Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

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NEWSLETTER

March 2012, Volume XXII, No. 2

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President's Message: Welcoming Spring with a Host of Chapter Activities...

Dear ISPE Boston Area Chapter Members

With the days starting to get longer and spring just around the corner, the Boston Area Chapter has a busy spring planned with lots of programs and activities to keep you connected. Here are a few upcoming events of note:

- March 2: Annual Ski outing, Loon Mountain
- March 6: Certified Pharmaceutical Industry Professional™ (CPIP™) certification program study group introductory session
- March 15: The Latest Standards in Pharmaceutical Water: We Wrote the Book (collaborative program with ISPE International)
- April 19: Engineering Documentation

As promised, our educational programs are being held on the third Thursday of every month. We have a number of top notch programs on tap and the full slate of Chapter events can be seen at http://www.ispeboston.org/eventcal/calendar.html. I want to bring your attention to two special events we're running this spring: a "first of its kind" collaborative pure water program, slated for March 15, and the completely revamped Certified Pharmaceutical Industry Professional™ (CPIP™) certification program study group launching with an introductory info session on March 6th.

On March 15, the Chapter will be collaborating with ISPE International to bring you a half-day pure water program featuring the world's best and brightest, who also happen to be the authors of ISPE's brand new *Baseline® Guide: Water and Steam Systems* (Second Edition). We've assembled the best speakers in the world and have brought them to Biogen Idec for you! As part of this program, ISPE will be offering special incentives for purchasing baseline guides and joining ISPE. The *Baseline® Guide: Water and Steam Systems* is the only objective guide on water systems in the world, and the first edition of the guide is ISPE's most widely read publication, with over 7,000 copies in circulation. Collaborating like this is a first for both the Boston Area Chapter and ISPE and it will serve as a model for delivering world class educational content on a local level in the future (see related article).

The FDA, recognizing ISPE's leading role as the largest non-profit organization of pharmaceutical professionals in the world, approached ISPE to develop a "certification program" to recognize excellence in the industry. This led to the introduction of the Certified Pharmaceutical Industry Professional™ (CPIP™) program a few years ago by ISPE's Professional Certification Commission (PCC). Unfortunately, the initial program had almost impossibly high eligibility requirements, dissuading many competent individuals from pursuing the certification. In Boston, the Chapter held two pilot program study groups with 70-80 participants, yielding just two professionals who obtained the CPIP credential. Based on this experience, the Chapter (and other Affiliates and Chapters) provided feedback to ISPE's PCC which responded by altering the program to retain the knowledge elements but streamline the rest of the process.

If you participate in a CPIP study group, ISPE has agreed to provide the educational content to the Chapter free of charge. Register today for an introductory session at http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=248 to learn more about the revamped program and decide if you want to add this credential of excellence to your title.

Our member surveys and brainstorming sessions in early 2011 surfaced the topics of paramount interest to our members and our Educational Program Committee has worked long and hard to design a 12-month

series of educational programs based on this input. A quick look back at the first two programs of 2012 attests to their success. Our January program featured two excellent speakers focused on the topic of Process Automation. Jay Zaino provided an introduction to the topic using an HVAC system as a real world example for his discussion. Doug Brenner did a deeper dive into some of the challenges facing automation professionals such as interfacing with engineering and quality, and dealing with scope changes. Our February program on Project Management featured great presentations by Keith Gibbs, Patrick Watters, and Harold Engstrom. See related articles for overviews of these two high-quality programs.

I wish you the best as we come through winter and into the spring season. While the sting of the Super Bowl lingers for many of us, the Patriots surely exceeded my pre-season expectations and gave us quite a ride this past season. With next year looking even more promising for the Patriots, coupled with more new construction gearing up in the area and the local economy showing signs of strength, we can all afford to be optimistic for the coming year. It's great to be living in Boston!

Thank you,

Brian Hagopian
President, ISPE Boston Area Chapter

Chapter Bulletin Board - March 2012

Join the Experts for a Half-Day Seminar on Pharmaceutical Water & Steam

Come hear the world's top water experts discuss the 2011 revision of the ISPE *Baseline® Guide: Water and Steam Systems* at this special half-day event to be held on March 15 at Biogen Idec in Cambridge. The Boston Area Chapter has partnered with ISPE International and the ISPE Critical Utilities Community of Practice (COP) to bring you this world class program. ISPE has literally written the book on pharmaceutical water and steam systems, and now we're bringing together the guide's authors for an interactive look at the last ten years of water system innovation. If you are involved in pharmaceutical water - or ever will be - you can't afford to miss this once-in-a-lifetime event.

Learn about this vitally important subject straight from the international team of experts who wrote the Baseline Guide and be among the first to hear about the yet to be released "*ISPE Good Practice Guide: Ozone Sanitization of Pharmaceutical Water Systems*." As a special incentive, attendees will have the chance to purchase the guides at discounted prices. Sponsorships are also available for this unique event. Space is limited so be sure to visit http://www.ispe.org/wewrotethewaterbook to register today, before it's too late!

Prepare for CPIP Certification - Join the Chapter's Spring Study Group

The Certified Pharmaceutical Industry Professional™ (CPIP)™) certification demonstrates competence in pharmaceutical industry practices. The CPIP study group will prepare industry professionals to qualify for certification. Come to an informational meeting to learn more about the CPIP program and the spring study group. The study group will consist of nine study sessions held at the Genzyme campus in Framingham from 6 to 9pm. The $100 registration fee covers all sessions, beginning with the introductory session on March 6 and ending on May 22, and includes free use of ISPE study materials. If after the informational session you choose not to continue the course, the full registration fee will be refunded. Please note: This is a Members-Only event. To join ISPE, visit www.ispe.org/join or call (813) 960-2105.

Calling All Student Members...

The Chapter is pleased to announce two exciting programs designed for our Student Members. Both

programs are free and provide great opportunities to interact with fellow Chapter Members, network with other Student Chapters and gain valuable insight into the exciting world of biotech.

• Monday, March 12 - Educational Seminar and Tour of Genzyme, Framingham This evening program at Genzyme's newest manufacturing facility will provide a behind-the-scenes look at a biotech plant in action. For more information, please visit email the office at office@ispeboston.org.

• Saturday, April 14 - Student Poster Contest, Luncheon and Career Seminar, WPI Campus Center, Worcester This is planned as a Saturday program to allow enough time for the Poster Contest, luncheon and career seminar. Poster Contest graduate and undergraduate winners will each earn a free trip to the ISPE Annual Meeting in San Francisco where they will compete at the International Student Poster Competition. The career seminar will introduce attendees to the broad range of biotech careers, who is hiring currently and what skills are hot right now. For more information, please email the office at office@ispeboston.org.

For students who plan to attend, please RSVP as soon as possible by contacting the Chapter office at office@ispeboston.org or 781.647.4773. We realize there is travel associated with these events and will be happy to discuss logistics and provide budget support if needed.

Bio-Ball Needs Chapter Member Volunteers on April 28th

The Boston Area Chapter is once again a proud sponsor of Bio-Ball -- a one-day basketball tournament and Special Olympics fundraiser which brings together teams from participating biopharma companies and partners them with Special Olympics athletes. Thus far Bio-Ball has raised over $500,000 for basketball programs and activities at Special Olympics Massachusetts.

This year's tournament will be held on April 28th at Buckingham Browne and Nichols School in Cambridge. In addition to the ISPE Boston Area Chapter, participating companies and organizations include Alnylam, Ariad, Aveo, Cubist, Genzyme/Sanofi, Infinity, Ironwood, MassBio, Momenta, Novartis, Biogen, Sunovion and Vertex.

Chapter Members can join in on the excitement as volunteers to help pull the event together and support the teams. While the opportunity to participate in this high-profile event is a "slam dunk" for Chapter Members, the Chapter will also sponsorbe recognized with its prominent sponsorship of the CEO Free Throw competition. The Bio-Ball tournament will take place Saturday, April 28 at the athletic center of the Buckingham, Browne, & Nichols school in Cambridge. CLICK HERE if you would like to help.

