Boston Area Chapter
ENGINEERING PHARMACEUTICAL INNOVATION

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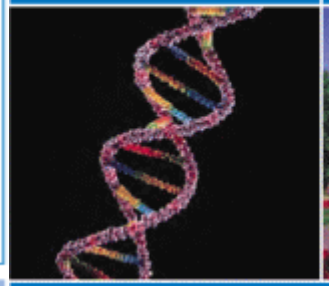

NEWSLETTER

January 2010, Volume XX, No. 1

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President's Message: Happy New Year to My Fellow ISPE Members!

Happy New Year to My Fellow ISPE Members!

Another year has passed, not without some bumps along the way. The weak economy is still a factor in all of our lives and we must work smarter - not harder. The Boston Area Chapter has held many programs to help you work smarter and we plan on continuing that through 2010. A brief recap of 2009 in case you missed our "ISPE Chapter of the Year" Celebration Party:

Educational Programs

- LEED: The Path to Environmental Enlightenment
- ASTM E2500 Standard and Its Use in the Real World
- Magnetic Nanoparticles in Bioprocessing (co-sponsored by MIT)
- Strategies to Survive the Recession: Business Partnering & Contract Manufacturing
- Young Professionals Series: Biotechnology and Career Development Seminar
- Young Professionals Series: Engineering Leadership and How to Influence without Authority (panel discussion)
- Forefronts in Bioengineering: Stem Cells, Soft Body Robots, Bio-Optics. (presentation and tour)
- Combination Products and Convergence

Facility Tours

- Bristol Myers Squibb - Devens

Social Activities

- Annual New Year's Social, Flat Top Johnny's, Cambridge
- Annual Ski Trip, Loon Mountain, New Hampshire
- Summer Social and Volunteer Appreciation Night, Beer Works, Boston
- Annual Golf Outing, Ferncroft Country Club, Middleton
- Young Professionals Boston Harbor Cruise
- "Chapter of the Year" Celebration Party

Career Management

- Marketing Yourself
- Selling Your Skills in Biotech

We also launched a new series in November - CEO/Executive Dinners - with an outstanding presentation by execs from Lantheus Medical Imaging. Plan on more of these in 2010. And the BIG event of course - the Product Show. In other words, our activities for 2009 covered all the bases - educational, social, facility tours, career development and more.

I want to stress to every member that we, the Board of the Boston Area Chapter, take your membership in this great organization very seriously. We are creating programs and events that will help you in your career and personal life through educational programs, social events for networking and volunteer committees for your willingness to give back. And most of all, we will be here as your friend.

I want to remind everyone that if you do become unemployed, ISPE waives your membership fee until you find employment, provided you are a current member. You can also attend Boston Area Chapter educational programs at a reduced rate. Please contact Amy or Hannah at our Chapter headquarters for more information. Also, don't forget to update your email address in your ISPE profile so you will continue to receive notices of programs and events.

With many companies cutting back on travel expenses, we continue to offer in-house training. We purchase educational programs from ISPE and use their materials and speakers to offer the programs locally at company sites for a fraction of what it would cost to send people out of state. See information elsewhere in this newsletter and contact Amy or Hannah for a list of the programs available.

I want to personally thank every volunteer who has worked on a committee this past year. Without your dedication and hard work, we would not be able to accomplish what we have this past year. I hope every member will consider some form of volunteerism, whether it is on a committee, for a specific event or for our upcoming sponsorship of the Bio-Ball event for the Special Olympics in March. In these tough times, when it seems that everything is being taken away from you, you can shine and give back to your community.

I look forward to seeing you all at our New Year's Party on January 14th at Flat Top Johnny's in Cambridge and please remember to bring an item for our Marine Care Package drive.

Sincerely,

Sylvia Bealieu
President, ISPE Boston Area Chapter

Upcoming Chapter Events: Mark Your Calendar

Tuesday, January 12, 2010
Career Management Workshops

Kick off the New Year with a boost to your career at these dynamic workshops, co-sponsored for the very first time by MDG and the ISPE Boston Area Chapter. Attendees can select two of these four workshops geared toward:

* Succeeding within your current company
* Conducting a successful job search

To achieve your career aspirations, you need to take charge by actively capitalizing on your strengths and building relationships. Completing your tasks and projects successfully may not be sufficient to achieve your career goals. This program is tailored to help you network within your company and showcase your strengths based on corporate goals.

In an economic downturn, successful job seekers find innovative ways to stand out by creating an effective marketing campaign. Our job seeker program is designed to help you communicate your value and develop the goals, plan, and process to help you land a new job.

Foley Hoag, Waltham, Massachusetts

Click Here to Register!

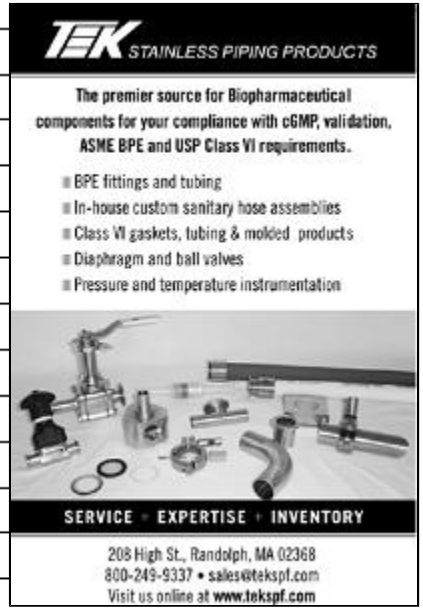
Thursday, January 14, 2010
New Year's Social

Celebrate the New Year's Season with Friends and Colleagues at Flat Top Johnny's Billiards, One Kendall Sq., Cambridge

Thursday, January 14, 2010
6:00 pm to 10:00 pm

Parking is available at a discounted rate at One Kendall Garage located on Old Binney Street. Flat Top Johnny's is conveniently located near the T at the Kendall Square stop. This garage only accepts cash.

Bring a MarineParents.com care package item with you to receive a raffle ticket.



Visit http://www.carepackageproject.com/carepkg-project-needs-list.asp for a list of care package items.

Flat Top Johnny's Billiards, Cambridge, Massachusetts

Click Here to Register!

Thursday, January 21, 2010

Process Analytical Technology and Bioreactors

The event is sponsored by Genzyme and will be held at their facility at 500 Kendall St. in Cambridge MA. The program will consist of two educational seminars. The first seminar: "Process Analytical Technology: What it is and Why it is the Future of Process Engineering, Validation and Quality" will be given by Lou Traglia of Commissioning Agents. This lecture will benefit anyone in the process industry and give people an insight into the latest developments and the future benefits of Process Analytical Technology.

The second seminar, "Bioreactors: Making Sense of the Requirements, Operations and the Utilities They Require" will be given by Aarash Navabi. This lecture will benefit anyone that would like to expand their knowledge of bioreactors.

Genzyme Center, Cambridge, Massachusetts

Click Here to Register!

Tuesday, January 26, 2010

Biotech Process Scale-up & Tech Transfer: Everything You Need to Know for Success the First Time

Attendees will discover the complexities of biopharmaceutical manufacturing processes and the challenges of transferring processes from development laboratories to cGMP production or from early stage production to the larger scales and greater compliance required for later stages. The analytical, process, management, and governance tools that are essential to facilitate effective tech transfer in biotechnology will be revealed by speakers who have worked first-hand in this area and who know what the challenges and solutions are.

Foley Hoag LLP, Seaport World Trade Center, Boston, Massachusetts

Click Here to Register!

Enthusiastic Members Celebrate "Chapter of the Year" Win

by Janet Tice, GMP Piping, with photos by Peter Teague, Boston Scientific

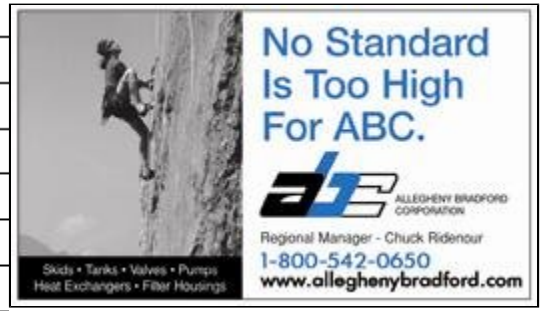
This year, the Boston Area Chapter won the top award presented at the ISPE Annual Meeting in November, the coveted "North American/South American Affiliate Council Platinum Grand Award for Excellence and Innovation." The award recognizes the Chapter with the best overall activities, accomplishments and achievements in Chapter management, services to members and contributions to the community during 2009.

Sometimes a single photo says it all!

Board Member Marita King, Maritek, with Dan Rufo, UMass Medical School

What better reason for a celebration to sing the Chapter's praises and thank the many volunteers who made this exciting win possible? And celebrate we did! The festivities included a live band providing background music, drinks and hors d'oeuvres, and a cake with icing proclaiming our win. And just in case anyone doubted the hard work and the impressive range of activities that cemented our win, the room was filled with posters describing the Chapter's many accomplishments for 2009.

Chapter Officers Sylvia Beaulieu,



Mike Marino, Boston Scientific Corp, with Board Member Jay Zaino, GxP Automation

Columbia Construction; Doyle Johnson, CDI; and Jim Grunwald, A/Z

Attendees included Chapter Past Presidents and Advisory Board Members, many of whom are recognized leaders in the local life sciences community, who turned out in an impressive show of support for the Chapter and its mission. With the many posters acting as thought-provoking conversation starters, members were overheard discussing creative ideas for future Chapter activities and initiatives in addition to sharing the usual industry updates. If the energy in the room that evening was any indication, Chapter members are well on the way toward securing another win for the Chapter in 2010!

