of how Member input has helped to strengthen and shape Chapter activities was when the Educational Program Committee actively solicited input on topics of interest for future educational programs this past spring. Dozens of Members who had not previously participated "came out of the woodwork" and voiced their opinions and passions on program content. Their input has helped to put diverse and exciting programs in place for the next year. So, I would suggest that you find something that you can be passionate about, and channel some of that energy toward ISPE - you won't regret it!

The Board has already held its strategic planning meeting to help guide us through the year ahead. Our focus will be in the following three targeted areas:

- delivering quality educational programs,
- strengthening our Student Chapters and young professionals group, and
- increasing membership.

The Chapter has committed to delivering one high quality educational program each month, September through June. These are generally held on the third Thursday of each month, unless individual speakers or plant tours require schedule adjustments. An annual exception to this rule is the Product Show and accompanying educational sessions, to be held this year on Wednesday, October 5th (see related article). Check the calendar on our website at www.ispeboston.org/events for content and support our Chapter by planning to attend at least one educational program this year. You won't be disappointed.

The Boston Area Chapter has Student Chapters at six local universities (Northeastern, UMass Lowell, UMass Amherst, Tufts, UNH and WPI) and we're actively looking for alumni from these universities to donate a little bit of their time and expertise to their alma mater and ISPE at the same time. Visit the Student Affairs Committee on our website at http://www.ispeboston.org/Boston_Area_Chapter_Committees for more information.

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Lastly, to continue to strengthen our Chapter by growing our membership, we're planning several "membership drive" activities throughout the year and may even take our efforts "on the road" to a few operating companies during the year. Stay tuned.

There are a lot of exciting things happening in the next few months, starting with our first educational program of the year on risk management on Wednesday, September 14th (oops, we've already broken the "third Thursday" rule) followed by our "one of a kind" Product Show on Wednesday, October 5th. This year, we've expanded the Show to both sides of Gillette Stadium and have booked Jonathan Kraft as our keynote speaker (see related articles in this issue).

Finally, I want to thank last year's president, Jim Grunwald, for steering the Boston Area Chapter ship so well this past year. Now it's my turn, and I look forward to the challenge! Please know that the Board is here to serve you, so feel free to get in touch with any of us. It's going to be a great year!

Thank you,

Brian Hagopian
President, ISPE Boston Area Chapter

Chapter Scholarship Fund Awards its First Three Scholarships

by Janet Tice, GMP Piping

The Boston Area Chapter is happy to announce that the first three Joel Goldenberg Scholarships have been awarded to Chapter Members. The successful applicants are all Student Members of the Chapter and represent a variety of academic endeavors. One is an undergraduate studying chemical engineering at UNH; another is a recent Tufts graduate pursuing his masters degree in bioengineering at BU while working full time in the industry; and the last is a Member in career transition working toward a certificate in biomedical research at BU. All will benefit from the generous financial support provided by the Chapter, as will their current and future biotech or pharma employers.

The Scholarship Fund is named for Boston Area Chapter Past President Joel Goldenberg whose wish was to help support the educational pursuits of Chapter Members and their families; it was introduced in May of 2011. The Fund provides financial support to Chapter Members who are continuing their formal education in the life sciences at an accredited college or university. Children of Members entering their freshman year of college who plan to major in a life sciences field are also eligible to apply. Recipients receive up to \$2,000 or an amount equal to the cost of a specific course (including course-related fees and supplies) minus employer tuition reimbursement, whichever is less.

The Fund is supported by proceeds from Chapter activities, subject to approval by the Chapter's Board of Directors. During the 2010-11 inaugural year, the Board voted to fund the program with an initial investment of \$10,000 and expects to award between five and ten scholarships of \$1000 to \$2000 each during the course of the year.

The application process has been designed for simplicity, with two due dates during the calendar year, June 15th for fall courses and November 15th for spring courses. Applicants are asked to describe their future goals, how the scholarship would help them meet their goals, their volunteer activities, their prior academic or other significant achievements and their need for financial assistance. They are

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also asked to provide basic information regarding the course to be covered by the scholarship and three references. Decisions regarding scholarship awards are made by a committee consisting of the Chapter officers and Immediate Past President. Please visit the Chapter website at <http://www.ispeboston.org/scholarship> for detailed information and an application.

Don't Miss Out - Be Sure You're Receiving Important Chapter eMails

If ISPE email is not reaching you, it probably means you've told ISPE you don't want to receive email from us. Unfortunately, this may include email from the Boston Area Chapter as well as ISPE International. You can fix this by changing your Member profile so that you receive email from the Chapter about the many exciting things we have going on in the Boston area this year.

Go to http://www.ispe.org/csnc/members_section/member_service_center to update your Member profile. You will need your Member number and password to log in. Once logged in, select "access my profile" and click "my email options" near the upper right corner of the screen. Choosing "I would like to receive emails from my local ISPE Affiliate or Chapter" will ensure you get important updates from the Boston Area Chapter on upcoming events.

Upcoming Chapter Events - Mark Your Calendar

Wednesday, September 14, 2011

["Risk Management within the Quality System"](#)

[Royal Sonesta Hotel, Cambridge, MA](#)

Have you ever used "operator error" as a cause for a failure? In many cases the root cause is not use-error, it may be procedural, system, design, or a combination of all. How do we get to the root cause of errors like this? On Wed September 14, 2011 come join the ISPE Boston chapter to learn how to use Human Factors to mitigate potential manufacturing and lab equipment use-error risks prospectively in the design phase and learn how to use the risk tool box to identify, correct and prevent root causes of errors retrospectively in day to day manufacturing.

Pre-Registration for this program has closed. Walk-in Registrations are Welcome!

Thursday, September 29, 2011

[The Young Professionals - Annual Boston Boat Cruise](#)

[Boston Harbor Hotel Dock, Boston, MA](#)

Come join the ISPE Boston Area Chapter ,Young Professionals for our kick-off event of the season! New and returning Members are welcome to enjoy in a night of appetizers, socializing, and networking as we tour the Boston waters.This event is geared towards

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facilitating social and professional networking between people in the pharmaceutical, biotech, and life sciences fields. Hosted by the Boston Belle Charter Company-this is a great opportunity to meet other people from different areas of these exciting and diverse industries and get involved with the ISPE. manufacturing.

Register Today: <http://www.ispeboston.org/events/registration.htm?eventID=224>

Wednesday, October 5, 2011

[Annual Product Show and Educational Sessions](#)

[Gillette Stadium Clubhouse, Foxborough, MA](#)

9:00 am - 12:00 pm Educational Sessions

12:00 pm - 7:30 pm Exhibit Floor Open

3:30 pm Keynote Address: Jonathan Kraft, President, The Kraft Group

7:30 pm After Party at CBS Scene with an appearance by Jerod Mayo, New England Patriots Linebacker

Register Today: www.ISPEBoston.org/Events

Sneak Preview of Upcoming Events

Tuesday, November 15, 2011

Educational Program

"Pharmacogenomics: The future of clinical trials, new product development and the practice of medicine"

Location: Genzyme Center, Framingham

Thursday, December 15, 2011

Educational Program

"E2500"

Location: TBA

Thursday, January 19, 2011

Educational Program

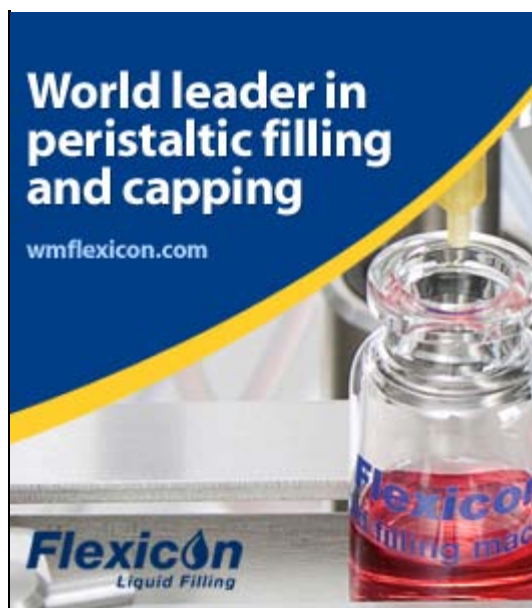
"Automation"

Location: TBA

It's That Time: Product Show XX is Here at Gillette Stadium

by Mark Sitcoske, High Purity New England, and Brian Hagopian, Clear Water Consulting, Inc.

We're proud to announce the 20th Anniversary of the ISPE Boston Area Chapter Product Show! Yes, 20 Years! It has been 20 years since the



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An expansive view of Gillette Stadium creates a spectacular backdrop for the Annual Product Show.