Want to Become a Chapter Sponsor? It's Easy!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at [insert link], containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Scholarship Program for Chapter Members - Next Deadline June 15

Chapter Members (and their families) who are continuing their formal education in the life sciences or pursuing a degree in a life sciences field are eligible to apply for a scholarship. Scholarship awards - up to $2,000 per individual - are funded by proceeds from Chapter activities and are designed to help defray tuition expenses. The Chapter hopes to be able to award up to 10 scholarships each year.

The application process has been streamlined to make it as efficient as possible. Application due dates are June 15 for fall courses and November 15 for spring courses. Full information and application can be found on the Chapter website at www.ISPEBoston.org/Scholarship. Questions should be directed to the Chapter by email at office@ISPEBoston.org or by telephone at 781-647-4773.

Upcoming Chapter Events - Mark Your Calendar

Thursday, March 15, 2012
The Latest Standards in Pharmaceutical Water: We Wrote the Book

Biogen Idec, 14 Cambridge Center, Cambridge, MA 02142

Come hear the world's top water experts discuss the 2011 revision of the ***ISPE Baseline Guide: Water and Steam Systems (Second Edition)*** and how to apply it to your work. ISPE has literally written the book on pharmaceutical water and steam systems, and now we're bringing together the Guide's authors for an interactive look at the last 10 years of water system innovation. If you are involved in pharmaceutical water - or ever *will* be involved in pharmaceutical water - you can't afford to miss this once-in-a-lifetime event!

Register Today: http://www.ispe.org/We-Wrote-the-Water-Book

Tuesday, March 20, 2012
Harpoon Brewery Tour and Tasting

Harpoon Brewery, Boston, MA

Come join the ISPE Boston Chapter's Young Professionals at the Harpoon Brewery for an in-depth informational session about Harpoon's brewing processes as well as some sampling of the great beers they brew. A knowledgeable member from Harpoon will be on hand to give a history of the brewery as well as some insight to the scientific aspects of their brewing operations.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=257

March 6, 2012-May 22, 2012
CPIP Study Group - It's Not Too Late to Join!

Genzyme Corporation, 49 New York Avenue, Framingham, MA 01701

The Certified Pharmaceutical Industry Professional (CPIP) certification demonstrates competence in pharmaceutical industry practices. The study group will prepare industry professionals to qualify for the CPIP certification. The Chapter has drawn on experience and enhanced the curriculum to help you develop strategies for the Experience exemplars leading to the eligibility to test, manage the hours required for the preparation, and a risk-based study program that you can tailor to your learning style.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=248

Sneak Preview of Upcoming Events

Saturday, April 14, 2012
Student Poster Contest

Thursday, April 19, 2012
Educational Program focusing on Engineering Documentation

Saturday, April 28, 2012
Bio-Ball

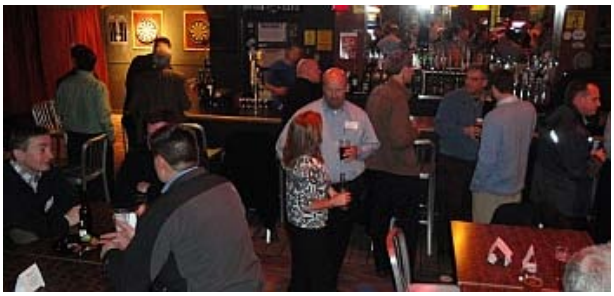
Thursday, May 10, 2012
Educational Program focusing on Process Design Principles

Holiday Social Raises $1200 for Cystic Fibrosis

Previous Issues

by Tom Choyce, Biogen Idec, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

Pool sharks, food and drink, and lively conversation - the Chapter's annual Holiday Social had it all. Over 80 ISPE members came together at Flat Top Johnny's in Kendall Square on January 12 to celebrate a great year and meet up with new and old friends. It was also an evening of charity where patrons bid on several great prizes. Lucky winners walked away with a GPS, an Ipod Nano and a future afternoon of golf among other items donated by members' companies.



The annual holiday social always draws a fun crowd to Flat Top Johnny's in Kendall Square.

The raffle raised close to $1200 to benefit the Joey Fund and the Cystic Fibrosis Foundation. Pam Spitzer was at Flat Top Johnny's representing the Joey Fund, which works in partnership with the Cystic Fibrosis Foundation. It is an independent fund established by individuals in November 1986 in memory of Joey O'Donnell, a courageous fighter and victim of cystic fibrosis.

Past President Sylvia Beaulieu reconnects with Chapter Members Jim Berry and Kevin Lear.

Members Olga Torres and Brian Ip enjoy the festivities.

Cystic fibrosis (CF) is a genetic disease currently affecting approximately 30,000 children and adults in the US. One in 31 Americans are symptom-less carriers of the defective CF gene. Since CF is relatively rare, patients rely on non-profit groups such as the Joey Fund and the Cystic Fibrosis Foundation to advocate on their behalf. These groups, in turn, rely on the contributions of donors and fundraisers such as the Holiday Social. Although there is no cure or fully effective treatment for the majority of CF cases, Cambridge-based Vertex recently received FDA approval for a drug which treats a small subset of CF patients.

Noted in attendance were several Chapter Past Presidents, including Sylvia Beaulieu, Jim Grunwald, Doyle Johnson, Niall Johnson, Joe Musiak, Dave Novak, and Rick Pierro. Current president Brian Hagopian said a few words encouraging all of us to celebrate the ISPE awards recently won by the Chapter, including Chapter of the Year for the third straight year. The Boston Area Chapter is firmly established as one of the leading Chapters in the nation, so we should all be very proud!

In between tense games of eight ball, many folks present agreed to continue the good time and meet at the upcoming events on the Chapter's social calendar, including the Ski Trip to Loon on March 2 and the golf outing later this summer. All in all, it was a perfect opportunity to

Newsletter Archive

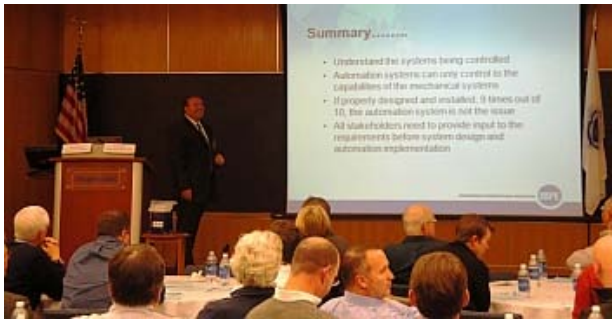
Bill Malone proves the more (raffle tickets, that is) the merrier!

spend a wonderful evening and network with fellow members, while contributing to a good cause.

Many thanks to the Chapter's Social Committee under the able leadership of Chris Opolski for planning another thoroughly enjoyable social event; and to the companies that donated raffle items for the benefit of the Joey Fund and the Cystic Fibrosis Foundation: UltraFiltronics, Superior Controls, Shawmut, Scitech Builders, HDR and R.W. Sullivan Engineering.

Always a Popular Topic - "Automation" Draws a Crowd to Biogen Idec

by Jack E. Greene, Allena Pharmaceuticals, with photos by Joyce Chiu, CPIP, Honeywell Safety Products, and Tom Choyce, Biogen Idec



Chapter Vice President Jay Zaino of GxP Automation opened by introducing the basics of HVAC systems.

Each year when Boston Area Chapter members are polled for the topics they would like to have addressed in educational programs, automation is always near the top of the list. On the evening of January 19 in the Biogen Idec auditorium, Jay Zaino and Doug Brenner presented a talk collectively titled "Automation - The Real Story Behind the Curtain." Each presentation tried to demystify and shine some light into the black box of automation. Jay Zaino, President of GxP Automation, spoke first about "The Basics of HVAC Operation and the Role of Automation" and Doug Brenner, Information and Technology Manager at Superior Controls, then continued with his talk on "Process Automation Challenges" which addressed how to manage complexity in defining, designing and implementing process control solutions.