Chapter Past Presidents Rick Pierro, Superior Controls, and Doyle Johnson, CDI, with Advisory Board Member Joe Musiak, Biogen Idec

Membership Committee Member Joyce Chiu, Parexel, with Allan MacDonald, BosBio, and Board Member Kevin Lynch, Shire HGT

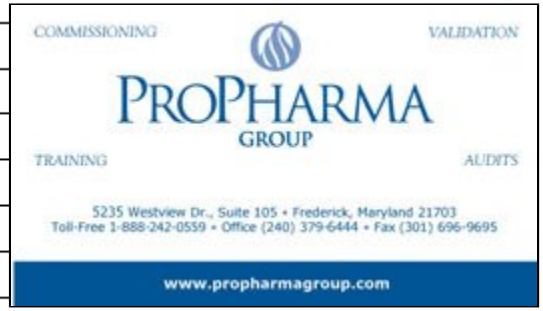
From Fort to Pharma: Members Tour the Bristol-Myers Squibb Large-Scale Cell Culture (LSCC) Facility at Devens

by Lee J. Ward, Rockwell Automation, with photos provided by Bristol-Myers Squibb

The setting? A mid-November afternoon in blustery Devens, Massachusetts, on the site of what was once part of the "Fort Devens" military base, now seeing new life in the form of Bristol-Myers Squibb's newest addition to their world wide manufacturing strategy. The occasion? The Bristol-Myers Squibb Large-Scale Cell Culture (LSCC) team played host to the Boston Area Chapter's educational program, "From Fort to Pharma," designed to showcase their approach to the site re-development and the challenges they met and overcame during the redevelopment process.

The program began in the late afternoon in order to accommodate the almost one hundred attendees (ISPE members only!) who were given a comprehensive tour of the LSCC building. Attendees were split into groups of ten and entry to the facility was staggered.

Along the route, members were taken through the logical stages of the manufacturing process at their associated locations in the building. At each location, a knowledgeable BMS staffer was on hand to describe the specific processes that take place there and answer members' in-depth questions about the operation at that point. Key to the architecture of the manufacturing building was the modular nature of the construction



that is apparent in the layout of the building.

Upon returning to the cafeteria, we were met by our hosts: Chris Perley, Dave Schwabb, Geoff Attenborough, and Wayne McFarland. After hors d'oeuvres were served, the audience took to their seats and the program was introduced by Boston Area Chapter Educational Committee Member H. Steven Kennedy of Parsons.

Chris Perley, Vice President and General Manager of the LSCC site, began the program by describing Bristol-Myers Squibb as a $25 billion, "mid size" biopharm company with a goal. That goal, according to Chris, is "to become the next generation, best of bio, best of pharma company, globally." He sees the execution of that plan manifesting itself at the Devens facility. He then went on to describe how the facility fits into BMS's "String of Pearls" strategy whereby they grow as a corporation through the development of technology sourced from "emerging companies," while not ruling out growth through acquisition.

The Devens project represents a three-year, $750M investment made in order to realize the demands of two key products: Orencia, prescribed for the treatment of rheumatoid arthritis, and a product being developed to manage tissue rejection. Chris posed the question, "Why here?" In answer, he commented that the Massachusetts area is strong in available talent and strong in the area of technology, both key ingredients required to ensure the success of the facility and position the site for growth in the future.

Next up was Wayne McFarland, Director, Technical Services, who began a presentation illustrating the project from concept to completion, beginning with the site re-development. History would represent a major part of the initial challenge, since unexploded ordinance was uncovered during the excavation phase of the project. This was not unexpected, however, as it was understood that parts of the site had served as a live firing range during two World Wars. In light of this, safety was a key element in the planning and execution of the project and policies and procedures were put in place to manage the situation. As in all of BMS's projects, site safety is paramount, and for that reason, every person admitted to the Devens construction site was subject to UXO (Unexploded Ordinance) training in addition to the usual site safety training.

Wayne went on to describe the vast 89-acre site as supporting five main buildings in the current "Phase 1" development. However, he added that the site had been laid out to accommodate two additional LSCCs in future phases. The LSCC as it stands today is a 200,000 sq/ft building comprised of four floors housing everything from air handling equipment to process vessels. The LSCC module was designed with gravity in mind and makes use of the height of the building to go from seeding, to reaction, to harvesting, to purification, to bulk product released for shipping.

Wayne next described the central utilities building. This 45,000 sq/ft facility is designed to provide all that the site requires in terms of chilled water, process steam, compressed air, and building management, and is sized with expansion in mind. In addition, there is a 38,000 sq/ft warehouse, a 5,000 sq/ft chemical storage building, and finally the 90,000 sq/ft lab/office building in which we found ourselves for this event. In addition to the buildings, a key essential is the processing of waste. To this end the site has its own large-capacity waste water treatment plant (or WWTP) to manage the waste water resulting from the process manufacturing.

Wayne stated that mindful of the sensitive nature of the bio process and the needs of the regulatory bodies, steps were taken to ensure quality and consistency. With that in mind, Wayne described the need for "high availability" as a primary design criterion and therefore adoption of an N+1 model for all critical equipment. This manifested itself in duality for boilers, chillers and compressors as well as various control systems throughout.

Geoff Attenborough, Program Director, Project Management, took the podium next, outlining the 17-month effort to realize manufacturing implementation. He described the elements of the process from lab culture, to media prep, to media feed, harvest and purification. He stated that in planning the desired outcome, a decision has to be made early on in the process whether to go modular or "stick-built." This forces the

Previous Issues

decision, as it is too late to follow a different design philosophy later in the process.

Once the design methodology has been decided upon, it is time to engage the A&E, fabrication engineers, process engineers and construction/project management team. In this particular project, the A&E was able to "3-D" model based on the given design information. This enabled BMS to gain an early appreciation of what the facility would look like and how it would fit together way before ground was even broken.

Bristol-Myers Squibb adopted a very "hands on" approach and was very involved in the design process. This ensured that the original vision of what the plant should be followed through to the fabrication and construction on site. Geoff went on to describe that once the design decisions had been made, all of the capital procurement was undertaken by the A&E and all of the OEM and vendor purchasing was completed by the A&E as well.

Key to the design for process manufacturing was the adoption of the ASTME 2500 standard that was applied to the entire facility. This was mapped out from beginning to end and tied in the check points along the way including FAT (Factory Acceptance Testing) and the commissioning process.

Geoff went on to explain that one of the main elements in choosing a design and manufacturing approach based on the employment of standards and modular design is up to a 75 percent reduction in engineering and a savings of up to 3 percent on every $100M of investment. Over a $750M project, this will have saved BMS almost $23M and helped manage cash flow. Geoff then addressed the pros and cons of the choice to go modular, again reiterating that an early decision is the only way to make this methodology pay, as the perceived "on cost" for choosing to go modular must outweigh the cost of a delayed product launch, the potential result of a decision to go with the stick-built approach. In other words, the modular approach facilitates schedule compression realizing manufacturing sooner in the cycle.

Dave Schwab, Director of Manufacturing, took over for the final part of the program and discussed how the employment of the E2500 standard helped them proceed with a "risk-based" approach and taught the team that constant evaluation was a critical part of the process. The planning around the method helped harmonize and rationalize the testing and performance expectations such that repetition could be avoided where appropriate in order to shorten the time to complete. This not only became the "modus operandi" at FAT, but extended to some of the complex software in use throughout the facility.

Throughout the entire project, attention has been paid to how the teams involved got to the end goal. In the process, BMS and its construction partners strived to make sure all involved were able to work in a safe and relatively clean environment. To that end, the construction manager, Parsons, received OSHA VPP Star status for having a comprehensive and effective safety and health management system, for achieving injury and illness rates below the national average and for demonstrating their ability to control workplace hazards. Since breaking ground in February 2007, there have been 2.6 million man-hours and 700 days without a lost-time accident. In addition to this achievement, BMS was also extremely sensitive to the impact the site would have on the environment. As such, the entire facility has been designed and constructed with LEED in mind, and BMS will be pursuing that accreditation in the very near future.

As the session drew to a close, the presenters invited questions from the audience, all of which were answered with a refreshing combination of enthusiasm and honesty which, in my experience, has been the pattern for the entire project.

In closing I would like to thank all of the many BMS representatives involved for offering the Boston Area Chapter membership a highly informative and extremely well-organized visit to their impressive facility and a unique, behind-the-scenes glimpse into the long process of planning and execution that brought the Devens site "from Fort to Pharma."

Combination Products and Convergence: Clinical Benefits, Regulatory Issues & Manufacturing Challenges™

by Paul L. Smock, Pfizer Global Manufacturing, Quality Operations with photos by Rami Mitri, Spectra Automation

On Tuesday, December 8, the Boston Area Chapter presented an educational program at the Royal Sonesta Hotel in Cambridge. Our presenter was Dr. Michael Drues, President of Vascular Sciences in Grafton and an Adjunct Professor of Medicine, Biomedical Engineering and Biotechnology at a number of universities including Northeastern. Dr. Drues brought his extensive experience in medical devices, drugs, biotechnology, biomedical engineering and medicine, as well as his experiences as a consultant to the FDA to bear in an educational and visionary presentation on combination products now and in the future.

After a brief introduction by Paul Smock, Past President and current Educational Program Committee member, Dr. Drues got the group immediately engaged in a brain teaser to get us to consider how we approach problem solving. His point was that we often focus on the wrong part of the problem and information about it, and then don't ask the right questions. He also indicated, as an example of this, clinical trials designs ending up being biased by asking the wrong questions. The idea of questioning everything was an excellent backdrop to some of his later examples of a not-so-science-fiction-like potential for combination products in the future.