Product Show began at the "Old HoJos" on Memorial Drive in Cambridge. And what a run it's been. This year's Show will (once again) be held at Gillette Stadium on Wednesday, October 5th, and it has everything you've come to expect and much, much more. With Jonathan Kraft as our keynote speaker, Jerod Mayo signing autographs at the after-party and a host of exciting educational sessions and vendor booths, we're sure to break all attendance records.

This year for the first time we've taken over both sides of Gillette Stadium, giving us more room to do more things than ever before. The Krafts have expanded the luxury box area, so this year's Show will have more exhibitors but will be less crowded than previous years. The area has been renamed as the Putnam Club House and improved with new floor-to-ceiling windows for an even better view of the field.

We've packed nine quality educational programs into our first-ever "morning session" (see related article and schedule), including a half-day symposium on ELSIE (Extractables and Leachables Safety Information Exchange). We're bringing you Jonathan Kraft, President of the New England Patriots, as our keynote speaker this year. We've expanded the "after party" which will be held at CBS Scene and will feature Jerod Mayo, anchor of the Patriots defense. And the Career Fair is back in a new location with added privacy.

There are dozens of reasons to attend this show. Here are just a few:

- Free admission, free parking and free hot and cold food, bottled water, and non-alcoholic beverages all day long
- A full-day of excitement, beginning at 8.30 with nine industry-specific educational sessions (see related article) held in Gillette's luxury club level boxes
- A half-day symposium covering extractables and leachables in disposables presented by ELSIE (Extractables and Leachables Safety Information Exchange)
- Over 300 exhibitors - a new record for the event - with more than 50 new exhibitors you've never seen here before
- Career Fair with added privacy featuring companies looking to add staff
- Keynote speaker Jonathan Kraft, President of the New England Patriots
- Presentation of the Hank Moes Lifetime Achievement Award to one of the Chapter's outstanding volunteers
- Student and young professional gathering - meet the industry's future leaders
- Tours of the Patriots Hall of Fame
- After party at CBS Scene, with special guest Patriot's linebacker Jerod Mayo



The Clubhouse bar provides a convenient area for networking with colleagues.

There is no other single event where members of the local life sciences community can mingle with one another and meet the ISPE Boston Area Chapter Board of Directors, past presidents and advisory committee members (many of whom are local industry leaders) - all while viewing new and exciting

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Delicious buffet offerings keep attendees well-fed throughout the day.

products and services offered by the exhibitor community. The Product Show Committee has worked diligently to bring products and services of interest to you in a fun, exciting, and welcoming location.

We've heard from so many exhibitors and attendees that this Product Show surpasses other local shows. In fact, it's the one show everyone goes to. It's so easy to take this Show for granted, because it's in our backyard. But please don't. After traveling the country and meeting leaders from other ISPE Chapters this past year, I've come to appreciate just how special our Show really is. And it's just a short drive away - only a 35-minute ride from Kendall Square and Boston (we timed it!) and only a few minutes farther from Worcester, so it's closer than you think. We suggest you plan ahead to take full advantage of the day-long event (Gillette opens at 8.30 for the morning educational sessions).

Gillette provides a unique venue that holds a special place in the hearts of New England Patriots fans. Excitement and anticipation are high this year as the Patriots vie to add another championship banner to the rafters. We're offering guided tours of the Patriots Hall of Fame this year (another first). And, weather permitting, attendees will be able to enjoy Gillette's outdoor "red seats" during the Show (an area normally reserved for season ticket holders) and possibly one of Gillette's luxury club boxes.

This year the educational sessions will be held in the morning, not during the show, a departure from the way we've done it in the past. See the companion article for a complete roster of programs and speakers and visit our website www.ispeboston.org to register to attend these sessions and the Show itself. Last year, participation at seminars and the keynote address reached record levels, with over 800 attendees taking advantage of scheduled events. So be sure to save your spot for this year's sessions by pre-registering online.



A packed exhibit hall greeted the 1800 attendees at last year's Product Show.



The educational programs run from 9.00 - 12.00 (registration opens at 8.30) and the Show runs from 12.00 - 19.30. We guarantee you will find the educational program and Show rich in content. Plan ahead to take full advantage of the opportunities offered. We promise you a rewarding day well worth the short trip from your workplace. And remember, the Show, including the keynote presentations and educational program is free (free parking, too). Plus, complimentary food and non-alcoholic beverages are offered throughout the day, plus a cash bar and a complimentary lunch for exhibitors. The food at Gillette is top-shelf all the way - just ask anyone who's been there!



Informal seating areas provide a great opportunity for impromptu meetings.

The Product Show generates the funds needed to operate the Boston Area Chapter, so your attendance not only provides you with valuable and pertinent information, but helps to attract the exhibitors whose participation in the Show ensures that the Chapter continues to be able to sponsor top flight educational programs, social events, facility tours, workshops, Student Chapters, young professionals, communities of practice, our brand new scholarship program and much more throughout the year.

Register at our website (www.ispeboston.org) and show your support for the Boston Area Chapter by attending this event. It's a decision you won't regret; we promise! To the many volunteers, supporters, attendees and vendors who have made the Product Show successful, the Chapter thanks you! See you on October 5th!

Free Educational Program Moves to Morning Time Slot at Product Show

by Joyce Chiu, Honeywell Safety Products

This year, the education program at the Boston Area Chapter's premier event of the year, the Product Show, has created several new records. For the first time, the educational program is the result of collaboration among three of the Chapter's volunteer committees - the Educational Program Committee (EPC), the Member Services Committee (MSC) and the Young Professionals Committee (YPC).

And for the first time, the entire education program takes place in the morning, from 9.00 - 12.00, before the vendor exhibit area opens on the main floor. The program features a major, half-day symposium on the burgeoning topic of extractables and leachables. Or choose from among eight one-hour seminars at staggered times in concurrent sessions.

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The Product Show educational agenda covers the range from introductory to advanced topics.

and amenities. Instead they will be able to focus their full attention on the educational topics being presented, then visit with vendors and relax with peers on the exhibit floor. So plan on rising early and spending the whole day at the Product Show this year, beginning with the morning's educational offerings and ending with the not-to-be-missed after-party at CBS Scene.

The Chapter extends its sincerest gratitude to the sixteen speakers, ten event chairpersons, and many Chapter volunteers whose tireless efforts led to creation of this unprecedented educational program, and, in addition, to all those who offered ideas, recommendations and assistance. See you there!

The range of topics covered by the sessions means the morning will offer something for everyone. The featured symposium is presented by the Extractables and Leachables Safety Information Exchange (ELSIE), with three distinguished speakers from Pfizer, AstraZeneca, and Boehringer Ingelheim. ELSIE has just rolled out its time-saving, license-winning, shared industry database available to its members. See how your company can reap the benefits from this not-for-profit industry consortium.

The eight short seminars range from Biotech 101: Trends in Facility Design and Introduction to Validation, presented by the Young Professionals Committee; to Coaching and Mentoring and Bridging the Gap of Science and Business, hosted by the Member Services Committee; plus Risk Management, Cold Chain Distribution, Future Challenges in Manufacturing and Packaging, and "Rouge" in Water Systems presented by the Educational Programs Committee.

The eight short seminars include "Biotech 101: Trends in Facility Design" and "Introduction to Validation," both geared toward early career professionals. Mainstream topics include "Risk Management," "Cold Chain Distribution," "Future Challenges in Manufacturing and Packaging" and the ever-popular "Rouge in Water Systems." Rounding out the morning's offerings are two career-focused sessions, "Coaching and Mentoring" and "Bridging the Gap between Science and Business."

Moving the educational sessions to the morning time slot means that attendees won't be distracted by the excitement of the exhibit area with its many attractions

Patriots President Jonathan Kraft to Give Keynote Address

by Laurie Masiello, Masy Systems

The Boston Area Chapter is privileged to announce Jonathan Kraft will be the keynote speaker at the 20th Annual Product Show, to be held at the Gillette Stadium Clubhouse on October 5th. Mr. Kraft is the President for The Kraft Group, the holding company of the Kraft family's varied business interests. The Kraft Group is a privately owned, family-operated company. Mr. Kraft is also the President of the three-time Super Bowl Champion New England Patriots. As President of the Patriots, Kraft oversees the management and strategic planning of each department within the organization.



Jonathan Kraft

A Williams College graduate, Kraft also earned an MBA from Harvard Business School. He is on the boards of directors for several organizations, including the US Soccer Federation, Children's Hospital Trust and Pop Warner Little Scholars. Kraft is active in youth athletics, coaching Pop Warner football, youth soccer and Little League baseball in the greater Boston area. In 2006, he was the recipient of the Warner Award, named after Glenn S. "Pop" Warner. The award is presented annually and is considered Pop Warner's highest national honor.