Jay started off by explaining to the audience how the HVAC system in their home works and extending that model to explain how the technologies and controls are scaled to facility-wide systems. He then described three types of HVAC solutions and the strengths and weaknesses of each:

- A basic system where a single heating/cooling unit is controlled by a small number of thermostats and used to send air at a "best-guess" temperature to the entire building. These systems result in uneven temperature control where some rooms are too hot, others are too cold and only the rooms that have the thermostats are well-controlled.

- A more advanced system where the rooms with the highest cooling demand control the cooling level and all other rooms (with lower cooling needs) are then reheated with a hot water coil to meet that room's needs. These systems provide good temperature control, but they are very wasteful of energy as most rooms are supplied with too much cold air which then requires a great deal of reheating energy.

- A modern system where the amount of cool air to a room is modulated using a Variable Air Volume (VAV) box which controls the amount of cool air delivered to a room and only uses reheating when the VAV box is at the minimum flow position and the room is still too cold. These systems provide good temperature control and reduce energy usage by only giving a room the amount of cool air that is required.

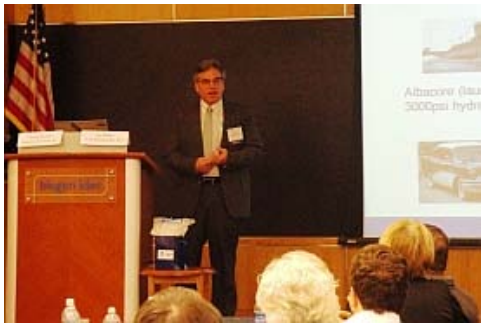
Once VAV box-type systems are in place, they can be placed on both the supply and return systems. With the ability to track and control the volume of air delivered to and removed from a room, it becomes possible to maintain the differential pressures required by GMP clean rooms.

Jay then explained how the older direct expansion systems do not modulate well (they usually have only a few steps between off and 100% cooling), which does not allow for the fine temperature control required by

GMP manufacturing spaces. Newer systems use chilled water and hot water with control valves to cool and heat the air in the air handler which allows for tight control on the air coming out of the systems, even when the outside temperature swings.

At the end of Jay's presentation, there were discussions about GMP controls in clean rooms and ways of managing/validating the fact that Building Management Systems typically have both GMP controls and data collection (from clean rooms) and non-GMP data (from office spaces) on the same systems. Also discussed were the cost and maintainability differences between PLC based control systems versus packaged BMS systems for air handler and VAV box control.

At this point, Jay handed the floor to Doug Brenner who switched gears to how automation and controls for manufacturing process controls have evolved over the years. Doug opened with a historical perspective of automated controls - from the hydraulic controls used on submarines in the 1950s to the relay/pneumatic controls used in the 1960s to the advent of the PLC in the late 1960s.



Doug Brenner of Superior Controls followed with a discussion of process automation challenges.

At a high level, PLC and DCS based systems work by reading in data from analog inputs (like temperature sensors) and discrete inputs (like level switches), doing math and then using that math to control analog outputs (like control valves and variable speed motors) as well as discrete outputs (like diaphragm valves). These systems need some type of user interface (whether it be a panel of push buttons or a computer screen-based graphical system), as well as some mechanism for alarm annunciation.

Doug then explained that the role of automation is to deliver whatever Process Engineering and Manufacturing need and, while it is important to follow industry standards and best practices like GAMP, ISA-S88 and ISA-S95, it is equally important to follow the procedures established by the local Validation and Quality groups.

In designed automation systems there are a series of core decisions that need to be made. Will the plant select a highly integrated control system or will there be islands of automation for each piece of capital equipment? If the island approach is used, will there be multiple plant historians or a single, centralized one? Will the plant use hardwired I/O, bus technologies like Foundation Fieldbus or a hybrid approach? Will the software use the ISA-S88 modular software architecture or use a more traditional approach? These choices have far reaching consequences for how the plant will operate and how it will be validated and maintained.

Doug pointed out that regardless, it is important that a plant develop a standard library of software used to directly control, monitor, alarm and display I/O. This is referred to as a Control Module library and there is one software module for each class of I/O. There was an open discussion about how large the library should be. The consensus was that it should be fairly small. When cases come up where an I/O point cannot fit into the library, new modules can be built but if this is taken too far, the library can get large and difficult to maintain. If a plant does not have a standard library, almost all control systems integrators will be able to provide one, but it is critical that a mature library be used to ensure a smooth commissioning effort and long term stable operation.

Doug described that the ISA-S88 uses a hierarchal layer model to combine Control Modules together to build function blocks called phases (such as temperature control or material addition). A recipe is the ordered sequence of when phases are used and with what setpoints and alarms.

The key element in all automation is development of the requirement and the importance of collaboration. Older models had groups working separately with design information handed off to each successive team. As the automation has become more complex, it has become critical for the various disciplines (Process Engineering, Automation, Quality and Validation) to work together to develop the design. This approach helps to prevent the message from being lost in translation along the way between conceptual design and final execution of the valve sequencing in software.

Specifications are the written location where all of this collaborative knowledge gets captured and used as the basis of the programming. Doug reviewed a number of ways that simple issues in specifications could result in the wrong function being developed.

Doug ended the evening by sharing the valuable lessons learned in his 30 years developing automation systems:

- The importance of developing or collaborating with experienced people who know how to make things work and come to the table with established, proven models.
- The importance of using a solid software library that is known to work well in the field.
- The need to make sure that the versions of automation software selected for a project or a

plant are new enough that they are supported but mature enough that they work as advertised.

• The importance of making informed choices on build vs. buy (because each case is different).

Finally Doug reiterated the central theme: All subject matter experts need to be engaged and there needs to be collaboration from conceptual design all the way to the end of validation for automation to be truly successful.

The Chapter would like to thank the presenters, program sponsor Rovisys, our generous host, Biogen Idec, and everyone who joined us to hear an excellent presentation on this topic of perennial interest.

"Between Love & Madness Lies Obsession: Project Management in the Pharmaceutical Industry"

by Robert Lucas with photos by Joyce Chiu,CPIP, Honeywell Safety Products

All educational programs begin with a networking reception where attendees can socialize while enjoying a light dinner.

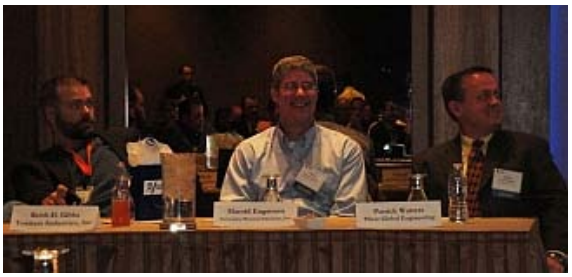
The recent educational program on project management for the pharmaceutical industry couldn't have chosen a title more perfect for the week of Valentine's Day. The intriguing title - plus a topic near and dear to the hearts of ISPE members - drew over 100 industry professionals to the three-part educational program held at the Royal Sonesta in Cambridge on February 16. Attendees were greeted by spectacular views of the Boston skyline and a sumptuous buffet dinner and enjoyed an hour of socializing and networking before entering the full-to-capacity auditorium for the first of three presentations.

Kickoff speaker Keith Gibbs with Amanda Holmgren of Xcellerex.

In Part I, and the main focus of the program, the audience was treated to a highly interactive and energetic presentation introducing the recently published ISPE *Good Practice Guide: Project Management for the Pharmaceutical Industry* by Keith Gibbs, Yonkers Industries, current chair of the ISPE Project Management Community of Practice (COP). Keith, a driving force behind the publication, outlined the guide's intent, structure and content and described the key elements that make up an effective project team. He used the process that led to the guide's publication as a case study illustrating many of the project management principles described in the guide itself. Adherence to these principles enabled the project to be delivered effectively and efficiently. More detail regarding the Good Practice Guide can be found at http://www.ispe.org/ispe-good-practice-guides/project-management-pharmaceutical-industry where it is also available for purchase.

The second part of the program focused on the "people" aspect of project management and was presented by Patrick Watters of Pfizer. His presentation highlighted the key requirements of an effective project manager and balanced those against the expectations of project team members. This real world perspective, stressing the importance of people in the process of project management, had some audience members e-mailing themselves the key best practices presented so they could start using them in the workplace the very next day.