Meeting Manager Paul Smock introduced the evening's presentation

We were next introduced to what is and what is not a combination product. Dr. Drues reviewed some examples of each, and included a discussion on pre-filled syringes, which are typically regulated as drugs or biologics but may be more properly classified as combination products. Basically combination products are combinations of two or more components from the drug, biologics and medical device areas (e.g. drug-device, biologic-device, drug-biologic, drug-biologic-device), but not combinations within an area (e.g. drug-drug).

Next we reviewed the regulatory framework for combination products. This designation is only used in the US and prior to 1990 was applied on a case-by-case basis by FDA. There is now in place the Office of Combination Products (OCP), which doesn't regulate these products but establishes for each new application which center (CBER, CDER or CDRH) will have primary regulatory responsibility for the product. OCP also helps to manage the inter-center relationships, which are often somewhat challenging. The lead agency decision is currently based on the primary mode of action of the product, as proposed by

Attendees enjoyed a buffet dinner during the networking reception

the sponsor. As the combination products become more complex, this is rapidly becoming an outmoded concept! To help bring these concepts into sharper focus, several case studies of current products that are combination products, or should be considered as such, were presented. Included were the Mirena Intrauterine Contraceptive and a drug-biologic comprised of a monoclonal antibody with a bound cytotoxic drug. It was noted that not all combination products have a device component at all; and many older products that probably should be designated as such have not been and are not the focus of FDA's efforts.

Chapter President Sylvia Beaulieu shared a light moment with presenter Dr. Michael Drues

Next we looked at the world of stents, particularly drug-coated stents, and some of the controversy surrounding their use for cardiac disease along with angioplasty. This is where Dr. Drues began to circle back to the beginning of his talk on questioning everything and asking the right questions. His fundamental point was that stents, as manufactured and used today, are primarily trying to fix a "plumbing" problem, when the real problem is with biology, and not just with atherosclerosis. He challenged us to think biology first, then let the engineering follow for a future of second generation stents with multiple drugs attached. These could be used to treat the multiple underlying biology issues that address multiple biologic causes or outcomes; and to extend stent use to other diseases like cancer, diabetes, and Alzheimer's disease.

Lastly, Dr. Drues shared some visionary concepts on multiple combination products of the future - at the edge of science fiction but potentially in our grasp if we accept the challenge to think differently. These concepts included stents with multiple inner and outer layers comprised of different biologics, drugs and biomaterials that would be absorbed (and thus no longer in place) after their function was completed (unlike stainless steel stents), as well as bare stents that could have multiple different rings of drug-biologic combinations manufactured and placed on the stent by the treating physician - a real application of personalized medicine. Also presented was the idea of viewing tissue engineering as the quintessential combination product, regenerative organ replacements grown on-demand!

Throughout the talk there were many video vignettes presented that added greatly to our understanding and quotes from Socrates to Mark Twain to engage us, not just in the science and technology of this field but the philosophy as well. Mark Twain may have said it best with his famous, "It ain't what you don't know that gets you into trouble....it's what you know for sure that just ain't so."

Young Professionals Look Ahead to 2010

by Robert DeCoste, Commissioning Agents

The ISPE Boston Young Professionals are currently planning their events for the year 2010. For those who may be unfamiliar with the ISPE Young Professionals (ISPE YP), it is an internationally recognized group that was recently formed to foster the ideas and professional needs of individuals who are establishing their careers in the biotechnology and pharmaceutical industry. The primary focus of this group is education, career/professional development, and networking. ISPE YP Boston, along with its Committee Co-Chair Dan Ramsey, were recently recognized at the ISPE Annual Meeting held in San Diego. In addition, Dan has been asked to co-chair and help develop additional Young Professional groups across the United States.

The Young Professionals have recently launched a Facebook page, ISPE Boston Young Professionals, thanks to the help of Jillian Willard of Genzyme. This page will be used for advertising upcoming events, maintaining communication, and sharing ideas and discussing new developments within the industry. Please visit us for additional information. The web address is: http://www.facebook.com/home.php?filter=app_2361831622#/group.php?gid=170893141157&ref=ts,

Currently, the group is actively planning its next educational event to be hosted by Genzyme on January 21, 2010 at their Cambridge site at 500 Kendall Street. The evening will consist of two presentations: Lou Traglia of Commissioning Agents will present "Process Analytical Technology: What it is and Why it is the Future of Process Engineering, Validation and Quality" and Aarash Navabi will present "Bioreactors: Making Sense of the Requirements, Operations and the Utilities They Require." Lou is a senior engineer and an expert in biotechnology. Aarash has many years of experience and specializes in the operation, commissioning, validation and troubleshooting of bioreactors at Invensys. This event was made possible through the efforts of ISPEYP member Jared Marshall of Genzyme. Keep an eye out for additional details and registration information coming soon.

Additional 2010 activities in the planning stages include a Red Sox outing, a summer boat cruise and other educational and social events. Please contact Dan Ramsey at Daniel.ramsey@cagents.com if you would like to join the group or need additional information about the Young Professionals.

Spotlight Interview with James Koloski, RDK Engineers

- Where did you grow up, go to school (college/grad school)? What do you like to do for fun when not at work?

I grew up on Cape Cod, in Sandwich, and went to college at Merrimack in North Andover, Massachusetts. When I am not at work, I am chasing my 5 and 2 year old sons around and occasionally playing golf.

- Describe your job. What do you like best about it?

I am responsible for Business Development for RDK Engineers. I like that I am able to meet and get to know people across multiple industries. It is helpful to get many perspectives on how different companies operate their businesses.

- How did you get to where you are today?

I was lucky enough to have worked for a small interiors firm called GHK. The leaders at GHK gave me the opportunity to work in Business Development starting in 2000. Through my efforts in this area, I was able to network and meet people in the industry. During this time, I was fortunate to have met and worked with several of RDK's principals and was delighted when they offered me the opportunity to come on board two years ago.

- Where do you see yourself in 5-10 years?

I am excited for the future of the built environment in Boston over the next 5-10 years.

- Why did you decide to join ISPE?

RDK has a very strong commitment to biotech, so it makes sense for us to be active participants in the association.

- What changes have occurred in your field during the course of your career?

Technology has changed so much, so fast. That and the commitment to the environment. Ten years ago, "Green" was a puppet frog, not a way of life. It is amazing to watch my 5 year old recycle without thinking twice. Pretty cool.

- What is your biggest challenge in your current position?

No surprise in this economy, my greatest challenge is fighting to bring work in the door. The quantity of projects are less and the amount of good firms competing for that work is still there; so it's even more important to be able to differentiate yourself from your competition and solidify existing relationships.

- What do you see as the biggest challenge for the pharma/biotech industry?

Competing for resources and talent to stay ahead of the challenges they face.

- Where do you see the pharma/biotech industry going over the next five to ten years?

My hope is that we'll see tremendous strides in curing cancer. It speaks volumes to what a powerful disease it is. Although the strides we've made are amazing, we can't seem to knock it out.

- What do you see as the future of the pharma/biotech industry in Massachusetts?

What an amazing geography to be in this industry! The best colleges and universities in the world, the leading hospitals and a vibrant life sciences community add up to a limitless future for biotech in Massachusetts.

- What changes (if any) have you seen in the industry in response to the launch of the FDA's risk-based initiative?

N/A

- What is your favorite biotech term, product, or process? Why?

"Congratulations, the job is yours!"

- How do you balance the demands of your career while continuing to stay current?

I rely a lot on associations like ISPE. The educational programs and information they provide are invaluable.

- What publications do you read? Which do you find the most worthwhile and why?

There's so much to read these days, and it is tough to stay on top of it all. My dad told me that if you read nothing but the front page of the Wall Street Journal every day, you will be able to keep a grasp on what's going on in the world. For me, that's still the best source of information going. I do read it online though.

- What ISPE activities have you participated in?

I try to get to as many as I can. I enjoy the product show and the CEO forums especially.

- If you weren't in the pharma/biotech industry, what other profession do you see yourself in?

I'm incredibly jealous of what Ken Burns does for a living. If I weren't doing this, I'd probably be getting him coffee.

- How do you balance the demands of your career and the needs of your family?

It's always a tightrope that everyone needs to walk. I'm fortunate to work for an organization that values its employees and their families as much out of the office as in it. This makes things much easier to balance.

- What advice would you give new graduates planning a career your field?

Don't be afraid to jump into the water; the people in this industry are incredibly nice and genuine. The competition is tough, but it's fair, and fun.

It's Time for You to Learn More and Earn More!
It's Time for Your Company to Benefit from Your Membership in ISPE!

How?

- Invest a day in one of ISPE's practical training programs held at your company.

Managers will like it!

- Practical, up-to-date information that can be applied immediately.
- Modular programs that facilitate customization, allowing you to focus on your specific needs.
- No travel time involved - your time is used to ultimate effectiveness.

Financial folks will like it!

- Costs are minimized - time, airfare, venue.
- Why pay for something you already have? Plus - your location is often better suited to your needs.

Trainees will enjoy it!

- Hassle-free training - no time wasted on extraneous travel activities.
- Industry experts provide a perspective different from in-house experts, helping to foster creative thinking and innovation.
- Training contributes to career advancement and financial rewards.

Here are some comments from those who have already benefited from these programs:

"He (the instructor) did a great job of being able to speak to all levels of employees, whether they had just started in the industry or have been in the industry for years."

"The customized program conducted by ISPE was a success for Shire HGT and we are looking forward to scheduling more training sessions."

Think your company might be interested? Give the Boston Area Chapter a call today at 781-647-4773 or email us at ispe@camihq.com to learn more about this timely, cost-effective training alternative.

Join a Committee - Have Fun & Make a Contribution to Your Chapter!