Since his family purchased the Patriots football team in 1994, Kraft has been the day-to-day driving force behind the rebuilding and rebranding of the franchise. As a lifelong Patriots fan, Kraft was committed to expanding the Patriots' audiences through an innovative multimedia outreach. Under his directive, the Patriots became the first professional sports team to launch an official Web site in March of 1995.

In May of 2002, the Kraft Group received New England's Environmental Merit Award from the US Environmental Protection Agency for the development and construction of Gillette Stadium. Adjacent to Gillette Stadium, Patriot Place features more than one million square feet of shopping, entertainment and commercial uses.

The Annual Product Show has been held at Gillette Stadium for the past six years, and has been a flagship event for the ISPE Boston Area Chapter for the past 20 years. The Product Show offers a full day of networking and informational sessions. This year the educational programs are being held in the morning, from 9.00 - 12.00, and the keynote presentation has been moved from the east side of the stadium (where the exhibitor area is located) to the west side due to the growth of the Show and the size of the audience anticipated for the keynote. Over 300 exhibitor booths will greet the 2000 attendees expected this year. In addition, this year's event will also feature a career fair and an after-party at CBS Scene where Jerod Mayo, New England Patriots linebacker, will be available to sign autographs.



Exciting keynote speakers routinely draw an overflow crowd at the Annual Product Show.

Register early for the show and stay all day to attend the morning education sessions, the vendor exhibits, the career fair, Jonathan Kraft's keynote address and the party at CBS Scene.

Product Show Schedule of Events

20th ANNUAL PRODUCT SHOW

Wednesday, October 5, 2011

AGENDA - AT - A - GLANCE

8:30 am – 7:30 pm
Registration and Information Desks Open

9:00 am – 12:00 pm
Nine Educational Programs: **See Below For Full Listing**
ELSIE Symposium long program and four sets of concurrent, shorter programs

11:00 am – 12:00 pm
Lunch
Note: you must pre-purchase a ticket to attend the lunch. Tickets will not be sold onsite

12:00 pm – 7:30 pm
Show Floor Opens
Visit over 300 Exhibitor Tables and Booths
Career Fair: Visit Abbott Bioresearch Center, Biogen Idec, Bristol-Myers Squibb and Genzyme Corp

3:30 pm – 4:45 pm
Keynote AddressHear from **Jonathan Kraft**, President, The Kraft Group

6:00 pm – 7:00 pm
Young Professionals/Student Reception

7:30 pm – 9:30 pm
After Party Networking Reception
Appearance by **Jerod Mayo**, New England Patriots Linebacker
Location: CBS Scene Restaurant and Bar, Patriot Place

9:00 am – 12:00 pm		9:00 – 10:00 am CONCURRENT SESSIONS	
<i>E.L.S.I.E. Symposium: Practical Solutions to Address the Impact of Extractables and Leachables on Materials, Manufacturing Processes and Packaging</i>	<i>Biotech 101: Trends in Facility Design</i> Speaker: Marc Pelletier , CRB Consulting Engineers	<i>Risk Management: Next Steps Incorporating Risk Management into the Biopharmaceutical Quality System</i> Speaker: Emma Ramnarine , Roche	
	9:45 – 10:45 am		

<p>Speakers: Douglas J. Ball, MS, D.A.B.T., Pfizer, Inc.</p> <p>Lewis B. Kinter, Ph.D., D.A.B.T., Fellow A.T.S. , AstraZeneca Pharmaceuticals</p> <p>Daniel L. Norwood, Ph.D., Boehringer Ingelheim Pharmaceuticals, Inc. The Extractables and Leachables Safety Information Exchange (ELSIE) is developing a database containing safety information on E&L compounds and extraction profiles obtained using standardized protocols for a range of materials utilized for drug products, medical devices, and manufacturing processes. The ELSIE database seeks to facilitate early identification of safety issues at the initial stages of the development process, when materials are being screened and selected.</p>	CONCURRENT SESSIONS	
	<p><i>Cold Chain Distribution: Ensuring Product Integrity to the Patient</i></p> <p>Speaker: Anthony (TJ) Rizzo, Cold Chain Technologies</p>	<p><i>Every Gold Medal Winner Has a Coach and Mentors</i></p> <p><i>Accelerating Your Leadership Career</i></p> <p>Panelists: Daniel (Dan) Button, BS, Ph.D.</p> <p>Kathy Freitas, BA, SPHR, Draeger Medical</p> <p>Fabian Gusovsky, Ph.D., CSO Group, Eisai Inc.</p> <p>Kerry Harrison, BBA, SPHR, CCP, MIT Lincoln Laboratory</p> <p>Tawnya Johnson, Boston Red Sox</p> <p>Joe Maressa, Fitzgerald, Stevens & Ford/OI Partners</p>
	10:30 – 11:30 am CONCURRENT SESSIONS	
	<p><i>Introduction to Validation</i></p> <p>Speaker: Jack Campion, Genzyme Corporation</p>	<p><i>Future Manufacturing & Packaging Challenges: How to Avoid them with the FDA</i></p> <p>Speaker: Michael Druess, Ph.D., Vascular Sciences</p>
	11:00 – 12:00 pm CONCURRENT SESSIONS	
	<p><i>Rouge: Monitoring, Measuring and Remediating in Water and Steam Systems</i></p> <p>Speaker: Daryl Roll, P.E., Astro Pak Corporation</p>	<p><i>Thriving at the Intersection of Science and Business: How to Transition from Geeky to Business Savvy</i></p> <p>Speaker: Gwen Acton, Ph.D., Vivo Group</p>

ISPE Two-Day Professional Training Follows Product Show on October 6-7

ISPE is offering a two-day Professional Development Event immediately following the Product Show. Advance in your profession by choosing from the variety of professional development courses offered below. Each course will help you learn how to enhance your career development by applying new skills and practical knowledge as well as providing you with valuable solutions to daily work problems. Courses include:

- [Pharmaceutical Water Storage and Distribution \(T23\)](#)
- [Applying the GMPs\(G03\)](#)
- [Process Validation in Biotechnology Manufacturing \(T32\)](#)
- [Biopharmaceutical Manufacturing Facilities \(T31\)](#)

The event is being held at the Four Points Sheraton on Route 1 in Norwood, Massachusetts not far from Boston and Gillette Stadium. If

you're traveling from out of town to the Boston area for the Product Show, plan to extend your stay and add ISPE training to your plans. And if you're a Boston Area ISPE Member, be sure to take advantage of this exceptional educational opportunity taking place in your own backyard!

It's Five O'clock Somewhere! - Paradise in Fenway



text and photos by Chris Opolski, Alexion Pharmaceuticals

A little bit of the Caribbean came to downtown Boston in June during the ISPE Boston Area Chapter's Summer Social dubbed "It's Five O'clock Somewhere" where professional Parrot Heads from around New England danced to the music of the CocoBanana Band during an absolutely gorgeous night at the Baseball Tavern overlooking historic Fenway Park.

Each attendee received a tropical lei to get them in the mood for the Latin and Caribbean music. A highlight of the event was a fierce limbo contest. Two contestants ultimately prevailed and were awarded fine baskets of goodies. Here are a few pictures of the contestants trying desperately in vain to get under the limbo stick.

For this summer event our Members raised money and donated toys to support the Boston Children's Hospital Child Life Services Charity Toy Drive which provides donated toys to young children spending time at the Hospital. This year we raised \$500 and all the donated toys!



The Caribbean-themed summer social drew a crowd to the roof deck of the Baseball Tavern.



And you thought the CPIP exam was difficult ...

Finally, the group danced long into the star-filled evening listening to the music emanating from the roof top bar and throughout the Fenway area. None of us were "Dancing with the Stars" contenders; however, from the looks of the crowd we could probably sign up a few!



Children's Hospital was the beneficiary
of many generous donations.

Product Show Educational Program: A Model of Collaboration and Team Work

The following is an interview with Joyce Chiu, member of the Educational Program & Member Services Committees and coordinator of this year's Product Show educational program.

Q. We understand there are several new aspects to the educational program at the Product Show this year...

A. Yes, for the first time, the entire educational program takes place in the morning, between 8:30am and 12noon, before the vendor exhibit area opens. This will allow attendees to focus on the educational sessions without distraction and spend an uninterrupted afternoon visiting the exhibits and networking with colleagues. Also, for the first time, three committees have worked together to plan the program - the Educational Program, Member Services and Young Professionals Committees. All with the support of the Product Show Committee, of course!

Q. How did the planning process begin?

A. The Educational Program Committee has overall responsibility for the educational program at the Product Show. The EPC first discussed the program at our March meeting. We brainstormed possible ideas and topics and decided that in addition to one long seminar, there would be eight short, one-hour seminars. Two of the eight were reserved for the YPC which would select topics and speakers appropriate for students, early career professionals and others new to our industry.