The final portion of the program outlined the critical elements that ensure that the output of project management (i.e. the product) is not only right but right for the business. This aspect of project management was covered by Harold Engstrom of Innovative Process Solutions. He emphasized the importance of strong governance to the success of a project. Strong governance identifies the business constraints on the project and enables an appropriate decision-making framework to effectively manage risk, uncertainty and issues as the project progresses. Case studies were presented that illustrated the difference in outcomes (e.g. ongoing operating costs) for projects with very different levels of governance.



(l to r) Keith Gibbs, Harold Engstrom and Patrick Watters joined forces to cover the evening's topic.

All three presenters encouraged questions and responses from the audience, which led to lively discussions ranging from building and developing trust within a project team to the value of the project schedule and how scheduling may best be applied. Many of these discussions continued after the presentations concluded, a good indication that the program had addressed many of the practical challenges faced by Chapter members.

The Chapter would like to thank our distinguished presenters, the Boston University BioBusiness Organization which helped to sponsor the event, and everyone who joined us in Cambridge to hear three excellent presentations on this ever-popular topic.

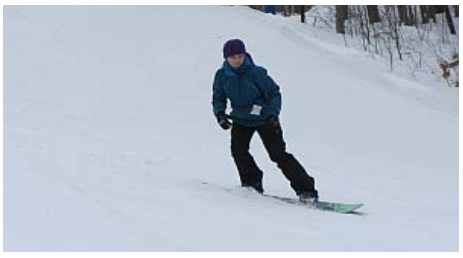
Chapter Skiers Return to Loon Mountain

by Jim Grunwald, SciTech Builders, with photos by Aarash Navabi, Genzyme

After a one-year hiatus, the Boston Area Chapter returned to the scene of our original Ski Outing - Loon Mountain in Lincoln, NH - where we celebrated our 11th annual event. The Snow Gods smiled upon us and we once again had a banner day on the hill.

We acknowledge the generosity of our Sponsors, Commissioning Agents, GxP Automation, RW Sullivan Engineers, SciTech Builders, Signer Harris Architects, Superior Controls and Ultrafiltronics, as their contributions facilitated the bus transportation and the apres ski festivities. This year we were treated to a great spread of food and beverages - Loon really stepped up their program beyond our expectations.

After a long day of skiing and celebration, the bus trip home was uneventful, with everyone on their best behavior while we took in cinema classic "Pulp Fiction." Special thanks to Event Manager Gene Dennen of Ultrafiltronics for another well-planned and thoroughly enjoyable outing.



Can't wait until next year! In the meantime, stay tuned for the next Chapter social event, rumored to be a Spring/Summer Social with a 70's theme. So dust off those bell bottoms - I'll see you there!

Industry News In Brief

by Patti Charek, Boston Area Chapter Past President

Genzyme's Framingham Work Clears Europe Hurdle

Genzyme, now owned by France-based Sanofi, has won European regulatory approval to restore normal supply levels of Fabrazyme, a drug made in Framingham that is used to treat the genetic disorder known as Fabry disease. The approval comes from the European Medicines Agency (EMA), which oversees the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. Genzyme said a complete return to normal supply levels of the drug globally are needed, but will take time to get regulatory approvals around the world. The company expects that to occur throughout the year.

"This approval ... represents an important milestone in our manufacturing recovery and path toward unconstrained supply for all patients," said David Meeker, president and CEO of Genzyme. "Providing the Fabry community with consistent access to treatment, increasing our inventory of Fabrazyme, and working toward all regulatory approvals of our Framingham plant are our highest priorities."

Last year, Genzyme encountered manufacturing problems at its plant in Allston that the company said could cause patients to miss doses of the drug. But the company was waiting on approvals to return to full production at the Framingham plant, located on New York Avenue and built in 2009.

"The EMA approval is an important milestone for Genzyme and a clear indication that our manufacturing recovery is well under way and on track," said Lori Gorski, a spokeswoman for the company. "Our plan has been to return to normal supply during 2012 and now we're another step closer to this crucial goal." (Source: Rick Saia, Worcester Business Journal, 18 January 2012)

MetroWest Firm Roadmaps Human Genome

During a 12-year period in the 1990s into the early 2000s, researchers spent somewhere between $3 billion and $4 billion mapping the human genome, which encompasses three billion strands of DNA that make up a living organism's heredity. Now Westborough-based GenomeQuest has a software system that can basically do that same analysis for about $1,000 in a few days to a week. Founded in 1999 in Paris, GenomeQuest is a venture-backed startup that now has about 40 employees, most of whom are in the Westborough headquarters.

The use of such information is endless. From analyzing causes of diseases to predicting which patients may develop them, to developing more durable and healthier agricultural products - so much can be learned by studying the genetic makeup of any living thing, said GenomeQuest President Richard Resnick.

It's complicated stuff, though. And the technology to analyze the data is still in early adoption by researchers and clinicians. In an effort to nudge the industry along, GenomeQuest has supplied $120,000 in grants to six research organizations around the country - including a molecular diagnostics lab in Worcester. Providing grant money to researchers has a two-fold goal for GenomeQuest: It will help distribute the company's product into the marketplace faster, and it will help researchers interpret this complex data quicker and more efficiently. The more researchers, doctors and clinicians that use the GenomeQuest software, the better, Resnick says.

One of the most promising uses of the GenomeQuest software is scientists being able to take samples of DNA, test it and use information from the genome to treat a patient. That's the type of work that could be done in Worcester at the UMass Memorial Medical Center Molecular Diagnostic Laboratory. Founded in 2002 as a joint venture between the University of Massachusetts Medical School and UMass Memorial Health Care, the lab now tests up to 40,000 DNA samples a year, providing information to researchers and clinicians working on a variety of projects.

As part of that research, the laboratory's director, Dr. Edward Ginns, applied for a nationwide grant from GenomeQuest to use the company's software to analyze the genomic information lab researchers are collecting. Specifically, Ginns hopes to use the GenomeQuest software to explore causes and potential treatments for cystic fibrosis. Because there is so much data in the human genome, Ginns said, it's important to be able to extract only the data researchers or clinicians truly need to more easily manage the information. (Source: Brandon Butler, MetroWest495 Biz, 17 January, 2012)

Life Technologies in Race to Introduce $1000 Gene Map

The quest to harness the power of DNA to develop personalized medicine is on the threshold of a major milestone: the $1,000 genome sequencing. Life Technologies, a Carlsbad, California genomics company, plans to introduce a machine it says will be able to map an individual's entire genetic makeup for $1,000 by the end of this year. Moreover, the machine and accompanying microchip technology, both developed by the company's Ion Torrent unit, will deliver the information in a day, the company says.

If Life Technologies delivers on the claim, it would likely make the company the first among a group of rivals racing to produce a $1,000 gene map. The current cheapest sequencing costs about $3,000 and takes a week. The goal, triggered in part by an initiative launched by the government's National Human Genome

Research Institute in 2004, already has resulted in a dramatic cost reduction in sequencing all three billion units of DNA, known as base-pairs, that make up the human genetic code.

Scientists say that breaking the $1,000 barrier will accelerate an already fast-moving transformation in genetic discovery and drug development. Some experts believe a person's genetic code eventually will be used routinely to guide prevention and treatment of illnesses throughout life.

Drug companies increasingly are identifying gene variants that they can target with drugs. And geneticists are identifying more and more diseases that result from a mutation in just one gene. The hope is that mapping variations in the entire human genome can speed up or improve disease diagnosis and aid in developing more medical treatments targeted to patients with a specific genetic makeup.

Genomic information also may give individuals information about their risk for a common disease and predict how one will respond to particular medications or environmental exposures, such as radiation from medical tests, according to the Department of Energy Genome Programs.

Whole-genome sequencing - as opposed to identifying just a subset of genes suspected of being linked to an illness - allows scientists to look broadly across all genes for mutations that are associated with diseases. This "broad net" approach is particularly useful when researchers don't have a good sense of which genes might be involved in a disease and may identify a novel drug target, said Richard K. Wilson, director of the Genome Institute at Washington University in St. Louis.