Make 2010 your year to take the plunge and join one of the Chapter's several committees. These committees are responsible for planning and implementing all of the Chapter's many activities and rely on the participation of Chapter members just like you for their success. Your contribution could be helping to plan a single event, making an ongoing contribution to the bimonthly eNewsletter or Chapter Web site, or contributing new ideas to expand Chapter membership. Plus you will develop new friendships and strengthen your professional network in the process. Follow this link [Amy - please insert] for more information on the committees and how to join, then take the plunge. You won't regret it!

Volunteer “STEM Ambassadors” Needed to Inspire Local Sixth Graders

The STEMTech Alliance has been formed by six of the region's industry organizations to help promote education in science, technology, engineering and math (STEM) through a school outreach program. This unique and exciting program, called DIGITS, is funded by the Massachusetts Department of Higher Education's STEM Pipeline Fund and is working in partnership with the Massachusetts Department of Elementary and Secondary Education.

Why is this program important? According to the STEMTech Alliance, Massachusetts is not graduating enough STEM-qualified students to continue its tradition of scientific and technological innovation and leadership. Science and technology companies need more students in the STEM pipeline to fill the jobs that are being created now and in the future. The STEMTech Alliance believes the best way to accomplish this is by working with schools to reinforce the importance of math and science education.

The DIGITS program will put a volunteer industry professional in each sixth grade classroom in Massachusetts. These volunteers or "STEM ambassadors" will tell the students about the jobs they do and

the industry they work in and how their education helped lead them there. The program was beta tested over the summer at 10 schools around the state, reaching 400 students. All of the students who were evaluated afterward expressed a greater interest in STEM fields.

Over the course of the 2009-10 academic year, STEM Ambassadors will visit schools by region, according to the following schedule:

- November - Central Massachusetts
- December - North Shore
- January and February - Greater Boston
- March - Southeastern Massachusetts and the Cape
- April - Pioneer Valley and the Berkshires

Being a STEM Ambassador means visiting one school and speaking to a minimum of two sixth grade math and/or science classes during the 2009-2010 school year. (Volunteers may, of course, choose to do more.) Each classroom visit takes approximately 40 minutes. Ideally, volunteers will be matched with a school that is close to where they live or work. The program provides training and materials for all volunteers, including best practices in presenting to sixth graders.

If you are interested in becoming a STEM Ambassador, please visit the following site to register as a volunteer: http://www.surveymonkey.com/s.aspx?sm=7ILQQ7ZoOsjBSn1pLCSX7A_3d_3d

For more information on DIGITS, please visit http://www.digits.us.com/ or contact project leaders Joyce Plotkin, Project Chair and President Emerita, Mass Technology Leadership Council, at joyce@masstlc.org or Susan Moulton, Project Director, at susankmoulton@hotmail.com.

Tech Talk: Implementing an Electronic Laboratory Notebook (ELN) System - A Case Study

by Richard Stember and Paul Kohler, LABTrack LLC

A paper lab notebook is the primary method of recording research. Researchers have used lab notebooks for hundreds of years to document their hypotheses, experiments and their interpretation of the results. The notebook serves as an organizational tool and can also be used to protect any intellectual property that comes from the research. One of the most widely known lab notebooks was that of Leonardo Da Vinci. Da Vinci, a thought leader of his time, employed methods that made his notebook unreadable to the casual viewer by using a reverse writing technique. His rationale for doing this is unknown but, coincidentally, these same issues of security and safety remain present today with paper lab notebooks.

Over the last decade software vendors have been developing solutions specifically focused on the automation and replacement of paper laboratory notebooks. As technology has advanced, the capabilities of these systems have developed to the point that they are now a viable alternative to using paper. Some of the benefits realized from implementing an electronic system include, but are not limited to, the following: backup, security, compliant electronic signature, collaboration and indexing. These benefits save time for the researcher and allow more time for doing science and less time annotating results.

Replacing paper notebooks can at first seem like a daunting task. While the rules for authoring a notebook are well understood, every scientist tends to work differently. It is easy to draw parallels to front office procedures where word processors and spreadsheets long ago replaced typewriters and ledgers. But science has its own set of rules, with professional and legal requirements that are quite different.

Scientists are trained to maintain notes in a fashion that allows for review and discovery. Deletion of data is not allowed but corrections are permitted and transparency is a must. Both the existence as well as the absence of data can be crucial, not only at the end of the experiment - but even years later. The notebooks themselves are considered legal documents that can be used as evidence in a court of law - even if the scientist is not available to testify.

To a business or research organization, the content of their lab notebooks is the "crown jewels" - the organization's intellectual property. The notebook is where ideas are captured which one day may be patented. In the United States, patents are awarded based upon "date of invention." Accordingly, making sure that each entry in the lab notebook is signed and dated is critical. Additionally, many organizations need an Electronic Lab Notebook (ELN) that supports collaboration, data mining and automated communications. Each of these requires a level of standardization for data entry, database schemas and terminology that goes well beyond paper-based systems.

To ensure success with the implementation of an ELN, many companies follow a structured evaluation and selection process. In its simplest form this process often consists of:

1. Documenting the user and corporate needs in a User Requirements Document (URD).
2. Surveying and evaluating ELN solutions available from vendors.
3. Evaluating the selected ELN solution with a pilot implementation.
4. Rolling out the ELN solution to the whole organization with a phased implementation plan.

Two organizations that recently evaluated and implemented ELN solutions are described below. While very different, these two organizations shared many of the same objectives that other labs identify for their ELN projects. Their successful implementations can serve as models for other labs looking to replace paper lab notebooks with an ELN system.

The US Veterans Administration - Cooperative Studies Program (CSP)

The Cooperative Studies Program Clinical Research Pharmacy Coordinating Center is run by the US Veterans Administration. The CSP conducts clinical trials and epidemiological research on diseases affecting US veterans. In 2007, the Quality Control Laboratory of the CSP, under the direction of Mr. Gary Eden, QC Lab Chemist, evaluated commercial ELNs.

The requirements for the ELN included ease of use, the need to create custom templates to support queries and data mining, and integration with the US government security infrastructure for wireless networking. The ELN needed to be a thin client application (browser-based) that aligned with the IT-supported platforms in place in the VA. It also needed to be validated to meet cGMP requirements of the US Food and Drug Administration.

The selected ELN was implemented and validated within two months time. Within four months of purchase the QC Laboratory was fully operational in a "paper-less" mode.

According to Gary Eden, the ELN implementation was very successful. He stated it "enabled our lab to be more cGMP compliant - having all our data and write-ups in one place and organized makes it easier for us to find information when we need it." When asked about the challenges posed by switching from paper, he added it was a "quick learning curve and easy to use in practice."

Regulus Therapeutics

Biotechnology is at the forefront of fighting many diseases today. And Regulus Therapeutics is right there on the front lines. Its mission is to discover, develop and commercialize micro-RNA based therapeutics.

In 2009, Regulus set out to replace all of its paper notebooks with an ELN. Like many companies in life science, their researchers use a variety of computers, including both Macs and Windows PCs. Although many requirements were defined and evaluated, a dual platform was a high priority for Regulus. The selected ELN would need to run in a browser and support the Windows and Mac Operating Systems, allowing the users to share notebooks and files seamlessly.

As Aimee Jackson, Director of Drug Discovery, recently wrote, "Regulus Therapeutics embraces leading edge technologies to improve efficiency and advance scientific discoveries. With the implementation of the ELN technology, we have realized enhanced communication through rapid, effective, and secure archiving and sharing of data and information. This enables us to spend more time doing research and less time tracking and retrieving information."

For both of these companies, the selected ELN proved to be a great productivity tool. Paper can be a large drag on the productivity of laboratories. ELNs provide almost instant access to all of the laboratory-generated data when it is needed and where it is needed. Searching and retrieving notes and files is much faster than with paper-based systems.

Communications can also be greatly improved by an ELN system. No scientist works in an isolated environment. Laboratory work needs to be witnessed, approved and communicated to others. In both of these case studies, the ELN user discovered many benefits from the built-in communications functions of the ELN software.

Selecting the right ELN is not hard and it doesn't have to be complicated. The key to success is clearly defining your organization's and your users' requirements. Choosing a system that best meets those requirements can be done by surveying the market place and thoroughly evaluating the choices.

To summarize, ELNs offer many benefits. They save time and money as researchers can spend more time doing science and less time annotating results. Additionally, organizations benefit from the convenience of the communication and collaboration tools and have the peace of mind that comes with knowing their intellectual property is safe. Finally, ELNs are a bargain when compared to paper. The investment need not be large and the return on investment is quick and substantial. And most telling of all: if you were to ask an ELN user if they would switch back to paper, most would quickly say, "Not without a fight!"

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Paul Kohler has worked in the life sciences industry for over 20 years. In 2004, Paul started working with LABTrack in a business development role. Currently Paul works as a sales representative for LABTrack covering the east coast. Paul holds a BS in Computer Science from Elizabethtown College and an MBA from Lebanon Valley College. Paul has been active in ISPE for the last 6 years. He has held Board positions in the Delaware Valley Chapter and has been an active member of the Boston Area Chapter Communications Committee. Paul can be reached at paul@labtrack.com.