Q. What happened next?

A. Following the April EPC meeting, we drafted a request to all Committee Members asking for volunteers, ideas and topics. This surfaced the risk management topic. Meanwhile, we had received inquiries from several potential presenters and the Product Show Committee (PSC) had offered a speaker on cold chain.

Q. How did you choose the final roster of topics and speakers?

A. Everyone was asked to email information - with as much detail as possible - describing the presentation they had in mind. After reviewing the information, I spoke with each person to be sure I fully understood the nature of the presentation, the speaker's credentials and the potential fit with the overall program.

Q. How did the Member Services Committee get involved?

A. In recent years, the Product Show has offered at least one non-technical, career-oriented session at the Product Show. Since I am also a member of the MSC, I knew that the Committee had talked about a coaching & mentoring program without bringing the plans to fruition. I contacted the moderator to see if he could help flesh out the program and find panelists - which it turned out he was happy to do.

Q. So it sounds like the overall program came together rather smoothly...

A. By May, the program slate looked pretty promising, however there were still three or four seminars with speakers but without event chairs - that is, someone to keep in touch with the presenter to work out any last minute details and preside over the actual session at the Product Show, introduce the speaker & so on. I asked my fellow EPC and MSC members for help and thankfully several volunteered. Since they were not experienced event chairs, with CAMI's help I drafted a SOP that outlined their responsibilities, "scope of work" and milestone dates. I also explained the respective roles of the PSC and EPC. This helped event chairs realize that they were part of a much bigger effort. - in fact, part of a community of volunteers all contributing to the success of the Chapter's most important event.

Q. So it sounds like all the effort has really paid off this year...

A. Absolutely! In all, the Chapter is offering a half-day symposium on extractables and leachables presented by ELSIE, the Extractables and Leachables Safety Information Exchange, with speakers from Pfizer, AstraZeneca, and Boehringer Ingelheim; eight one-hour seminars including introductory level sessions on biotechnology and validation; advanced sessions on risk management, cold chain distribution, future challenges in manufacturing and packaging, and "rouge" in water systems; and bonus sessions on coaching and mentoring and "bridging the gap" between science and business. All in all, one of the strongest educational programs we've ever offered at the Product Show!

Q. I bet you can't wait to attend the Show & see the fruits of your efforts...

A. Actually, I'm going to have to hear all about it from my colleagues. Instead of attending, I'll be on a trip to Taiwan, where I grew up, to join my parents and reunite with my elementary school friends. We'll be celebrating the 100th anniversary of the founding of the Republic of China. I'm very lucky to have John Sheridan, a fellow EPC member, willing to step in as Product Show seminar organizer and coordinator. Thank you, John!

I would like to take this opportunity to thank everyone who has offered ideas and suggestions, agreed to serve as an event chair or speaker, or contributed in any way - large or small - to the success of this year's educational program. This has been a true model of working together across boundaries for a common goal - helping our beloved Chapter reach ever higher levels of excellence in fulfilling the needs of our community!

Industry News in Brief

by Patti Charek, RF Walsh Collaborative Partners

Biogen Idec Expanding in Cambridge

Biogen Idec will construct two office buildings as part of its move back to Cambridge, where the biotechnology company is planning an expansive office and research campus to replace the headquarters it opened just a year ago in Weston.

George A. Scangos, Chief Executive, said the return of 530 employees to Kendall Square will put the firm's entire Massachusetts workforce in a single location - at the heart of a rapidly growing cluster of pharmaceutical companies near Harvard University and the Massachusetts Institute of Technology. The move is a stunning reversal from Biogen Idec's much talked about relocation of its corporate operations last summer to Weston, a move orchestrated by Biogen Idec's former Chief Executive, James C. Mullen, who stepped down last June, following a battle with activist investor Carl C. Icahn.

The company wants to break ground on its new office buildings later this year. One will be a 190,000-square-foot building with an address of 17 Cambridge Center; it will be developed by Boston Properties. The other will contain about 305,000 square feet across Binney Street and will be developed by Alexandria Real Estate Equities Inc., which is planning to construct five new buildings in the area in coming years. With its new structures, Biogen Idec will have its 2,000 Massachusetts employees in six buildings in Kendall Square.

A leader in making drugs to treat multiple sclerosis, Biogen Idec is one of many global science and technology firms to expand operations in Cambridge in recent years. Pharmaceutical giants Novartis AG, Amgen, and Sanofi SA are growing in the area, along with the Broad Institute and other academic research labs. Google Inc. and Microsoft Corp. have also planted large flags in the neighborhood.

The area suffered a setback with the pending departure of Vertex Pharmaceuticals Inc. to the South Boston Waterfront, but real estate specialists said Biogen Idec's return will help to offset that move and spur additional development in the area. "East Cambridge will see 1.5 million square feet of construction get underway in the next six to seven months," said Steve Purpura, a partner with the real estate firm Richards Barry Joyce and Partners. "In any other market, you lose a tenant like Vertex, and everyone is running for cover, but Cambridge didn't miss a beat." (Source: Casey Ross and Robert Weisman, The Boston Globe, 20 July, 2011)

Novartis Drug Afinitor Succeeds in Phase III Breast Cancer Study

Novartis has announced that an interim analysis of a pivotal Phase III study showed Afinitor (everolimus) tablets in combination with exemestane significantly extended progression-free survival (PFS), or time without tumor growth, when compared to placebo plus exemestane in women with advanced breast cancer. The trial was stopped early after interim results showed the primary endpoint of PFS was met. The study included postmenopausal women with ER+HER2- metastatic breast cancer whose disease has progressed, despite initial endocrine therapy. Results will be presented at an upcoming medical conference and worldwide regulatory submissions are being planned by the end of 2011.

"Despite clinical progress in advanced breast cancer, most women are either initially resistant or develop resistance to endocrine therapy over time. As a result, there is a significant need for new treatment options," said Hervé Hoppenot, President, Novartis Oncology. "Based on these study results, this combination has the potential to extend the time until chemotherapy is needed for these patients."

Everolimus targets mTOR in cancer cells, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism. Everolimus is also being investigated for the treatment of patients with HER2+ advanced breast cancer. (Source: Novartis Website, 05 July, 2011)

Boston Scientific to Expand in China, Reduce Global Workforce

Boston Scientific has recently announced a five-year, \$150 million investment in China, including the construction of new manufacturing and research facilities with plans to hire up to 1,000 workers in the country, plus a \$225 million to \$275 million restructuring that will include reducing its domestic and international workforce by between 1,200 and 1,500 jobs by 2013.

Analysts who track the company are largely praising the moves, saying that the Chinese investment sets Boston Scientific up for growth in an expanding market, while the restructuring is a right-sizing that reflects the firm's place in the medical device market. "They need to cut costs and they need to find new revenues," said Jeff Jonas, an analyst with New York-based Gabelli & Co. Inc.

Attempting to tap into the Chinese market is a particularly savvy move for Boston Scientific, according to Glenn Novarro of RBC Capital Markets in New York, who also tracks the company. "That's one of the underpenetrated markets in the world for medical devices," he said.

Significantly ramping up operations and sales in China has its risks, however. China has a reputation for being lax on intellectual property rights, so manufacturing and selling a product in China could open it up to competitors making knock-offs. However, Novarro noted that Boston Scientific will set up its own R&D and manufacturing operations, as opposed to relying on a third-party in China. By keeping the manufacturing in house, the company's IP may be better protected, he said.

The move to Asian markets is important for the company because the North American and European markets that Boston Scientific

competes in are maturing, according to Novarro. The company's top products, including implantable cardio defibrillators, stents and pacemakers, have not seen the double-digit growth they did in years past. Some of these markets have experienced product recalls, which can raise safety concerns and impact sales. Plus, there are more companies entering the market, leading to increased competition. (Source: Brandon Butler, Worcester Business Journal 17 August, 2011)

IQuum of Marlborough Receives FDA 510(k) Clearance for Influenza Test

Marlborough-based IQuum has received FDA 510(k) clearance to market the Liat™ Influenza A/B Assay and the Liat™ Analyzer. This molecular diagnostic test is an automated assay for the detection and discrimination of influenza A and influenza B in approximately 20 minutes. The test is intended for use in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform "moderate complexity" tests, enabling its use in hospital labs or other near-patient settings.

"The Liat Influenza A/B Assay presents a revolutionary improvement in the speed and ease-of-use of nucleic acid testing," said Dr. Shuqi Chen, Chief Executive Officer of IQuum, Inc. "IQuum's goal is to provide sophisticated nucleic acid tests that can be performed in near-patient settings and deliver accurate results to physicians and patients instantly. This regulatory clearance demonstrates the capability of the Liat system to realize this goal."