Eventually, if people can be sequenced early in life to learn about health risks, such as aneurysms or early-onset heart attacks, they may be able to take preventive drugs or boost the monitoring of their health, Dr. Wilson said.

With single-gene conditions such as sickle-cell disease, sequencing the whole genome could be useful in identifying "modifier" genes that work with the primary mutation to make a disease more or less severe, Dr. Wilson added. But understanding how genes work together to cause a condition or to develop a treatment will require extensive laboratory research far beyond merely analyzing the genome, said Karen Kaul, a molecular pathologist at NorthShore University HealthSystem in Evanston, Ill., and spokeswoman for the American Society for Clinical Pathology.

Completion of the Human Genome Project in 2003-which for the first time mapped the human genome-created high expectations that a stream of new drugs would soon flow out of pharmaceutical labs. When that didn't happen, skeptics questioned the value of the effort. But in the past year or two, drugs based on genomic information have begun to reach the market.

Current machines marketed by Illumina Inc. of San Diego, the market leader in sequencing devices, can decode an entire human genome in about a week for about $3,000. In the wings, said Jeff Schloss, a program director and technology expert at NHGRI, are newer approaches to sequencing that could help drive the price of a genome down to $100. (Source: Ron Winslow and Shirley S. Wang, Wall Street Journal, 10 January 2012)

Drug Maker Cubist Plans Suit over Would-Be Generic

Cubist Pharmaceuticals has said it will file a patent infringement lawsuit against generic drug maker Hospira after being alerted that the Illinois company has asked regulators for permission to market a generic version of Cubist's best-selling drug.

Cubist, based in Lexington, said it received notice that Hospira has filed an abbreviated new drug application with the FDA to sell its own version of the injectable antibiotic daptomycin, which Cubist markets under the brand name Cubicin. Cubicin, which treats skin and bloodstream infections, generated about 98 percent of the company's nearly $700 million in sales last year. It is currently protected by five US patents, which are scheduled to expire between 2016 and 2028.

The move by Hospira is the second challenge to Cubicin in three years under the Hatch-Waxman Act, a 28-year-old US law that encourages makers of generic drugs to contest patents on proprietary medicines so consumers can get cheaper versions sooner. Companies selling brand-name treatments contend they need longer exclusivity periods to recoup their costly investments on therapies, such as antibiotics, that fill important medical needs.

Cubist said it will file its suit within the 45-day response period allowed under the law. After that, the FDA is required to impose a 30-month stay before acting on Hospira's application. "We knew this challenge was a possibility," said Cubist chief executive Michael W. Bonney. "It's indicative of the fact that we have a very competitive product. We've been down this road before, and we're well prepared to defend our patents."

The new patent dispute comes 10 months after Cubist settled long-running patent litigation with Israeli generic drug giant Teva Pharmaceutical Industries. Under that settlement, Cubist granted Teva a license to sell generic daptomycin in the US starting in 2017 or 2018. In exchange, Teva agreed to buy its US supply of daptomycin from Cubist, giving the Lexington company a revenue stream after its top-selling drug comes off patent later in the decade. Meanwhile, Cubist is developing new products, including antibiotics, to become more diversified by the time its Cubicin patents expire.

Cubist had accused Teva of violating three patents. Since the two companies reached their settlement last April, Cubist has acquired two more patents on Cubicin. That creates a higher legal bar for Hospira, a former Abbott Laboratories division that was spun off in 2003. Hospira sells proprietary and generic drugs along with medical supplies. (Source: Robert Weisman, Boston Globe, 10 February 2012)

Bristol-Myers Squibb to Acquire Inhibitex for $2.5 Billion

Bristol-Myers Squibb has agreed to buy Inhibitex, a Georgia-based maker of a hepatitis C, for about $2.5 billion in cash, as major drug companies seek to bolster their pipelines with more profitable specialty products. Under the deal, Bristol-Myers will pay $26 a share through a two-step merger, beginning with a tender offer. That represents a huge 163 percent premium over Inhibitex's January 6th closing price.

"The acquisition of Inhibitex builds on Bristol-Myers Squibb's long history of discovering, developing and delivering innovative new medicines in virology and enriches our portfolio of investigational medicines for hepatitis C," Lamberto Andreotti, chief executive of Bristol-Myers, said in a statement.

Many big pharmaceutical companies have turned to mergers in recent years to plug holes in their drug pipelines, in large part to replace products that are set to face generic competition. Such companies are turning increasingly to smaller biopharmaceutical players developing specialized - and therefore hard to replicate - treatments.

In Inhibitex, Bristol-Myers will buy a company focused on antiviral products. Its main drug, INX-189, is an oral medicine being developed for hepatitis C that the company hopes will form the basis for simpler treatments of the disease. (Source: Michael J. De La Merced, New York Times, 9 January 2012)

Sanofi Says It Will Trim $170m in Annual Costs

Sanofi SA plans to wring $170 million in annual cost savings out of its operations after having acquired Genzyme, but many of the cuts will be outside the Boston area, Sanofi's chief executive said. For instance, Sanofi is closing a New Jersey research laboratory because it has been less productive than Genzyme's labs, which have developed treatments for rare diseases, chief executive Christopher A. Viehbacher told investors at the 30th annual J.P. Morgan Healthcare Conference in San Francisco. "Genzyme's having a big impact on the Sanofi culture," Viehbacher said. "Being a leader in life sciences in Cambridge, Mass., means we're able to look at all our facilities. We decided we didn't need a research facility in Bridgewater, New Jersey. So all of the cost savings are not coming out of Genzyme."

Sanofi acquired Genyzme last year after drawn-out negotiations that began with an unsolicited takeover offer by the pharmaceutical giant. Sanofi has eliminated some jobs at Genzyme headquarters in Kendall Square but has added research and manufacturing jobs in the Boston area, keeping its MA workforce stable at about 4,500 employees.

Sanofi has also begun using its $20.1 billion Genzyme purchase to reorganize its drug-discovery efforts, concentrating more of them at a small number of research and development centers in Cambridge, France, Germany, and China, Viehbacher said.

Tapping into Boston's life sciences cluster, Sanofi said that it will coinvest with the Boston venture capital firm Third Rock Ventures in Cambridge-based Warp Drive Bio, which is developing technology that will allow it to make drugs from microbes found in plant extracts. Also participating in the $125 million funding round will be Greylock Partners, a venture firm with offices in Silicon Valley and Cambridge.

"Coinvesting with a VC gives you a second opinion," Viehbacher said. While his Paris-based company will not start its own venture capital arm, as some rival drug makers have, "We're prepared to take equity positions in start-ups, he said.

Viehbacher said Sanofi's cost-reduction push is part of a strategy to develop fewer drugs at its own research sites and more in collaboration with other companies and institutions, a strategy employed by other drug makers. Viehbacher said 50 percent of drugs will be developed in collaboration with partners, compared to 30 percent currently.

Sanofi is facing a so-called patent cliff as the patents for several of its best-selling drugs expire this year, enabling competing low-cost generic therapies to enter the market. As a result, Sanofi is expanding into areas such as biotech drugs, vaccines, consumer health care, and pet and animal medicines to lessen its exposure to traditional chemical-based drugs, Viehbacher said. Those markets are "fundamentally changing the structure of the company," he said, and now represent two-thirds of Sanofi's annual business.

"2012 has been one of the years that's been circled in red at Sanofi," said Viehbacher. "It's the year of the infamous patent cliff. This is the third patent cliff of my career, and I'm determined to avoid a fourth." Sanofi's diversification has positioned the company for renewed growth in coming years, Viehbacher said. He projected annual sales growth of 5 percent from 2012 to 2015. (Source: Robert Weisman, Boston Globe, 11 January 2012)

Takeda Pharmaceutical to Cut 150 Chicago-Area Jobs

Takeda Pharmaceutical plans to cut about 150 jobs in the Chicago area, about 18 percent of its local workforce, part of a restructuring plan that will slash 2,800 jobs globally by the end of March. Japan-based Takeda, which has its Takeda Pharmaceuticals North America headquarters in Deerfield, employs about 30,000 people worldwide.