Industry News In Brief

by Patti Charek, RF Walsh Collaborative Partners

Helicos No Longer Pondering a Sale

Helicos BioSciences, a genetic analysis instrument company, has taken itself off the auction block. In September, the company said it had hired Thomas Weisel Partners to evaluate strategic alternatives. Those options ranged from an outright sale to options such as joint ventures or partnerships with other gene-sequencing companies. "Based on the company's improving standalone prospects and its current market valuation, the board of directors has decided to disengage from discussions involving a potential sale of the company at the current time," Helicos said. "We are seeing a growing number of novel discoveries resulting from the Helicos Genetic Analysis System's unique capabilities and have seen an increased interest in clinical applications for which the Helicos system is uniquely suited," chief executive Ron Lowy said. (Source: Boston Globe, 11 November 2009)

California Firm Agrees to Acquire Biotrove

BioTrove, a Woburn maker of biological research tools that in December 2008 canceled plans for an initial public offering, has agreed to be acquired by a California company for an undisclosed sum. Life Technologies, a publicly traded, life sciences company based in Carlsbad, California, said it signed a definitive agreement to buy BioTrove, which makes a genotyping analysis system used by genetics researchers. BioTrove, a venture-backed start-up, was one of the first companies funded by Excel Venture Management, a two-year-old Boston partnership focusing on health care, life sciences, and medical technology. The venture capital firm has raised $125 million for its first investment vehicle, called Excel Medical fund. (Source: Robert Weisman, Boston Globe, 11 November 2009)

Genzyme Gives Up on Phosphate Drug

Genzyme said it will abandon development of a drug to lower phosphorus levels in the blood after the medicine failed to work better than a current product. The advanced phosphate binder "did not show a significant improvement" in a study comparing the product with Genzyme's Renvela. The new product was better than a placebo, meeting the primary goal of a 349-person trial in the final stages of testing that is usually required for US approval.

The drug was designed to be a more potent version of Renvela, approved in 2007 to control phosphorus levels in patients with chronic kidney disease. Renvela and an older version called Renagel account for about 17% of the company's revenue but begin to lose patent protection within five years. "This product was supposed to replace the Renvela blockbuster franchise when it could face generics," said Michael Yee, an analyst at RBC Capital Markets in San Francisco, in a note to clients. (Source: Bloomberg News, 19 November 2009)

BioVex Raises Additional $30 Million

BioVex, a Woburn biotechnology company that raised $40 million in venture capital in March 2009 to develop a novel cancer-fighting treatment, will disclose it has raised another $30 million. The funding rounds together represent the second-largest venture investment in a US biotechnology company in 2009, according to data from the National Venture Capital Association. The largest outlay, $145 million, went in May to Clovis Oncology, a Boulder, Colorado start-up.

Unlike the BioVex financing in March, which came from existing investors, the latest round comes from a consortium of new investors, led by a pair of Boston venture capital firms, MVM Life Science Partners and Morningside Venture. BioVex will use the funds to complete an ongoing late-stage clinical study of its drug, OncoVex, to treat recurrent and metastatic melanoma, said Philip Astley-Sparke, the company's chief executive. Astley-Sparke said BioVex expects to finish the study at the end of 2010. If the results are positive, Biovex will file a biologic license application with the FDA in 2011, Astley-Sparke said. "We now have sufficient capital to complete the clinical program," he said in an interview. "If the results are successful, this would be the first commercial product using a virus to treat cancer, so it really could be a medical milestone."

The company is among a small group of biotechs working on oncolytic drugs - a new class of treatments that use viruses engineered to replicate and destroy tumor tissue without harming healthy tissue, partly by stimulating the immune system. Although melanoma is the first indication for BioVex's drug, the company hopes to later apply it to treating head and neck cancer.

Steve Reeders, the MVM Life Sciences managing partner who will join the board of BioVex, said his firm has been monitoring its progress for more than a decade and believes oncolytic drugs could become the largest class of cancer treatments. "This could have general application for a whole range of cancers where we know there is some surveillance by the immune system," Reeders said. "We've believed for a very long time that generating an immune response could be one of the more effective ways to treat cancer because the side effects will be so few." In current treatments, he said, side effects often prevent physicians from increasing doses to the most effective levels.

Astley-Sparke said the company, which has about 50 employees in Woburn and 25 at an Oxford research lab in England, may try again to go public or strike a partnership with a larger drug maker to market OncoVex once the treatment is approved. (Source: Robert Weisman, Boston Globe, 10 November 2009)

Pfizer Deal Poses Challenge to Genzyme

Drug giant Pfizer, mounting a direct challenge to Genzyme, said it will spend up to $110 million to license the global rights to a treatment being developed for the rare genetic disorder Gaucher disease. Pfizer's alliance with Israeli biotechnology start-up Protalix BioTherapeutics to eventually sell the drug, which is based on plant cell technology, takes aim at Genzyme's top-selling product, Cerezyme, which also treats Gaucher disease. The disorder is an enzyme deficiency that can result in bleeding, bone weakness, and enlargement of the liver and spleen, and afflicts about 5,700 people worldwide.

Genzyme, which charges about $200,000 per patient annually for Cerezyme, had to suspend production and ration delivery of the treatment to thousands of patients over the summer after finding a virus in a bioreactor at its Allston Landing plant where the drug is made. The company has since begun shipping vials of newly produced Cerezyme.

Beyond the licensing deal unveiled, Pfizer said it wants to use its partnership with Protalix as a template to move into the lucrative market of treating rare diseases - a strategic decision made last year. The deal with Protalix is its first initiative in that area. Pfizer chief executive Jeff Kindler called the Protalix deal "the first of many that we're trying to meet unmet medical needs in a way we haven't done before." Kindler said the push into rare diseases is being led by one of the smaller divisions it created to make the company more entrepreneurial.

Pfizer is especially interested in the novel technology behind Protalix's drug for Gaucher disease, which is derived from genetically engineered carrot cells. Genzyme, by contrast, makes Cerezyme from genetically modified hamster cells. Protalix's drug, called taliglucerase alfa, is the first of what its executives hope will be a pipeline of drugs similarly based on plant cells. The company believes such products would be cheaper to make, potentially enabling Protalix to gain market share by underpricing drugs such as Cerezyme.

David Aviezer, president and chief executive of Protalix, said the company plans to file a new drug application with the FDA later this month that, if approved, would allow it to market taliglucerase alfa as a rival to Cerezyme in the US. "We were basically a research and development company, and were seeking the best company to help us market this product," Aviezer said. "This partnership with Pfizer gives us validation and will generate revenue that will help us develop additional products." Under the licensing deal, Pfizer will make a $60 million upfront payment to Protalix and additional payments of as much as $55 million if the drug program meets certain milestones. Pfizer also agreed to pay 60 percent of the cost of marketing the new drug.

Analysts said taliglucerase alfa and another drug for Gaucher disease, Shire's velaglucerase alfa, are likely

to be approved by regulators and begin competing with Cerezyme in the US in 2010. *(Source: Robert Weisman, Boston Globe, 2 December 2009)*

Cubist Acquires California Drug Maker Calixa Therapeutics

Cubist Pharmaceuticals, a leading acute care therapeutics company, has completed its acquisition of Calixa Therapeutics, a biopharmaceutical company focused on the development of novel antibiotics that address the expanding problem of multi-drug resistant Gram-negative pathogens.

Calixa's lead compound, CXA-201 is an intravenously administered combination of Calixa's novel anti-pseudomonal cephalosporin CXA-101, which is currently in Phase 2 clinical trials for cUTI, and the b-lactamase inhibitor tazobactam. CXA-201 is being developed as a first-line intravenous therapy for the treatment of certain serious Gram-negative bacterial infections in the hospital, including those caused by multi-drug resistant Pseudomonas aeruginosa. Its demonstrated potency against P. aeruginosa would give CXA-201 a highly differentiated profile versus marketed antibiotics.

Cubist President and CEO Michael Bonney said, "We are excited about the opportunity to add CXA-201 to our clinical pipeline. If successfully developed and launched, we believe that CXA-201 would be a potent weapon in the treatment of serious infections caused by multi-drug-resistant strains of the Gram negative pathogen Pseudomonas aeruginosa, playing a role similar to our Gram positive therapy Cubicin (daptomycin for injection) for the treatment of complicated skin infections and bacteremia caused by MRSA. We believe Cubist is ideally positioned to develop and commercialize this novel antibiotic that, assuming success, will provide physicians with a critically needed new weapon to treat certain serious infections caused by multi-drug-resistant Gram-negative pathogens, including those caused by Pseudomonas aeruginosa."

On closing, Cubist is to pay to the Calixa stockholders $92.5 million in cash, subject to certain adjustments, and Calixa would become a wholly-owned subsidiary of Cubist. Cubist also would be required to make potential payments to the Calixa stockholders of up to $310 million upon achieving certain development, regulatory, and commercial milestones related to products which incorporate CXA-101. No financing would be necessary to complete the acquisition of Calixa or to fund the development of Calixa's product candidates. (Source: Cubist Pharmaceuticals website, 14 & 16 November, 2009)

Epizyme Secures More Funding

Epizyme, a Cambridge biopharmaceutical company that snagged a $32 million venture capital funding round in October 2009, led by San Francisco's Bay City Capital, has added another $8 million in financing and closed on a $40 million round. The new participant in the financing is New Enterprise Associates, a venture firm in Menlo Park, California. Its general partner, David M. Mott, will join the Epizyme board of directors.

Epizyme, which employs 16 people in Cambridge, is developing drugs to treat cancers and other diseases through gene regulation. It is one of a handful of companies, including another Cambridge biotech, Constellation Pharmaceuticals, that is working in the emerging field of epigenetics, which seeks to control how genes are read by the molecules that convert them into proteins.

In 2008, Epizyme received its $14 million first round of funding from venture capital firms MPM Capital of Boston and Kleiner Perkins Caufield and Byers of Menlo Park. Other firms taking part in its new funding round are Amgen Ventures of Thousand Oaks, California, and Astellas Venture of Los Altos, California. *(Source: Robert Weisman, Boston Globe, 9 December 2009)*

Genzyme Names Leaders in Key Areas

Genzyme said it has tapped senior executives from major pharmaceutical and biotechnology companies to strengthen its leadership ranks in regulatory and clinical affairs and other areas. The company also said its

board of directors has appointed a new member, Robert Bertolini, who was chief financial officer at drug maker Schering-Plough before it was bought by Merck & Co.