Influenza is a highly contagious acute respiratory illness that affects between 5 and 20 percent of the US population each year, leading to more than 200,000 hospitalizations and as many as 49,000 deaths, according to the CDC. Influenza A, including subtypes A/2009 H1N1 and H3N2, and influenza B, are considered to be the predominant seasonal influenza viruses. Current near-patient influenza testing is performed using rapid immunoassays. However, studies have shown that such immunoassays have limited sensitivity.

The Liat Influenza A/B Assay is currently the only test that has equivalent or better sensitivity and specificity as current lab-based nucleic acid tests, while substantially matching the time-to-result and ease-of-use of rapid immunoassays. Having an operator hands-on time of less than 1 minute and a total time-to-result of approximately 20 minutes, the Liat test can be performed on-demand in hospital near-patient settings, providing physicians with accurate and timely results. (Source: IQuum Website, 23 August, 2011)

Pfizer Plans New Research Center, New Hires in Cambridge

Pfizer is growing its Massachusetts presence further with a new lease agreement in Cambridge to house a research center that will employ 400 people, with plans to hire more. The New York-based company said in a news release that the new site, measured at 180,000 square feet and leased from MIT, will be used for its Cardiovascular, Metabolic and Endocrine Disease (CVMED) and Neuroscience Research Units.

According to a spokesperson at the Massachusetts Life Sciences Center, some of the 400 jobs the research units will bring to Cambridge are jobs relocated from a Pfizer site in Groton, Connecticut. The company has had significant layoffs in its Connecticut office, as well as job transfers from the office to its Massachusetts location. A report by the Norwich Bulletin as recently as June noted that Pfizer confirmed to the Chamber of Commerce of Eastern Connecticut that it would not leave Eastern Connecticut entirely.

"We were very deliberate in our choice to move to Cambridge as a key part of our R&D strategy," Rod MacKenzie, senior vice president and head of PharmaTherapeutics Research & Development, said in a statement. "By expanding our presence in one of the world's great centers of scientific and medical innovation, we will provide the best environment for our researchers to invent the next generation of medicines in areas of greatest need such as Alzheimer's disease, schizophrenia, diabetes and cardiovascular disease."

Pfizer plans to hire biologists, chemists and other researchers for its new Cambridge facility. The new building is expected to be completed in the fourth quarter of 2013.

(Source: Michelle Lang, Mass High Tech, 01 September, 2011)

Ironwood Pharma Seeks FDA Approval of IBS Drug

Ironwood Pharmaceuticals has submitted a new drug application for its irritable bowel syndrome drug candidate, linaclotide, with partner

Forest Laboratories to the FDA.

Linaclotide is intended to treat irritable bowel syndrome with constipation and chronic constipation. The Cambridge pharmaceutical firm and its New York City-based partner gave the FDA data from its first and second Phase 3 trials, which garnered positive results and improved abdominal and bowel symptoms for patients taking linaclotide over a placebo.

Ironwood CEO Peter Hecht told Mass High Tech in January that there have not been good therapeutic approaches to date, especially for people suffering from abdominal pain. "This is an opportunity to have the first drug to treat pain and constipation," he said at the time. "We have a chance to create a whole new medical category."

Earlier this year, Ironwood expanded its potential drug portfolio when it made a deal with Protagonist Therapeutics of Redwood City, California to collaborate on novel peptide discoveries for possible development by Ironwood. (Source: Michelle Lang, Mass High Tech, 10 August, 2011)

Cambridge-based Verastem Raises \$32 Million in Financing

Verastem, a Cambridge biopharmaceutical company focused on discovering and developing drugs to treat breast and other cancers by targeting cancer stem cells, announced today that it has raised \$32 million through a Series B financing. Proceeds from the financing will support ongoing research and development and will progress drug candidates into clinical development. The first candidate is projected to enter the clinic in 2012.

"This financing is a recognition of the significant potential for targeted cancer stem cell therapies in clinical practice," said Christoph Westphal, M.D., Ph.D., Chairman of Verastem. "Targeting cancer stem cells via the epithelial-to-mesenchymal transition, or EMT, has the potential to transform the treatment paradigm for certain serious cancers, such as triple negative breast cancer," said Robert Weinberg, Ph.D., Verastem co-founder and co-chair of the Scientific Advisory Board.

Advanced Technology Ventures (ATV) and Astellas Venture Management (AVM) led the Series B, and were joined by all existing investors, Longwood Founders Fund, Bessemer Venture Partners, Cardinal Partners and MPM Capital. "We are delighted that ATV and AVM are joining us in this round of financing," said Steve Kraus, Partner at Bessemer Venture Partners. "It is a strong sign of support for Verastem's mission to develop novel therapies targeting cancer stem cells. They share our confidence that this approach can transform how cancer is treated."

Verastem is a private biopharmaceutical company focused on discovering and developing drugs to treat breast and other cancers by targeting cancer stem cells. Cancer stem cells are an underlying cause of tumor recurrence and metastasis. Verastem is translating breakthrough discoveries in cancer stem cell research into new medicines for the treatment of major cancers such as breast cancer. (Source: Verastem Website, 14 July, 2011)

Pfizer to Spend \$100M on Research in Partnership with Massachusetts Institutions

Pfizer plans to spend about \$100 million over the next five years on collaborations to develop new medical treatments with Massachusetts academic researchers at UMass Medical, Beth Israel Deaconess Medical Center, Boston University School of Medicine, Children's Hospital Boston, Harvard University, Partners HealthCare, Tufts Medical School and Tufts University.

Pfizer will establish a Center for Therapeutic Innovation in Boston, similar to partnerships it has with researchers in San Francisco and New York City, where Pfizer is based. The Boston center will serve as the headquarters for all three research centers.

UMass Medical School is the only participating Massachusetts institution outside the Boston area. The collaboration brings Pfizer's resources, including its data and scientists, to academic researchers early in the scientific process, said Dr. John L. Sullivan, the medical school's vice provost for research.

For Pfizer, the goal is to speed up the discovery and development of drugs. The company said earlier this year it would slash research

spending and close a research center in England to hold down costs at a time when its top product, the cholesterol treatment Lipitor, is facing competition from generics. Pfizer said it would halt research funding in areas such as urology and focus on cancer, neuroscience, inflammation, vaccines and immunology.

Pfizer operates a Research Technology Center in Cambridge. The company said it has leased space in Boston's Longwood medical area for its new innovation center, and part of the \$100 million investment will go to support the facility. (Source: Lisa Eckelbecker, Worcester Telegram & Gazette, 09 June, 2011)

Judge Dismisses Challenge to Stem Cell Funding

A lawsuit filed to stop federal funding for human embryonic stem cell research has been dismissed by a judge after it created months of uncertainty for scientists in Boston and beyond. The decision ends the limbo that began last year, when the challenge to President Obama's stem cell policy resulted in a legal zig-zag that included a temporary halt to funding for research, which was later reversed.

When Obama lifted restrictions on federal funding for embryonic stem cell research through an executive order, many scientists and patient groups hailed it as the beginning of a new era for science and medicine. Stem cell research is a promising area of biomedical research that scientists and patients hope will be the basis for the development of treatments for human ailments ranging from juvenile diabetes to spinal cord injury. Opponents of the research, however, criticized the decision, saying it is unethical because it requires the destruction of human embryos.

Then, last August, Judge Royce Lamberth, a district court judge in Washington, DC, granted a preliminary injunction halting funding for embryonic stem cell research. That ruling was put on hold and eventually reversed by a higher court. As the lawsuit moved forward, the evolving legal landscape kept scientists on their toes as they tried to ensure their laboratories complied with changing guidelines. The NIH had to make complicated decisions about how to fund future research as court decisions ping-ponged back and forth.

In a 38-page memorandum of opinion issued, Lamberth dismissed the case, stating that he is bound by a conclusion reached by the higher court. "The question of whether embryonic stem cell research should be funded at all was not a question left on the table for the NIH by President Obama's order," Lamberth wrote. "Indeed, had the NIH adopted plaintiffs' views and refused to consider funding any embryonic stem cell research projects, its regulation would have been inconsistent with the Executive Order and unlawful." (Source: Carolyn Y. Johnson, Boston Globe, 28 July 2011)

Idera Says Merck Ending Cancer Drug Development

Idera Pharmaceuticals Inc. said that its partner Merck KGaA has abandoned development of an experimental cancer drug due to side effects, including blood cell abnormalities. German drug maker Merck has been paying licensing fees to Idera for its compound IMO-2055, which is under investigation as a treatment for cancerous tumors of the head and neck. Merck decided to drop the drug after an early-stage study showed patients were more likely to have low white blood cell counts and electrolyte imbalances. Idera said Merck intends to complete a midstage trial of the drug that is already underway. The companies will continue to collaborate on similar drugs in the future. (Source: Associated Press, 8 July 2011)

Regulatory and Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

FDA Approves Bristol-Myers Squibb Nulojix for Kidney Transplant Patients

The FDA has approved Bristol-Myers Squibb Nulojix (belatacept) to prevent acute rejection in adult patients who have had a kidney transplant. The drug is approved for use with other immunosuppressants (medications that suppress the immune system), specifically

basiliximab, mycophenolate mofetil, and corticosteroids.