The restructuring will better align the company's global workforce and consolidate operations, enabling it to integrate its acquisition of drugmaker Nycomed, the company said. Takeda also is responding to the loss of exclusivity on some of its products, the ongoing effects of the economy and regulatory hurdles, said Takeda Pharmaceuticals North America spokeswoman Kara Hoeger. (Source: Sun-Times Media, 18 January 2012)

Eye Study is First Involving Human Stem Cells

Researchers at the University of California Los Angeles and Advanced Cell Technology in Marlborough have become the first to publish a study involving the use of embryonic stem cells in humans. The study, published online in the British medical journal The Lancet and involving two patients, was designed to test the safety of injecting the cells into patients with degenerative eye conditions. In both patients, the cells behaved as expected after four months, with no safety concerns arising, and the patients reported improved vision. The study provides a boost for the beleaguered field of embryonic stem cell research but must be viewed cautiously, said Dr. George Q. Daley, director of the Stem Cell Transplantation Program at Children's Hospital Boston and a faculty member at the Harvard Stem Cell Institute.

"We're all enthusiastic to see actual trials of cells based on human embryonic stem cells," he said, "but it really is far too preliminary to conclude anything other than that more studies are warranted. What we have to do is temper our hope with real skepticism." The researchers injected one eye of each patient with specialized eye cells derived from embryonic stem cells, which promote the health of photoreceptors in the eye. One, an adult woman, had Stargardt disease, a form of inherited juvenile macular degeneration. The other had age-related macular degeneration.

Dr. Robert Lanza, an author of the study and chief scientific officer at Advanced Cell Technology, a publicly traded company that funded the research, said the fact that the patients both reported improvements in their vision was a bonus, though he acknowledged that some of the change could be attributed to the placebo effect, or the patient's own expectation for improvement as a result of the study.

The study authors said the goal ultimately will be to treat patients with these conditions early, with the hope of stopping or slowing the degenerative process. Lanza said the work could help pave the way for the regenerative use of other kinds of cells, such as adult skin cells that are manipulated to behave like embryonic stem cells. (Source: Chelsea Conaboy, Boston Globe, 24 January 2012)

AstraZeneca Plans to Cut 7,300 Jobs

AstraZeneca PLC said it would eliminate another 7,300 jobs, bringing its total cuts over the past five years to nearly 30,000. The company announced the new job cuts as it reported an 8.3 percent decline in fourth-quarter net profit, to $1.49 billion from $1.62 billion a year earlier. Revenue in the quarter was $8.66 billion, compared with $8.62 billion a year earlier. The aggressive reduction in jobs - motivated by frugal insurers, generic competition and a dearth of new medicines - has transformed the company into a leaner organization that is now outsourcing much of its drug research.

AstraZeneca is ripping up some of its research roots in Europe and North America and forging more virtual research alliances with academic institutions and small biotech companies. It is also slashing its sales force and instead using cheaper digital-marketing tools.

Most of AstraZeneca's job cuts have occurred in mature markets like the US and Europe, where the company's R&D has traditionally been based, and where pharmaceutical sales have slowed markedly in recent years. At the same time, the company has also hired thousands of new employees for its expansion into emerging markets and for researching and producing biotech drugs. As a result, the net number of job cuts over the past five years was about 9,600, AstraZeneca said, giving the company a current level of 61,000 employees.

Now, the company plans to cut another 7,300 jobs by the end of 2014, including 2,200 in research and development, 1,350 in manufacturing and operations and 3,750 in sales and administration. The R&D cuts include the closing of neuroscience-research laboratories in Sodertalje, Sweden and Montreal. In their place the company is establishing what it calls a "virtual" neuroscience unit, with a small group of 40 to 50 AstraZeneca employees forging research partnerships with academic groups and other scientists outside the company.

AstraZeneca is making the cuts as it braces for a number of crucial patent expirations between 2012 and 2015, including on schizophrenia treatment Seroquel and heartburn medication Nexium. Crestor, the company's cholesterol-lowering drug, loses patent protection in the US in 2016. (Source: Jeanne Whalen

and Sten Stovall, Wall Street Journal, 3 February 2012)

With $32.5 Million Gift, Broad Institute to Open "Cell Observatory"

Scientists are launching an ambitious effort to diagram how the human genome controls cells by tracing the chemical pathways it uses to send instructions zinging through them like balls in a pinball machine.

The Broad Institute, a biomedical research juggernaut in Cambridge that is affiliated with Harvard University and MIT, announced a $32.5 million gift from the Klarman Family Foundation to open a "Cell Observatory." The center will allow researchers from Boston and around the world to investigate the molecular contents - not just the genes, but also the many chemicals that interact with them - of different human cell types, using large-scale techniques available only in advanced labs.

As a start, the Broad Institute will designate a space in its Kendall Square building where scientists can gather to exchange ideas and use existing and new equipment. Some researchers at Harvard, MIT, and the area's teaching hospitals are already working together; others will be recruited. Several other major research institutions, including the Mt. Sinai School of Medicine in New York, the Salk Institute in La Jolla, CA, and the University of California, San Diego are considering similar plans. There is talk of a "Human Circuit Project" in which centers would coordinate and share data as they did in sequencing the first human genome.

"The task at hand is enormous - mapping pathways is much larger, more ambitious and ill-defined a goal than the Human Genome Project," said Trey Ideker, a systems biologist at UCSD who is running an early parallel initiative. (Source: Mary Carmichael, Boston Globe, 27 January 2012)

Amylin, Alkermes get OK for diabetes drug

Amylin Pharmaceuticals won approval for its long-delayed diabetes drug Bydureon, a next-generation treatment that requires fewer injections than the company's 7-year old diabetes medicine, Byetta. Bydureon is a once-a-week version of Byetta, which is taken twice a day to control blood sugar. Amylin executives say the drug's convenient regimen will give it a competitive advantage. However, after multiple delays it enters a crowded market, including one diabetes treatment in the same class that has shown superior results. The FDA approval comes after two rejections in 2010, when the agency asked Amylin to conduct a new study of the drug's effects on the heart.

Bydureon was co-developed with Eli Lilly, which also helped co-market Byetta. Both drugs are scheduled to transfer to Amylin by the end of 2013. Waltham-based Alkermes created Bydureon's formulation technology, which gradually releases the drug over the course of a week. (Source: Associated Press, 28 January 2012)

Novartis Job Cuts Spare Cambridge

A new cutback by Swiss drug giant Novartis AG, which will pare 1,630 US sales jobs and 330 jobs at its US pharmaceuticals headquarters in East Hanover, New Jersey, won't affect the planned expansion of Novartis research and drug development operations in Cambridge, the company said. Novartis spokesman Jeff Lockwood said the latest round of layoffs stemmed partly from the loss of a Novartis patent for Diovan, a hypertension drug, which the company had anticipated.

The global research and vaccines and diagnostics sites in Cambridge, which currently employ more than 2,000 workers, are still scheduled to add about 300 jobs over the next five years, Lockwood said. While some of the sales force cuts may involve Massachusetts-based employees, Novartis hasn't specified where those cuts will be made, he said.

Last October Novartis disclosed a broader restructuring plan aimed at shedding 2,000 jobs in the US and Europe but the company said no jobs would be eliminated at its Cambridge sites in that rollback either. Cambridge is world headquarters of the Novartis Institutes for BioMedical Research, the company's research and development engine, and also is home to a vaccine and diagnostic division. (Source: Robert Weisman Boston Globe, 18 January 2012)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

FDA Expands Use of Merck's HIV Drug Isentress to Children and Adolescents

Isentress (raltegravir) has been approved by the FDA for use with other antiretroviral drugs for the treatment of HIV-1 infection for children and adolescents ages 2-18. The drug is part of a class of medications called HIV integrase strand transfer inhibitors that works by slowing the spread of HIV in the

body. It was first approved for use in adult patients in October 2007, under 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. Isentress does not cure HIV infection. Patients must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses. (Source: FDA Website, 21 December, 2011).