In a rare letter to shareholders, Genzyme chief executive Henri A. Termeer outlined steps the company has taken to regain its footing in what he called the most challenging year in the company's history. They ranged from putting up safeguards to prevent a viral contamination, such as the one found at its Allston plant this past June, to expanding its production capacity in Framingham and Ireland.

Termeer said Genzyme also hired Pamela Williamson from Serono to be Genzyme's senior vice president and head of regulatory affairs and corporate quality compliance; Ulrich Goldmann from Novartis to be Genzyme's senior vice president of global medical affairs; Andrew Lee from Pfizer to be senior vice president of clinical research; and Michael Panzara from Biogen Idec to be Genzyme's therapeutic area head and group vice president for multiple sclerosis and immune diseases. *(Source: Robert Weisman, Boston Globe, 11 December 2009)*

Cubist Stops Drug Trials After Deaths

Cubist Pharmaceuticals Inc. said that it stopped enrolling patients in trials of a drug intended to reduce bleeding during heart surgery because of deaths among patients who took it. Cubist said a data monitoring board wants to assess the difference between patients on the drug and those who were on an alternative treatment. The rate of deaths in the studies was consistent with expected outcomes, and the causes of death were typical for a group of patients at high risk for bleeding during cardiac surgery, Cubist said. The monitors suggested Cubist suspend enrollment in a study that compared the experimental drug with Cyklokapron, a drug approved in Europe to control bleeding. Cubist decided to stop enrolling patients in that study and in a second study that compared its drug with a placebo. (Source: Associated Press, 4 December 2009)

Dyax Wins FDA Approval for Treatment for Hereditary Angioedema

Cambridge biotech Dyax has announced that the FDA has granted approval for Kalbitor (ecallantide) for the treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older. HAE is a rare, genetic disorder characterized by severe, debilitating and often painful swelling, which can occur in the abdomen, face, hands, feet and airway. Kalbitor is a potent, selective and reversible plasma kallikrein inhibitor discovered and developed by Dyax. It is the first subcutaneous HAE treatment approved in the US.

As part of product approval, Dyax has, together with the FDA, established a Risk Evaluation and Mitigation Strategy (REMS) program to communicate the risk of anaphylaxis and the importance of distinguishing between a hypersensitivity reaction and HAE attack symptoms.

"The approval of KALBITOR represents an important milestone in our ongoing commitment to the HAE community," said Gustav A. Christensen, President and Chief Executive Officer of Dyax. "Furthermore, bringing Kalbitor to market validates our mission to discover, develop, and commercialize innovative biopharmaceuticals for unmet medical needs."

HAE attacks, which occur on average more than 20 times yearly, are unpredictable and range in progression and severity. An acute episode may occur in one or more anatomical sites, sometimes moving from one site to another. "HAE is a highly unpredictable disease because most attacks occur spontaneously with no identifiable trigger. Kalbitor will provide patients...with an FDA-approved subcutaneous therapy for treating painful and debilitating HAE acute attacks," stated Anthony J. Castaldo, President of the United States Hereditary Angioedema Association (HAEA), a nonprofit patient advocacy organization that represents approximately 6,500 HAE patients in the United States. (Source: Dyax website, 1 December, 2009)

French Biotech Opens Subsidiary in Massachusetts

Cytoo Cell Architects, a French biotech company focused on analysis and cell screening, became the third European life sciences company to set up shop in Massachusetts in the past two months. Based in Grenoble, France, Cytoo initially will employ four workers at its new US subsidiary in Framingham but plans to eventually expand. The operation will serve US researchers.

Other foreign biotechnology companies have been drawn to the state, in part because of the Massachusetts Life Science Initiative aimed at strengthening the industry, said Lieutenant Governor Timothy Murray, who attended a Framingham ceremony officially opening the Cytoo headquarters. Biocell Center of Italy, a company that harvests and preserves stem cells, opened its North American headquarters in Medford in October 2009. And in November, Systagenix Wound Management, a British company specializing in the care of chronic wounds, established its headquarters for North, South, and Central America in Quincy. (Source: Robert Weisman, Boston Globe, 12 December 2009)

Genzyme Plans to Boost Lumizyme Production

Genzyme said it has scrapped its application to produce Lumizyme, a drug to treat the rare genetic disorder Pompe disease, in midsize bioreactors and instead will pursue a new pathway toward making the drug on a larger scale. After inspectors from the FDA identified nearly 50 deficiencies at Genzyme's manufacturing plant in Boston in November, including foreign particle contamination, the agency said it was delaying approval of the Lumizyme application until the company corrected the persistent production problems. But even as it works to respond to the inspectors' findings and fix the problems at its Allston Landing plant, Genzyme said the FDA now has agreed to let it apply to make Lumizyme in 4,000-liter vats, which had been the company's ultimate aim. Previously, the agency had required approval for smaller-scale production - 2,000-liter batches - as a first step.

Genzyme said it would expand a temporary access program that gives adults suffering from Pompe disease doses of Lumizyme shipped from Europe, where the drug already is approved for adults. Adult patients use the drug, called Myozyme, outside the US. in more than 40 countries. Pompe disease interferes with muscle development and causes severe respiratory problems. A Genzyme spokesperson said about 170 adults are treated under the US temporary access program, while another 50 to 150 are on a waiting list to get the drug once it is approved for adults. Now, most of those on the waiting list will be able to take the treatment before it is approved. (Source: Robert Weisman, Boston Globe, 4 December 2009)

Local Biotechs Continue Merger Moves

Gloucester Pharmaceuticals, which in November won FDA approval to market its first drug in the US, said it has agreed to be acquired by publicly traded Celgene, a biopharmaceutical company based in Summit, New Jersey, for $340 million in cash plus up to $300 million in future milestone payments. In a second deal, Merrimack Pharmaceuticals, which is developing treatments for cancer and autoimmune disease, said it bought Hermes Biosciences based in South San Francisco, California, another privately owned firm, for an undisclosed sum.

These deals underscore a recent pickup in biotechnology business activity. Ninety merger and acquisition transactions involving US biotechs were unveiled in 2009, compared with 84 in 2008, according to the Thomson Reuters research firm. "You're seeing more investment in, and acquisition of, the small biotech companies," said Robert Coughlin, president of the Massachusetts Biotechnology Council.

The acquisition of Gloucester Pharmaceuticals will mean a payout for the venture capital firms that backed the six-year-old Cambridge start-up. Gloucester's most recent round of funding, in August, raised $29 million from five firms, including Apple Tree Partners of Cambridge. In November, the FDA approved Gloucester's Istodax, which treats a rare cancer known as cutaneous T-cell lymphoma. Gloucester, which has 15 full-time employees, used consultants to manage clinical development of the drug. It considered bringing Istodax to market itself but ultimately struck the deal with Celgene, said Alan Colowick, Gloucester's chief executive.

Merrimack Pharmaceuticals, an 11-year-old company with about 130 employees in Cambridge, bought Hermes Biosciences to acquire its drug delivery technology, said Merrimack chief executive Robert Mulroy. "It is totally a technology play," he said. Hermes develops lipidic nanocarriers that can deliver drugs directly to cells. That is a valuable tool for Merrimack, which has two cancer drugs in clinical trials and a pipeline of compounds in earlier stages of development. Mulroy said most of Hermes's seven employees have agreed to move to the Boston area. "It's not huge in scale, but it's very important to us," Mulroy said of the Hermes purchase. "We'll be able to attach antibodies to their nanocarriers so they can target cancer cells." (Source: Robert Weisman, Boston Globe, 8 December 2009)

Infinity Pharmaceuticals Names CEO

Cambridge biotech Infinity Pharmaceuticals, a nine-year-old company developing drugs to treat cancer and related conditions, has named Adelene Q. Perkins its chief executive. Perkins, currently president and chief business officer, will move into the new position on January 1st, when she will also join Infinity's board of directors. The company's founder and current chief executive, Steven H. Holtzman, will continue to work full time as executive chairman of the board, Infinity said. After starting her career at the consulting firm Bain & Company, Perkins worked for the Genetics Institute and TransForm Pharmaceuticals. (Source: Robert Weisman, Boston Globe, 8 December 2009)

AstraZeneca and Targacept Collaborate on Treatment for Major Depressive Disorder

AstraZeneca and Targacept have announced a collaboration and license agreement for the global development and commercialisation of TC-5214, Targacept's late-stage investigational product for major depressive disorder (MDD). TC-5214, which recently completed a phase IIb clinical trial, is a nicotinic channel blocker that is thought to treat depression by modulating the activity of various neuronal nicotinic receptor (NNR) subtypes.

Major Depressive Disorder is a common illness, affecting approximately 42 million people worldwide, and the global antidepressant market is valued at over $20 billion. Serotonin reuptake inhibitors (SSRIs) are the most commonly prescribed class of drugs for depression but many patients fail to respond adequately.

Under the new agreement, AstraZeneca will make an upfront payment to Targacept of $200 million upon effectiveness and up to an additional $540 million if specified development, regulatory and first commercial sale milestones are achieved. Targacept will also be eligible to receive up to $500 million if specified sales-related milestones are achieved, as well as significant stepped double-digit royalties on net sales worldwide. Targacept has retained an option for a co-promotion of TC-5214 to a limited target physician audience in the US.

AstraZeneca and Targacept will jointly design a global phase III clinical program anticipated to begin in mid-2010 with the goal of filing a new drug application (NDA) with the FDA in 2012. TC-5214 is being developed as an adjunct to antidepressant therapy in adults with MDD who do not respond adequately to first-line antidepressant treatment. The companies will also initiate a phase II study exploring TC-5214 as a monotherapy for MDD.