Nulojix is a type of drug called a selective T-cell costimulation blocker. The drug helps to prevent organ rejection after a kidney transplant. Without immunosuppression, the body can reject a transplanted organ because the immune system recognizes the new organ as foreign (transplant rejection). By preventing rejection, Nulojix, given through 30-minute intravenous infusions, works with other immunosuppressants to keep the new kidney working. (Source: FDA Website, 15 June, 2011)

FDA Unveils New Strategy to Help Ensure Safety and Quality of Imported Products

The FDA has unveiled a new strategy to meet the challenges posed by rapidly rising imports of FDA-regulated products and a complex global supply chain in a report called the "Pathway to Global Product Safety and Quality."

"Global production of FDA-regulated goods has exploded over the past ten years. In addition to an increase in imported finished products, manufacturers increasingly use imported materials and ingredients in their US production facilities, making the distinction between domestic and imported products obsolete," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "There has been a perfect storm - more products, more manufacturers, more countries and more access. A dramatic change in strategy must be implemented."

The FDA report calls for the agency to transform the way it conducts business and to act globally in order to promote and protect the health of US consumers. Highlights of the report include four key elements needed to make the change:

1. The FDA will partner with its counterparts worldwide to create global coalitions of regulators focused on ensuring and improving global product safety and quality.
2. The coalitions of regulators will develop international data information systems and networks and increase the regular and proactive sharing of data and regulatory resources across world markets.
3. The FDA will build in additional information gathering and analysis capabilities with an increased focus on risk analytics and information technology.
4. The FDA increasingly will leverage the efforts of public and private third parties and industry and allocate FDA resources based on risk.

The change in strategy will address trends expected to be seen worldwide in upcoming years:

- Western economies will increase their productivity to compete with emerging markets and economies, leading to more imports and increased pressure to reinvent manufacturing processes.
- Money, goods, data and people will increasingly and more quickly cross borders. Today, a typical US manufacturing company relies on more than 35 different contract manufacturers around the world.
- Growing demand, constrained supply, and increased regulatory and social scrutiny will determine what resources are used, how they are used, and the cost. Manufacturers will adopt new manufacturing processes and emerging technologies in response.
- Governments worldwide will increasingly be called upon to mitigate the sometimes negative impacts of globalization on their citizens, making the operating environment for companies more complex.

The new strategy also builds on changes already set in motion by the FDA. The FDA increased the number of foreign drug manufacturing inspections by 27 percent between 2007 and 2009 and has opened a series of international offices in key locations. FDA has also collaborated with its counterparts in the European Union and Australia on drug inspections, worked to harmonize certain aspects of drug regulation via the International Conference on Harmonization, and joined the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) which is an organization of the drug manufacturing inspectorates from 39 countries. The FDA and other global leaders are also creating an expanded global regulators forum for medical devices. (Source: FDA Website, 20 June, 2011)

FDA Issues Draft Guidance for Early Version of Artificial Pancreas System

The FDA has issued draft guidance that will help advance the development and approval of an artificial pancreas system to treat type 1 diabetes in the US.

Type 1 diabetes is a chronic condition in which the pancreas produces little or no insulin, a hormone needed to properly control blood glucose (sugar) levels. Without enough insulin, glucose builds up in the bloodstream instead of going into the cells.

An artificial pancreas system is an automated, closed-loop system that combines a continuous glucose monitor, an insulin infusion pump, and a glucose meter for calibrating the monitor. The devices are designed to work together, monitoring the body's glucose levels and automatically pumping appropriate doses of insulin as determined by a computer algorithm.

Today's draft guidance document addresses an early version of an artificial pancreas system, known as a Low Glucose Suspend system. The Low Glucose Suspend system can help reduce or lessen the severity of a dangerous drop in glucose levels (hypoglycemia) by temporarily reducing or stopping the delivery of insulin. However, patients must still manage their glucose levels with a glucose meter and give themselves insulin, if necessary. The draft guidance provides recommendations for those planning to develop and submit an application for a Low Glucose Suspend (LGS) system intended for single patient use in the home environment. (Source: FDA Website, 20 June, 2011)

FDA Approves Novartis Arcapta Neohaler for Chronic Obstructive Pulmonary Disease

The FDA approved Novartis Arcapta Neohaler (indacaterol inhalation powder) for the long term, once-daily maintenance bronchodilator treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.

COPD is a serious lung disease that makes breathing difficult. Symptoms can include breathlessness, chronic cough and excessive phlegm. Cigarette smoking is the leading cause of COPD, and is the fourth leading cause of death in the United States, according to the Centers for Disease Control and Prevention.

Arcapta Neohaler is a new molecular entity in the beta₂-adrenergic agonist class that helps muscles around the airways of the lungs stay relaxed to prevent symptoms of COPD, such as wheezing and breathlessness. Arcapta Neohaler is not intended to treat asthma or sudden, severe symptoms of COPD.

Arcapta Neohaler carries a boxed warning that long-acting beta₂ adrenergic agonists (LABA) increase the risk of asthma-related death. All LABA, including Arcapta Neohaler, should not be used in patients with asthma, unless used with a long-term asthma control medication. (Source: FDA Website, 01 July, 2011)

FDA Approves Xarelto to Reduce Risk of Blood Clots after Hip, Knee Replacements

The FDA has approved Xarelto (rivaroxaban) to reduce the risk of blood clots, deep vein thrombosis (DVT), and pulmonary embolism (PE) following knee or hip replacement surgery. Other FDA approved drugs to prevent blood clotting include Lovenox (enoxaparin), generic versions of enoxaparin, Arixtra (fondaparinux), Fragmin (dalteparin) for hip replacement surgery only, Coumadin (warfarin) and heparin.

Xarelto is marketed in the US by Raritan, NJ-based Janssen Pharmaceuticals, a member of the Janssen Pharmaceutical Companies of Johnson & Johnson. (Source: FDA Website, 05 July, 2011)

FDA Approves Boostrix to Prevent Tetanus, Diphtheria and Pertussis in Older People

The FDA has approved Boostrix vaccine to prevent tetanus, diphtheria, and pertussis (whooping cough) in people ages 65 and older. Currently, there are vaccines approved for the prevention of tetanus and diphtheria that can be used in adults 65 and older. Boostrix, which is given as a single-dose booster shot, is the first vaccine approved to prevent all three diseases in older people.

Tetanus can cause paralysis and is caused by bacteria that live in soil, dust, and manure. The bacteria usually enter the body through a deep cut. Diphtheria is a serious bacterial infection that usually causes a bad sore throat, swollen glands, fever, and chills. If not properly diagnosed and treated, serious complications such as heart failure or paralysis can result. Pertussis is a disease that causes uncontrollable coughing; the infected person makes a noise when they breathe after coughing that sounds like "whoop." The incidence of pertussis disease in the US has been increasing since 2007, with large local outbreaks occurring in 2010 in California, Michigan, and

Ohio.

Boostrix was originally approved on May 3, 2005 for use in adolescents ages 10 years through 18 years. It subsequently was approved in December 2008 to include adults 19 years through 64 years of age.

Boostrix is manufactured by GlaxoSmithKline Biologicals, based in Rixensart, Belgium. (Source: FDA Website, 08 July, 2011)

FDA Seeks Comment on Proposed Policy for Diagnostic Tests used with Targeted Drug Therapies

The FDA has issued a new draft guidance to facilitate the development and review of companion diagnostics - tests used to help health care professionals determine whether a patient with a particular disease or condition should receive a particular drug therapy or how much of the drug to give. The draft document is intended to provide companies with guidance on the Agency's policy for reviewing a companion diagnostic and the corresponding therapy.

One common type of companion diagnostic looks for whether a patient has a specific gene amplification or protein over-expression that could predict whether a drug might benefit the patient or lead to harm. For example, the FDA in 1998 approved Herceptin (trastuzumab), a breast cancer drug designed to target HER2 gene amplification or HER2 protein over-expression. The drug was approved with a companion test and today testing is routinely performed on women diagnosed with breast cancer to help health care professionals determine whether or not the patient should receive Herceptin. (Source: FDA Website, 12 July, 2011)

FDA Approves Vaccines for 2011-2012 Flu Season

The FDA announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States.

Vaccination remains the cornerstone of preventing influenza, a contagious respiratory disease caused by influenza viruses. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season.