FDA Expands Use of Wyeth's Prevnar 13 Vaccine for People 50 and Older

Prevnar 13, a pneumococcal 13-valent conjugate vaccine manufactured by Wyeth Pharmaceuticals, has been approved by the FDA for people ages 50 years and older to prevent pneumonia and invasive disease caused by the bacterium, Streptococcus pneumoniae. Pneumococcal pneumonia, caused when the bacterium Streptococcus pneumoniae infects the lungs, is the most common disease caused by this bacterium in adults. When the bacterium invades parts of the body that are normally free from germs, such as the blood or spinal fluid, the disease is considered "invasive."

Prevnar 13 is approved for use in children ages 6 weeks through 5 years for the prevention of invasive disease caused by 13 different serotypes of the bacterium Streptococcus pneumoniae and for the prevention of otitis media caused by seven of the serotypes of the bacterium. (Source: FDA Website, 30 December, 2011)

FDA Completes Work on Drug User Fee Programs

The FDA recently completed its recommendations for three user fee programs that will help speed safe and effective drugs and lower-cost generic drug and biosimilar biological products to patients. The recommendations were transmitted to Congress by Health and Human Services. The programs include the fifth authorization of the Prescription Drug User Fee Act (PDUFA) and new user fee programs for human generic drugs and biosimilar biological products.

Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's drug review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame.

The proposed user fee programs for generic drugs and biosimilars are modeled on the successful PDUFA program. As a result of the continued investment of PDUFA resources, the United States now leads the world in first introduction of novel drugs.

The proposed new Generic Drug User Fee program would provide the FDA with needed funding at a time when generic drug applications are on the rise. Generic drug user fees would help ensure consumers timely access to safe, high-quality and effective generic drugs, which account for two-thirds of all prescriptions dispensed in the US.

The recommended user fee program for biosimilars includes fees for products in development to generate revenue in the near-term and to provide FDA with the resources needed to support development-phase meetings with sponsors of biosimilar biological product candidates. (Source: FDA Website, 13 January, 2012)

FDA and Industry Reach Agreement on Medical Device User Fees

The FDA and representatives from the medical device industry have reached an agreement in principle on proposed recommendations for the third reauthorization of a medical device user fee program. The recommendations would authorize the FDA to collect $595 million in user fees over five years, plus adjustments for inflation.

Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame.

FDA will develop a package of proposed recommendations and give the public an opportunity to comment before they are submitted to Congress. The date of the public meeting has yet to be determined. (Source: FDA Website, 01 February, 2012)

FDA Permits Marketing of First Test for Risk of Rare Brain Infection in Some People Treated With Tysabri

The FDA has allowed marketing of the first test to help determine the risk for a rare brain infection called progressive multifocal leukoencephalopathy (PML) in people using the Biogen Idec drug Tysabri (natalizumab) to treat multiple sclerosis (MS) or Crohn's disease (CD). The Stratify JCV Antibody ELISA test, when used with other clinical data from the patient, can help health care providers determine the risk for developing PML in MS and CD patients.

The John Cunningham virus (JCV) is a common virus that many people have been exposed to at some point in their lives, and is generally harmless. However, people with weakened immune systems, such as patients using immunomodulatory therapies like Tysabri, have an increased chance of developing PML from JCV. PML usually causes death or severe disability.

Currently, there is no treatment, prevention, or cure for PML, and no certain way to predict who will develop it. This test in conjunction with other factors will allow the physicians and patients to carefully assess the risks and benefits of continuing Tysabri treatment depending on the complete clinical information for the particular patient.

Tysabri is co-marketed by Cambridge, Mass.-based Biogen Idec and Elan Pharmaceuticals whose US operations are based in South San Francisco. (Source: FDA Website, 20 January, 2012)

FDA Approves Pfizer's Inlyta for Patients with Type of Advanced Kidney Cancer

The FDA has approved Pfizer's Inlyta (axitinib) to treat patients with advanced kidney cancer (renal cell carcinoma) who have not responded to another drug for this type of cancer. Renal cell carcinoma is a type of kidney cancer that starts in the lining of very small tubes in the kidney. Inlyta works by blocking certain proteins called kinases that play a role in tumor growth and cancer progression. Inlyta is a pill that patients take twice a day. Recently approved drugs for the treatment of kidney cancer include sorafenib (2005), sunitinib (2006), temsirolimus (2007), everolimus (2009), bevacizumab (2009) and pazopanib (2009). (Source: FDA Website, 27 January, 2012)

FDA Approves Genentech Drug for Most Common Type of Skin Cancer

Genentech's Erivedge (vismodegib) has been approved by the FDA to treat adult patients with basal cell carcinoma, the most common type of skin cancer. The drug is intended for use in patients with locally advanced basal cell cancer who are not candidates for surgery or radiation and for patients whose cancer has spread to other parts of the body.

Erivedge, reviewed under the agency's priority review program, is the first FDA-approved drug for metastatic basal cell carcinoma. Erivedge was reviewed under the FDA's priority review program that provides for an expedited six-month review of drugs that may offer major advances in treatment. Basal cell carcinoma is generally a slow growing and painless form of skin cancer that starts in the top layer of the skin (epidermis). The cancer develops on areas of skin that are regularly exposed to sunlight or other ultraviolet radiation.

Erivedge is a pill taken once a day and works by inhibiting the Hedgehog pathway, a pathway that is active in most basal cell cancers and only a few normal tissues, such as hair follicles. Erivedge is being approved with a boxed warning alerting patients and health care professionals of the potential risk of death or severe birth effects to a fetus. (Source: FDA Website, 30 January, 2012)

FDA Approves Vertex Drug Kalydeco to Treat Rare Form of Cystic Fibrosis

The FDA recently approved Kalydeco (ivacaftor) for the treatment of a rare form of cystic fibrosis (CF) in patients ages 6 years and older who have the specific G551D mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene. CF, which affects about 30,000 people in the United States, is the most common fatal genetic disease in the Caucasian population. About 4 percent of those with CF, or roughly 1,200 people, are believed to have the G551D mutation.

The FDA reviewed and approved Kalydeco in approximately three months under the agency's priority review program that is designed to expedite the review of drugs. The priority review program uses a six-month review, instead of the standard 10 months, for drugs that may offer significant advances in treatment over available therapy.

Kalydeco is effective only in patients with CF who have the G551D mutation. It is not effective in CF patients with two copies of the F508 mutation in the CFTR gene, which is the most common mutation that results in CF. If a patient's mutation status is not known, an FDA-cleared CF mutation test should be used to determine whether the G551D mutation is present. (Source: FDA Website, 31 January, 2012)

FDA Approves Gleevec for Use in Patients with Rare Gastrointestinal Cancer

The FDA has granted the Novartis drug Gleevec (imatinib) regular approval for use in adult patients following surgical removal of CD117-positive gastrointestinal stromal tumors (GIST). GIST is a rare form of cancer that originates in cells found in the wall of the GI tract. These cells, known as interstitial cells of Cajal, are part of the autonomic nervous system, which regulates body processes such as food digestion. More than half of GISTs start in the stomach.

Gleevec is a pill that should be taken with a meal and a glass of water and was first approved by FDA in May 2001 to treat patients with advanced Philadelphia chromosome positive chronic myeloid leukemia, a blood and bone marrow disease linked to a genetic abnormality. (Source: FDA Website, 31 January, 2012)

FDA Issues Draft Guidance on Biosimilar Product Development

The FDA has issued three draft guidance documents on biosimilar product development to assist industry in developing such products in the United States.

The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amended the Public Health Service Act to create an abbreviated approval pathway - under section 351(k) - for biological products that are demonstrated to be highly similar (ie. biosimilar) to or interchangeable with an FDA-licensed biological product.

A biosimilar is a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency.