AstraZeneca will be responsible for 80 percent of the cost of the initial global development program, with Targacept responsible for the remaining 20 percent. AstraZeneca will be responsible for and will fund the costs of global commercialization of TC-5214, and will assume Targacept's manufacturing and supply agreements with third parties in relation to TC-5214. The agreement also provides for a specified period for the parties to negotiate a potential multi-year research program that would be conducted by Targacept to identify and develop additional NNR Therapeutics for MDD and possibly other indications.

Targacept and AstraZeneca previously entered into a global collaboration focused on cognitive disorders in 2005. Three product candidates in the collaboration are currently in clinical development; including AZD3480 for attention deficit/hyperactivity disorder (ADHD), AZD1446 planned for Alzheimer's disease, and

TC-5619, for cognitive dysfunction in schizophrenia. (Source: AstraZeneca website, 3 December 2009)

Johnson & Johnson Workforce to Shrink by 8,000

Johnson & Johnson said it will cut up to about 8,000 jobs and streamline its operations in an effort to cut costs as it braces for changes in the health care industry. The New Brunswick, New Jersey company said the cuts will affect 6 to 7 percent of its global workforce of roughly 118,700 workers.

J&J owns two companies in Massachusetts: Transform Pharmaceuticals in Lexington and Codman & Shurtleff, a Raynham company that develops and markets diagnostic and therapeutic products for the treatment of central nervous system disorders. The restructuring is one of J&J's biggest ever and will prompt a restructuring charge of up to $1.3 billion pretax in the fourth quarter. J&J plans to simplify its business structure and projects that it will save between $800 million and $900 million in 2010 and $1.4 billion and $1.7 billion annually after the restructuring is complete in 2011.

The company, the world's most diversified health-products maker, saw its revenue fall 5 percent in the third quarter of 2009 as intensifying generic competition slashed sales of about a half-dozen of its prescription drugs, including the schizophrenia drug Risperdal and the epilepsy treatment Topamax. Chairman and chief executive William C. Weldon said the moves are meant to position the company for long-term growth. (Source: Damian J. Troise, Associated Press, 4 November 2009)

Alkermes to Invest $10M in Acceleron

Cambridge biotech Alkermes said it will invest $10 million to license the rights to a drug technology developed by Acceleron Pharma and also take an equity stake in the small Cambridge biotech. In a filing with regulators, Alkermes, which makes drugs to treat alcoholism and other afflictions, said it was making a $2 million up-front payment and an additional $8 million investment in Acceleron, a venture-backed start-up developing treatments for musculoskeletal and metabolic diseases, and cancer. (Source: Robert Weisman, Boston Globe Staff, 4 December 2009)

Regulatory & Legislative Highlights

By Deepen Joshi, Sepracor

FDA Approves New GlaxoSmithKline Vaccine for Prevention of Cervical Cancer

The FDA has approved Cervarix, manufactured by GlaxoSmithKline Biologicals based in the United Kingdom, for use in girls and women ages 10 through 25. The new vaccine prevents cervical cancer and precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. Genital HPV infections are the most common sexually-transmitted diseases in the US and HPV types 16 and 18 are the cause of about 70 percent of cervical cancers worldwide. There will be an estimated 11,270 new cases and 4,070 deaths from cervical cancer in the US during 2009, according to the National Cancer Institute at the National Institutes of Health.

Cervarix is administered in three separate shots, with the initial dose being followed by two additional shots at one and six months. No vaccine is 100 percent effective, and Cervarix does not protect against HPV infections that an individual may already have at the time of vaccination, nor does Cervarix necessarily protect against those HPV types not in the vaccine. Therefore, regular Pap tests continue to be recommended for all women who receive Cervarix. (Source: FDA Website, 16 October, 2009)

FDA Approves GlaxoSmithKline Seasonal Flu Vaccine Fluarix for Pediatric Use

The FDA has approved use of the seasonal influenza vaccine Fluarix manufactured by GlaxoSmithKline Biologicals of Dresden, Germany for children ages 3 to 17. Previously, this vaccine, which contains

inactivated (killed) influenza A and B viruses, had been approved for use in adults, ages 18 and older.

Influenza is far more dangerous than the common cold for children, who often require medical care, especially if they are younger than 5. It is best to vaccinate children each fall, but vaccination also can occur in the winter months when influenza season often peaks. Common adverse events experienced after administration of Fluarix are typical of those for flu shots and include pain, redness, and swelling at the injection site as well as irritability, loss of appetite, and drowsiness. Because Fluarix contains a small amount of egg protein, it should not be administered to anyone allergic to eggs or egg products. (Source: FDA Website, 19 October, 2009)

FDA Approves GlaxoSmithKline Votrient for Advanced Form of Kidney Cancer

The FDA has approved Votrient (pazopanib), the sixth drug to be approved for kidney cancer since 2005. Votrient is an oral medication that interferes with angiogenesis, the growth of new blood vessels needed for solid tumors to grow and survive.

The safety and effectiveness of Votrient was evaluated in a 435-patient study that examined a patient's progression-free survival - the length of time before the tumor began growing again or before the patient died. Progression-free survival averaged 9.2 months for patients receiving Votrient compared to 4.2 months for patients who did not receive the drug. Votrient is manufactured by London-based GlaxoSmithKline. (Source: FDA Website, 19 October, 2009)

FDA Authorizes Emergency Use of Antiviral Peramivir for 2009 H1N1 Influenza

The FDA has announced that, in response to a request from the CDC, it has issued an emergency use authorization (EUA) for the investigational antiviral drug peramivir intravenous in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. There are no FDA-approved intravenously administered antivirals for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

Specifically, IV peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons: the patient is not responding to either oral or inhaled antiviral therapy; drug delivery by a route other than an intravenous is not expected to be dependable or feasible; for adults only, when the clinician judges IV therapy is appropriate due to other circumstances. (Source: FDA Website, 23 October, 2009)

FDA Approves New Treatment for Chronic Lymphocytic Leukemia

The FDA approved Arzerra (ofatumumab) for patients with chronic lymphocytic leukemia (CLL), a slowly progressing cancer of the blood and bone marrow. Arzerra, manufactured by London-based GlaxoSmithKline, is approved for patients with CLL whose cancer is no longer being controlled by other forms of chemotherapy. Arzerra is a monoclonal antibody and binds to a specific protein found on the surface of both normal and malignant B cells, making the cells more susceptible to immune system attack.

The product was approved under the FDA's accelerated approval process, which allows earlier approval of drugs that meet unmet medical needs. Products may receive accelerated approval based on a surrogate endpoint, such as a reduction in the size of the tumor or decrease in the number of cancerous white cells or in an enlarged spleen or lymph nodes. These indirect measures for clinical outcomes are considered reasonably likely to predict that the drug will allow patients to live longer or with fewer side effects of a disease. (Source: FDA Website, 26 October, 2009)

FDA and WebMD Expand Consumer Health Information Partnership

The FDA and WebMD Health Corp have announced an expansion of their partnership to provide increased

access to FDA's consumer health information. This second phase of the partnership includes expanded content and multimedia tools at www.webmd.com/fda. WebMD is personalizing FDA health information for consumers with five new online FDA sections that will initially focus on allergies and asthma, children's health, diabetes, heart health and vitamins and supplements.

Launched in December 2008, this joint effort has already proven effective in reaching consumers with important safety information. The FDA's information is also located within WebMD's homepage, http://www.webmd.com/, WebMD Health News, WebMD Health Search, RSS feeds, and targeted WebMD Newsletters and Special Reports. Since the launch, over 150,000 consumers have accessed the FDA destination on WebMD for health and wellness information on issues ranging from egg safety to contact lens safety to medicine safety. The FDA's consumer information is also available through *WebMD the Magazine*, distributed ten times a year and reaching an additional 11 million consumers with each issue. (Source: FDA Website, 29 October, 2009)

FDA Publishes Guidance on Diagnostic Tests for 2009 H1N1 Influenza Virus

The FDA has published a guidance document that should help manufacturers develop diagnostic tests for the 2009 H1N1 influenza virus. Although there are no FDA-approved or cleared tests that diagnose this specific infection, during this pandemic, manufacturers can submit a request to the FDA for an Emergency Use Authorization (EUA). The EUA authority is part of Project BioShield, which became law in July 2004. If granted, the EUA will allow the test to be used during the national public health emergency declared by HHS in April. The guidance document outlines what information the FDA recommends that manufacturers include in these EUA requests.

While the FDA encourages manufacturers to submit appropriate premarket applications for these tests, the agency also recognizes that it may not be possible to generate complete clinical validation data that would normally be included in an application. However, the guidance outlines information the FDA recommends be included, and the FDA gives these requests thorough and careful review to protect the public health. The guidance document is part of the FDA's ongoing efforts to provide public health authorities managing the pandemic with reliable and accessible diagnostic tests. (Source: FDA Website, 2 November, 2009)

FDA Transparency Task Force Holds Second Public Meeting

The FDA sought comments on three specific issues related to transparency at the agency during a daylong public meeting held on November 3, 2009. The purpose of the meeting was to receive detailed comments on the following three specific issues related to transparency at the FDA:

- Early communication about emerging safety issues concerning FDA-regulated products
- Disclosure of information about product applications that are abandoned, i.e., no work is being done or will be undertaken to have the application approved, or withdrawn by the applicant before approval
- Communication of agency decisions about pending product applications.