On average, between 5 percent and 20 percent of the US population develops influenza each year, leading to more than 200,000 hospitalizations from related complications, according to the CDC. Influenza-related deaths vary yearly, ranging from a low of about 3,000 to a high of 49,000 people. (Source: FDA Website, 18 July, 2011)

FDA Approves AstraZeneca's Blood-Thinning Drug Brilinta

The FDA approved AstraZeneca's blood-thinning drug Brilinta (ticagrelor) to reduce cardiovascular death and heart attack in patients with acute coronary syndromes (ACS). ACS includes a group of symptoms for any condition, such as unstable angina or heart attack, that could result from reduced blood flow to the heart. Brilinta works by preventing the formation of new blood clots, thus maintaining blood flow in the body to help reduce the risk of another cardiovascular event.

Brilinta has been studied in combination with aspirin. A boxed warning to health care professionals and patients warns that aspirin doses above 100 milligrams per day decrease the effectiveness of the medication. The boxed warning also says that, like other blood-thinning agents, Brilinta increases the rate of bleeding and can cause significant, sometimes fatal, bleeding.

Brilinta was approved with a Risk Evaluation and Mitigation Strategy, a plan to help ensure that the drug's benefits outweigh its risks. As part of that plan, the company must conduct educational outreach to physicians to alert them about the risk of using higher doses of aspirin. In addition, Brilinta will be dispensed with a Medication Guide that informs patients of the most important information about the medication. The guide will be distributed each time a patient fills their prescription. (Source: FDA Website, 20 July, 2011)

FDA Center for Drug Evaluation and Research Develops Strategic Science and Research Agenda

A FDA report from its Center for Drug Evaluation and Research (CDER), available in the *Federal Register*, identifies the current regulatory science needs that will guide CDER's strategic planning of internal research initiatives and contributions to the development of agency

regulatory science efforts. This docket will be open for review and public comment for 60 days after publication in the *Federal Register* notice. (Source: FDA Website, 25 July, 2011)

FDA Issues Draft Guidance on Device Changes that Warrant New Premarket Review

The FDA has issued draft guidance that clarifies when changes or modifications to a previously cleared 510(k) device require a new premarket submission. The 510(k) process is the most common review path to market for lower-risk medical devices. To legally market a device, manufacturers must submit a premarket notification or 510(k) demonstrating that the new or modified product is substantially equivalent to another legally marketed medical device.

Manufacturers often make changes or modifications to a device after FDA clearance such as incorporating new technology or upgrading certain aspects of the device. Many changes do not require a 510(k) submission. But when the changes could significantly affect the product's safety or effectiveness or constitute a major change to the intended use of the device, another 510(k) must be submitted.

The draft guidance clarifies the kinds of changes that trigger the need for a new submission, such as specific kinds of labeling changes, changes to the technology used in the device, changes in performance specifications, manufacturing changes, and changes in the materials used in the manufacture of the device.

This draft guidance is one of 25 action items listed in the FDA's Plan of Action for Implementation of 510(k) and Science Recommendations launched in 2011 to enhance predictability, consistency, and transparency of the FDA's premarket review programs. (Source: FDA Website, 26 July, 2011)

FDA to Seek Public Comment on IOM Recommendations on 510(k) Program

The FDA announced that it will open a public docket to begin receiving public comments on the Institute of Medicine's (IOM) report on the 510(k) program, the most common pathway to market for lower-risk medical devices.

The FDA commissioned the report in September 2009. While none of the IOM's recommendations are binding, the FDA is planning a public meeting in the coming weeks to discuss recommendations made in the report, titled "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years."

In order for a manufacturer to begin marketing a device subject to 510(k) review, FDA must "clear" a premarket notification (510(k)) demonstrating that the new or modified product is substantially equivalent to another legally marketed "predicate" device. (Source: FDA Website, 29 July, 2011)

FDA and International Counterparts Report Progress on Drug Inspection Collaboration

The FDA together with its European and Australian counterparts, released two reports detailing the results of pilot programs focused on increasing international regulatory collaboration among the agencies so that drug quality and safety can be enhanced globally.

The report on the Good Clinical Practice (GCP) initiative details the success of information-sharing and collaboration on inspections relating to clinical trials. Under the GCP pilot program, the FDA and the European Medicines Agency (EMA) exchanged more than 250 documents relating to 54 different drug products and, in conjunction with the GCP inspectors of the EU member states, organized 13 collaborative inspections of clinical trials. This lays the foundation for a more efficient use of limited resources, improved inspectional coverage, and better understanding of each agency's inspection procedures. It demonstrates how the agencies can work together to improve human subject protection and better ensure the integrity of data submitted as the basis for drug approvals. (Source: FDA Website, 02 August, 2011)

FDA and State of Arkansas Sign Agreement to Advance Regulatory Science

An agreement to establish a virtual Center of Excellence for Regulatory Science was signed between the FDA's National Center for Toxicological Research (NCTR) and the State of Arkansas. The Memorandum of Understanding (MOU) is the first between the FDA and a

state establishing a joint center to enhance regulatory science. It sets the framework for joint research, educational training, collaborations and outreach in support of the FDA's mission to protect and promote public health.

The memorandum also establishes a committee to be co-chaired by NCTR and the State of Arkansas, and includes state government representatives and academic institutions as partners with the FDA. The MOU will give scientists and regulators from around the world access to additional training and resources through the newly established Center of Excellence for Regulatory Science. (Source: FDA Website, 12 August, 2011)

FDA Proposes Guidelines that Clarify Benefit-Risk Determinations for Medical Devices

The FDA has provided draft guidance clarifying how benefit-risk determinations are made during premarket review of certain medical devices. The guidance focuses on premarket approval applications (PMAs), the regulatory pathway for high-risk medical devices. The recommendations made in the guidance are intended to improve the predictability, consistency and transparency of the premarket review process for applicable devices, and should help manufacturers navigate the approval process more easily.

In its review of PMAs, the FDA uses safety data and effectiveness data. The safety data addresses risk, and the manufacturer's ability to mitigate that risk. The effectiveness data considers benefits, as well as other information, to determine whether the probable benefits outweigh the probable risks associated with use of the device.

Safety and effectiveness data alone may not provide a complete picture of the benefits and risks. FDA medical device reviewers objectively look at other factors such as the severity of the disease the product diagnoses or treats and whether or not alternative tests or treatments are available. Device reviewers also may consider whether the device is new or a first-of-a-kind technology as part of the benefit-risk determination, particularly if the device treats a disease that has no other treatment.

The guidance also proposes that medical device reviewers use a worksheet to document how they make benefit-risk determinations. In certain cases, this document could be made public post-approval, making the FDA's decision making process even more transparent. (Source: FDA Website, 15 August, 2011)

FDA Seeks Comment on Proposed Guidelines for High-Quality Clinical Studies

The FDA issued draft guidance to help researchers and manufacturers design better quality clinical studies in support of premarket approval (PMA) applications for medical devices. Manufacturers submit PMA applications for high-risk (class III) medical devices. These applications undergo the most stringent type of FDA device review. PMA submissions include data from pivotal clinical studies which the FDA uses, along with other information, in determining approval.

The proposed guidance outlines Agency expectations for clinical trial design issues such as minimizing data bias and variability, setting appropriate study objectives, selecting the appropriate type of study, and choosing study sites and study participants. Although this guidance is developed primarily for clinical studies used to support PMAs, the recommendations of this guidance may also be used in designing clinical studies used to support 510(k) submissions. (Source: FDA Website, 15 August, 2011)

FDA Approves Genentech's Zelboraf and Roche's Companion Diagnostic Test for Late-Stage Melanoma

The FDA approved Zelboraf (vemurafenib), a drug to treat patients with late-stage (metastatic) or unresectable (cannot be removed by surgery) melanoma, the most dangerous type of skin cancer. Zelboraf is specifically indicated for the treatment of patients with melanoma whose tumors express a gene mutation called BRAF V600E.

Zelboraf is being approved with a first-of-a-kind test called the cobas 4800 BRAF V600 Mutation Test, a companion diagnostic that will help determine if a patient's melanoma cells have the BRAF V600E mutation. The drug has not been studied in patients whose melanoma tests negative for that mutation by an FDA approved diagnostic.

The BRAF protein is normally involved in regulating cell growth, but is mutated in about half of the patients with late-stage melanomas. Zelboraf is a BRAF inhibitor that is able to block the function of the V600E-mutated BRAF protein.

The median survival (the length of time a patient lives after treatment) of patients receiving Zelboraf has not been reached (77 percent still living) while the median survival for those who received dacarbazine was 8 months (64 percent still living).