FDA will seek public comment on the guidance documents and instructions on how to submit comments will be announced in an upcoming Federal Register notice. In finalizing the guidance documents, the agency will consider the information received from the public. (Source: FDA Website, 09 February, 2012)

Bristol-Myers Squibb and AstraZeneca Receive FDA Complete Response Letter for Dapagliflozin

Bristol-Myers Squibb and AstraZeneca have announced that the FDA has issued a "complete response letter" regarding the New Drug Application (NDA) for investigational compound dapagliflozin for the treatment of type 2 diabetes in adults. The complete response letter requests additional clinical data to allow a better assessment of the benefit-risk profile for dapagliflozin. This includes clinical trial data from ongoing studies and may require information from new clinical trials.

The companies will work closely with the FDA to determine the appropriate next steps for the dapagliflozin application, are in ongoing discussions with health authorities in Europe and other countries as part of the application procedures, and remain committed to the drug and its development.

Bristol-Myers Squibb and AstraZeneca entered into a collaboration in January 2007 to enable the companies to research, develop and commercialize select investigational drugs for type 2 diabetes. Dapagliflozin, an inhibitor of SGLT2, a target in the kidney, is being investigated to evaluate its safety and efficacy in improving glycemic control in adults with type 2 diabetes, both as a monotherapy and in combination with other anti-diabetic agents.

The kidney plays an important role in glucose balance, normally filtering about 180g of glucose each day, with virtually all glucose being reabsorbed back into circulation. SGLT2 is a major sodium-glucose cotransporter in the kidney and is an insulin-independent pathway for the reabsorption of glucose back into the blood.

The Centers for Disease Control and Prevention estimate that approximately one in every 11 adults in the United States has diagnosed diabetes. Type 2 diabetes accounts for approximately 90 to 95 percent of all cases of diagnosed diabetes in adults. It is a chronic, progressive disease characterized by insulin resistance and dysfunction of beta cells in the pancreas, which decreases insulin sensitivity and secretion, leading to elevated glucose levels. Over time, this sustained hyperglycemia contributes to worsening insulin resistance and further beta cell dysfunction. To date, treatments for type 2 diabetes have focused primarily on insulin-dependent mechanisms. An approach that acts independently of insulin could provide an additional option for adults with type 2 diabetes.

Significant unmet need still exists as nearly half of treated patients remain inadequately controlled on their current glucose-lowering regimen. Many patients with type 2 diabetes have additional comorbidities (such as obesity) which may complicate glycemic control. (Source: BMS Website, 19 January, 2012)

New Members

The Boston Area Chapter continues to grow at a record rate. Welcome to all our new Members...

Mr. Kyllan Alwyn, *Sr. Process Engineer,* Shire

Mr. Robert Babecki, *Student,* University of Massachusetts

Mr. Richard Blease, Genzyme Corp.

Mr. Ian Blizard, Commodore Builders

Mr. Ron Bouley, *VP - Business Development,* Dakota Systems, Inc.

Ms. Lia Brigida, *Research Associate,* Millenium Pharmaceuticals

Michael Cammarata, *Account Manager - Life Sciences,* Doe & Ingalls

Todd Carpenter, *Regional Sales Manager - Northeast,* Swan Analytical USA

Mr. Art Cox, *President,* Cox Systems Group

Mr. Joseph Fallis, *HVAC Supervisor,* Shire

Mike Freud, *Project Executive,* Consigli Construction

Mr. Paul Gauthier, *Manager, External Manufacturing Operations,* Shire HGT

Mr. Michael Gray, *Sr. Plant Engineer II,* Shire HGT

Mr. Prashant Gudka, *Process Engineer,* Panorama Consulting & Engineering, Inc.

Ms. Rebecca Hall, *VP, Software Development,* Innovative Process Solutions

Mr. Eric Hamann, *Sr. Technology Scientist - Informatics,* Pfizer

Ms. Delaney Harrigan, *Student,* Middlesex Community College

Mr. Danny Hughes, *Mechanic,* Biomeasure

Mr. David Kalbfleish, *Validation Scientist,* Commissioning Agents, Inc.

Mr. Kenneth Lamb, *Key Account Manager,* Thermo Scientific

Mr. Michael Lewis, *President,* Eisai Product Creation Systems

Mr. John Lucente, *Maintainence Supervisor/Specialist,* Genzyme Corp.

Mr. Francis Maheno, *Account Manager,* Webb Bio-Pharm

Daniel Mardirosian, *Sr. Operations Manager, Biomanufacturing Education and Training Center,* WPI

Regis Mauss, *Operational Excellence Business Consultant,* Genzyme

Mr. Timothy McDermott, *Program Coordinator,* HHT Services

Mr. Reza Mehmandoost, *Process Architect,* DPS Biometics

Mani Bhadra Mohapatra, *Engineering Services ENGG-II,* Genzyme

Christian Monsalves, *Program Manager,* NSTAR

Steven Moran, *Facilities Manager,* Genzyme

Sweta Murarka, *Sr. Compliance Specialist,* Genzyme Corp.

Mr. John Murray, *Facilities Tech.,* Genzyme Corp.

Mr. Rajan Nadimpalli, *Student,* University of Massachusetts

Pranoti Navare, *Graduate Student,* WPI

Mr. Aidan O'Dwyer, *VP Operations,* DPS Biometics

Kelly Ohare, *Director, QA,* Shire HGT

Mr. Sean O'Leary, *Senior Manager, Validation, Biogen Idec*

Ms. Ronda Paradis, *Principal, S+T Development,* HDR

Mr. Pasquale Petrillo, *Sr. Maintenance Mechanic,* Shire HGT

Mr. Francis Piccirillo, *Student,* Northeastern University

Jason We Yen Pui, *Student,* Boston University

William Rios, *Plant Engineer Critical Utilities,* Bristol-Myers Squibb

Lauriana Rodriguez, *Inventory Management Specialist,* HeartWare, Inc.

Ms. Karin Schlicht, *Manufacturing Associate III,* Lonza Biologics

Ms. Dalia Shash, Harvard School of Public Health

Mr. TJ Sheehan, *Marketing Manager,* M+W Group

Mr. Carl Townsend, *President,* Townsend Welding Co., Inc.

Mr. Stefan Tropsa, *Engineer, ICQ Consultants Corp*./Validation

Mr. John Ward, *Plant Engineer III,* Biogen Idec

Mr. Ralph Willette, *Regional Sales Manager,* TSI

Jim Winiarski, *Head of HGT Real Estate & Site Services,* Shire

Michael Wood, *Mechanical Engineer,* Microfluidics

Member Anniversaries

20+ Years of Membership

Mr. Saboo Aghababayan, Genzyme Corp

Dr. Charles L. Cooney, Massachusetts Institute of Technology

Mr. Brian M. Hagopian, CPD, Clear Water Consulting, Inc.

Mr. David C. Hardy

Mr. David G. Harney, Microfluidics

Mr. Jerome E. Justin, Shire HGT

Peter F. Levy, PL Consulting, LLC

Dr. Robert C. Menson, PhD, Menson & Associates Inc

Mr. Thomas A. Ramundo, New England Controls Inc

Mr. Gregory M. Ruklic, Independent

Mr. Robert P. Vecchione, Christ Aqua Pharma & Biotech NA

Mr. Jack N. Wentz, Lantheus

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

15 Year Anniversary

Mr. Sean M. Brown, Barry-Wehmiller Design Group

Mr. Joseph Musiak, Biogen Idec Inc

Mr. Andre L. Walker, CPIP, Biogen Idec

10 Year Anniversary

Mr. Brian T. Duffy, Genzyme

Mr. Glenn A. Yale, Pond Technical Sales, Inc.

5 Year Anniversary

Mr. Aarash Navabi, Genzyme Corporation

Mr. Guy Sylvester, Middlesex Gases & Technologies Inc

Mr. Christopher D. Blackwell, Lonza Biologics

Mr. Albert J. Evangelista, CRB Consulting Engineers

Mr. Paul DiBara, ImmunoGen Inc

Mr. Alexander G. Tschumakow, Shire HGT

Mr. Bruce Kozuma, PMP, CPIM, Alkermes Inc

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Chapter Manager: Amy Poole, CAMI - Tel: 1.781.647.4773 and E-mail: ispe@camihq.com