The FDA formed an internal Transparency Task Force in response to the Obama Administration's commitment to achieve "an unprecedented level of openness in Government." The Task Force is developing recommendations for making useful and understandable information about FDA activities and decision-making more readily available in a timely manner and in a user-friendly format, while appropriately protecting confidential information. The task force held its first daylong meeting in June 2009. (Source: FDA Website, 2 November, 2009)

FDA and Everyday Health Collaborate to Expand Reach of Consumer Health Info

The FDA and Everyday Health have announced a collaboration that will expand the delivery of the agency's

vital consumer health information to the 30 million unique users who visit Everyday Health each month. This joint effort reflects FDA's emphasis on using innovative, technology-based strategies to carry out its mission of protecting and promoting the public health. The partnership will initially include: a new online resource at www.EverydayHealth.com/FDA and a new FDA/Everyday Health co-branded weekly newsletter. (Source: FDA Website, 17 November, 2009)

FDA Approves New Treatment for Long-Term Pain Relief after Shingles Attacks

The FDA has approved Qutenza (capsaicin) 8% patch, a medicated skin patch that relieves the pain of post-herpetic neuralgia (PHN), a serious complication that can occur after a bout with shingles.

Shingles is an outbreak of rash or blisters on the skin that is caused by the same virus that causes chickenpox - the varicella-zoster virus. Anyone who once had chickenpox is at risk of shingles since the virus may become reactivated years after the initial infection. PHN is a condition affecting nerve fibers and the skin that can cause excruciating pain for weeks, months or even years. About 10 to 15 percent of patients who have shingles experience PHN and the complication is even more common in elderly patients.

Qutenza must be applied to the skin by a health care professional since placement of the patch can be quite painful, requiring use of a local topical anesthetic, as well as additional pain relief such as ice or use of opioid pain relievers. The patient must also be monitored for at least one hour since there is a risk of a significant rise in blood pressure following patch placement. The patch is manufactured by Lohmann Therapie-Systems AD of Andernach, Germany and distributed by NeurogesX Inc. of San Mateo, California. (Source: FDA Website, 17 November, 2009)

FDA Announces New Warning on Bristol-Myers Squibb Plavix

Patients should avoid using the stomach acid reducer Prilosec/Prilosec OTC (omeprazole) with the anti-clotting drug Plavix (clopidogrel), the FDA has warned. New data suggest that when patients take both Prilosec and Plavix, Plavix's ability to block platelet aggregation (anti-clotting effect) may be reduced by about half.

Plavix is used to prevent blood clots that could lead to heart attacks or strokes in at-risk patients. Omeprazole, the active ingredient of Prilosec and Prilosec OTC, is a proton pump inhibitor (PPI) used to reduce the production of stomach acid and prevent stomach irritation. Plavix does not have anti-clotting effects until it is converted or metabolized into its active form with the help of the liver enzyme, CYP2C19. Prilosec blocks this enzyme, thereby reducing the effectiveness of Plavix.

Patients who take Plavix and need to take a drug to reduce stomach acid should discuss their therapy with a health care professional. Zantac (ranitidine), Pepcid (famotidine), Axid (nizatidine), and antacids do not inhibit the CYP2C19 enzyme and aren't expected to interfere with the anti-clotting activity of Plavix.

Plavix's manufacturers have agreed to continue conducting studies to explore this and other drug interactions. When the FDA has reviewed additional data, the agency will communicate any new recommendations or conclusions. (Source: FDA Website, 18 November, 2009)

FDA Approves Novartis Agriflu Seasonal Flu Vaccine

The FDA has approved Agriflu for people ages 18 years and older to prevent disease caused by influenza virus subtypes A and B. Agriflu, manufactured by Novartis Vaccines and Diagnostics in Siena, Italy, was approved using the FDA's accelerated approval pathway, which helps safe and effective medical products for serious or life-threatening diseases become available sooner. In this case, Novartis demonstrated that the vaccine induced levels of antibodies in the blood likely to be effective in preventing seasonal influenza. Novartis is required to conduct further studies to verify that the vaccine will decrease seasonal influenza disease after vaccination. Agriflu is not intended to protect against the 2009 H1N1 influenza. Novartis also manufactures another licensed seasonal influenza vaccine, Fluvirin, for use in the US for people ages 4 and

older. (Source: FDA Website, 27 November, 2009)

First Human Embryonic Stem Cell Lines Approved for Use under New NIH Guidelines

The NIH has announced the approval of the first 13 human embryonic stem cell (hESC) lines for use in NIH-funded research under the NIH Guidelines for Human Stem Cell Research adopted in July 2009. Boston's Children's Hospital developed 11 of the approved lines and Rockefeller University in New York City developed two of the approved lines. An additional 96 lines have been submitted to NIH for either internal administrative review or consideration by the external Working Group for Human Embryonic Stem Cell Eligibility Review and the NIH Advisory Committee to the Director (ACD). The working group provides findings to the ACD, which makes recommendations to the NIH Director, who decides whether the hESCs may be used in NIH-funded research and lists those deemed eligible on the NIH Human Embryonic Stem Cell Registry.

Research using hESCs is already yielding information about the complex events that occur during human development. Researchers hope that eventually cells differentiated from hESCs may be used to treat a myriad of diseases, conditions, and disabilities and to test the safety of new drugs in the laboratory.

On March 9, 2009, President Obama issued Executive Order 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The executive order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

The NIH Guidelines for Human Stem Cell Research were published on July 7, 2009, and are available at http://stemcells.nih.gov/policy/2009guidelines.htm. The guidelines implement the executive order, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

More than 30 NIH grants funded in the 2009 fiscal year totaling more than $20 million proposed to use hESCs; these grants have been restricted until approved lines became available on the NIH registry. With this announcement and following NIH approval, these principal investigators may obtain registry-listed hESCs, if they are appropriate for their project, from the owners of the lines and proceed with their research. This group of grants includes research using hESCs for the therapeutic regeneration of diseased or damaged heart muscle cells, developing systems for the production of neural stem cells and different types of neurons from hESCs in culture, and developing a cell culture system for the large scale production and self-renewal of hESCs.

In addition, a number of Challenge Grant applications, which could be funded through the American Recovery and Reinvestment Act in the 2010 fiscal year, proposed to use hESCs. Researchers examining other topics that could benefit from the use of hESCs are encouraged to apply for funding using these approved lines.

The NIH Human Embryonic Stem Cell Registry of approved hESCs is found at http://grants.nih.gov/stem_cells/registry/current.htm. For additional information on stem cells and NIH research, go to http://stemcells.nih.gov/. (Source: NIH Website, 1 December, 2009)

FDA Expands Presence Outside US with Mexico City Post

As part of its continuing effort to buttress food and medical product safety in this country by working with its regulatory partners overseas, the FDA has announced the opening of its Mexico City post. This is the Agency's third post in Latin America and its tenth international post in the past 13 months. Staff assigned to the FDA's Mexico City post will work with their counterparts in the Mexican government to harmonize regulations and guidance standards and to work on other collaborative initiatives.

FDA staff will offer collaboration on the use of the latest laboratory techniques, foster other collaborative initiatives to ensure the safety of food and medical products marketed in the two countries, and be a "portal" to the FDA for counterpart Mexican agencies and the US-export industry in Mexico.

To date, the FDA has opened 10 international posts, including posts in China, India, Europe, and Latin America, along with its USA-based staff. The other posts in the Latin America Office are located in Santiago, Chile and at the FDA's Latin America Office headquarters in San José, Costa Rica. (Source: FDA Website, 15 December, 2009)

FDA Approves Generic Aricept to Treat Dementia Related to Alzheimer's Disease

The FDA has approved the first generic versions of Aricept (donepezil hydrochloride) orally disintegrating tablets manufactured by Mutual Pharmaceutical of Philadelphia. Donepezil hydrochloride is indicated for the treatment of dementia related to Alzheimer's disease. Orally disintegrating tablets dissolve on the tongue, without having to be swallowed whole. This may make taking the medication easier for older or disabled patients who have difficulty swallowing.

Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills and, eventually, the ability to carry out the simplest tasks of daily living. In most people with Alzheimer's disease, symptoms first appear after age 60.

Alzheimer's disease is the most common cause of dementia among older people, but it is not a normal part of aging. Dementia refers to a decline in cognitive function that interferes with daily life and activities. Alzheimer's disease starts in a region of the brain that affects recent memory, then gradually spreads to other parts of the brain. (Source: FDA Website, 15 December, 2009)

New Members

Mr. Walter J. Bateman, *Manager of Maintenance,* Biogen Idec Inc

Mr. Bryan Black, *AD, Quality,* Pulmatrix

Dr. Samuel Bogoch, MD, PhD, *Chairman,* Replikins,Ltd.

Mr. Bruce R. Cleary, *Validation Engineer,* ImmunoGen Inc

Cozette Cuppett, *Pharmaceutical Marketing,* Waters Corporation

Mr. Colin E. Dickie, *CQV Project Manager,* Bristol Myers Squibb

Ms. Ann Engelkemeir, *Process Engineer,* Genzyme Corp

Mrs. Kacey L. Fetcho-Phillips, *Student,* Massachusetts Institute of Technology

Karl Ginand, *Chief Estimator,* Jones Lang LaSalle Construction

Joshua Gudjohnsen, *Student,* Tufts University

Mr. Jeffrey Higgins, M.M., *Senior Manager of Operations,* Galenea Pharma

Ms. Susan T. Ikeda

Dr. Jasmin Kee, *Process Engineer,* Organogenesis Inc

Ms. Jolene Adkins Leathers, *Associate Director, External Quality,* Genentech

Peter L. Murphy

Eric Peter, *Business Development Manager,* Patheon, Inc.

Mr. Barry Potts, *Account Manager,* Automatech

Mr. Bryan E. Thorp, *Architect/Senior Associate,* Architectual Resources Cambridge

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