Zelboraf is marketed by South San Francisco based-Genentech, a member of the Roche Group. The cobas 4800 BRAF V600 Mutation Test is manufactured by Roche Molecular Systems in Pleasanton, California (Source: FDA Website, 17 August, 2011)

FDA Approves Adcetris to Treat Two Types of Lymphoma

The FDA has approved Adcetris (brentuximab vedotin) to treat Hodgkin lymphoma (HL) and a rare lymphoma known as systemic anaplastic large cell lymphoma (ALCL). Adcetris is marketed by Seattle Genetics of Bothell, Washington.

Lymphomas are cancers of the lymphatic system. Adcetris is an antibody-drug conjugate that combines an antibody and drug, allowing the antibody to direct the drug to a target on lymphoma cells known as CD30.

Systemic ALCL is a rare malignant tumor (non-Hodgkin lymphoma) that may appear in several parts of the body including the lymph nodes, skin, bones, soft tissue, lungs or liver, according to the NCI. Adcetris is the first new FDA-approved treatment for HL since 1977 and the first specifically indicated to treat ALCL.

The drug is being approved under the FDA's accelerated approval program, which allows the agency to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. The program is designed to provide patients with earlier access to promising new drugs, but the company will be required to submit additional clinical information after approval to confirm the drug's clinical benefit (Source: FDA Website, 19 August, 2011).

FDA Approves Shire HGT's Firazyr to Treat Hereditary Angioedema

The FDA has approved Firazyr (icatibant) Injection for the treatment of acute attacks of a rare condition called hereditary angioedema (HAE) in people ages 18 years and older.

HAE is caused by low levels or the improper function of a protein called C1 inhibitor, which is involved in regulating how certain immune system and blood clotting pathways function. There is usually a family history of the condition. Fewer than 30,000 people in the US have HAE.

People with HAE can develop rapid swelling of the hands, feet, limbs, face, intestinal tract, voice box, or windpipe, which may result in disfigurement, disability, or death. Swelling of the digestive tract may cause abdominal pain, nausea, and vomiting, while airway swelling puts patients at risk of suffocation.

Firazyr is the third drug approved in the United States to treat HAE attacks. In October 2009 the FDA approved Berinert to treat facial and abdominal attacks of HAE, and Kalbitor was approved in December 2009 to treat acute attacks of HAE in patients ages 16 years and older.

The FDA approved Firazyr with patient counseling information that includes injection instructions. The most common side effects reported by those using Firazyr were injection site reactions, fever, increased liver enzymes, dizziness, and rash. Firazyr is marketed by Shire Human Genetic Therapies of Cambridge, Massachusetts (Source: FDA Website, 25 August, 2011).

FDA Approves Xalkori with Companion Diagnostic for Late-Stage Lung Cancer

The FDA has approved Xalkori (crizotinib) to treat certain patients with late-stage (locally advanced or metastatic), non-small cell lung cancers (NSCLC) who express the abnormal anaplastic lymphoma kinase (ALK) gene. Xalkori is being approved with a companion diagnostic test that will help determine if a patient has the abnormal ALK gene, a first-of-a-kind genetic test called the Vysis ALK Break Apart FISH Probe Kit. It is the second such targeted therapy approved by the FDA this year.

This ALK gene abnormality causes cancer development and growth. About 1 percent to 7 percent of those with NSCLC have the ALK

gene abnormality. Patients with this form of lung cancer are typically non-smokers. Xalkori works by blocking certain proteins called kinases, including the protein produced by the abnormal ALK gene. Xalkori is a pill taken twice a day as a single-agent treatment.

Xalkori was reviewed under the FDA's priority review program, which provides for an expedited six-month review of drugs that may offer major advances in treatment or that provide a treatment when no adequate therapy exists.

Xalkori is being approved under the FDA's accelerated approval program, which allows the agency to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on an endpoint that is reasonably likely to predict a clinical benefit to patients. The program is designed to provide patients with earlier access to promising new drugs, followed by further studies to confirm the drug's clinical benefit.

"The trend in oncology research continues towards targeted therapies," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostic Device Evaluation and Safety in the FDA's Center for Devices and Radiological Health. "This test is an example of the important role companion diagnostics play in determining that the safest and most effective treatments are promptly delivered to patients living with serious and life-threatening diseases."

In July 2011, FDA issued a draft guidance industry on the agency's policy for reviewing a companion diagnostic and the corresponding drug therapy. The guidance is currently available for public comment.

Xalkori is marketed by New York City-based Pfizer. The Vysis ALK Break Apart FISH Probe Kit is marketed by Abbott Molecular of Des Plaines, Illinois (Source: FDA Website, 26 August, 2011).

New Members

Mr. James P. Almeida, *Validation Engineer*, Organogenesis Inc

Mr. Craig Beasley, *Sr Director Supply Chain Quality*, Biogen Idec

Kevin O. Bergin, *Senior HVAC Engineer*, Genzyme

Mr. Robert A. Bruno, *Senior Manager*, Biogen Idec

Edgardo Cabrera, *Validation Engineer*, Genzyme

Michael-Sean Cerullo, *Sr./Lead Technician..Water Systems*, Genzyme

Mr. Clifford R. Chambers, *Sr. Automation Engineer*, NNE Pharmaplan

Anthony Copas, *Process Engineer*, DPS Biometrics, Inc

Mr. Robert J. D'Orazio, *Manufacturing Supervisor*, Genzyme Corp

Peter N. Duncan, *Student*, Northeastern University

Mr. Patrick M. Farley, *Supervisor Manufacturing*, Genzyme Corporation

Ms. Sarah A. Francis, *Operation Supervisor*, Genzyme

Joel Gates, *Associate Director, Process and Cleaning Validation*, Shire

Mr. Nuno Goncalves, *Manager, Scientific Staffing*, HireMinds LLC

Mr. M Douglas Gurley, *Sales Engineer Llife Sciences*, INSCO Group

Mr. Jason Hale, Genzyme Corp
Mrs. Mary L. Hernandez, *Sr. Validation Engineer*, Alexion Pharmaceutical
Adam Kroft, Genzyme
Mr. Jim Lockhart, *Consultant*, OakTree Technologies, Inc.
Chris Matosic, New England Lab
Mr. Gregory L. McCarthy, *Sales Engineer*, 3M Purification Inc
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Mr. Jude A. Mendi, *Student*, MWCC
Mr. Michael Montiverdi, *Manufacturing Supervisor*, Genzyme Corporation
Ms. Christine Mosholder, Fort Point Project Management
Ms. Patricia L. Nardi, *Senior Director of Manufacturing*, Genzyme Corporation
Mr. James A. Quinn, PE, *Mechanical Engineer*, M+W Group
Dr. Harold P. Schaefer, DPS Biometrics, Inc.
Walter L. Sousa, III, *Account Executive*, Environmental Systems, Inc.
Mr. David T. Stodden, *Business Development*, Columbia Construction Co
Mr. Matthew J. Wainwright, *Validation Engineer I*, Organogenesis Inc
Seth Whitworth, Olympus Biotech
Mr. Timothy Williamson, *Director Ops-research Svc Clinical Pharm*, Genzyme
Mr. Douglas Yedwabnick, *Director of Sales*, Atlantium Technologies
Ms. Neda Zahid, *Manufacturing Chemical Engineer*, Nova Biomedical Corporation

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20+ Years of Membership

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Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation
Ms. Greta W. Davis, Lantheus Medical Imaging
Mr. John H. Evers, Lantheus Medical Imaging
Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz
Mr. David C. Hardy

Mr. Edwin L. Harmon, III, Genzyme Corp
Mr. Stephen R. Higham, PE, Genzyme Corp
Mr. David L. Hyde, Lantheus Medical Imaging, Inc.
Mr. Thomas R. Jerome
Mr. Robert W. Juffras, MS, Stryker Biotech
Mr. Jerome Justin, Shire HGT
Dr. Richard V. Levy, PDA
Mr. Frank J. Manning, VNE Corp
Mr. Hank Moes
Mr. Thomas W. Moss, Applied Process Solutions, Inc
Mr. Armen J. Nahabedian, Pfizer
Mr. Richard D. Priestester, Strategic Facility Planning LLC
Mr. Thomas Ramundo, New England Controls, Inc.
Mr. Thomas Ransohoff, BioProcess Technical Consultants Inc.
Mr. Pasquale M. Sacco, Shire HGT
Mr. Alexander E. Smith, Jr., Parsons

15 Year Anniversary

Mr. Euan S. Ross, Pfizer Inc.

10 Year Anniversary

Ms. Kristen M. Allain, Genzyme Corp
Mr. Herman H. Chang

5 Year Anniversary

Mr. Mark Goodsell, Genzyme Drug Discovery & Development
Mr. Stephen E. O'Brien, Pfizer
Mr. James E. Taylor, SLC Consulting, LLC

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