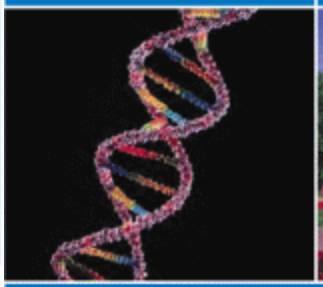
ISPE
Connecting a World of Pharmaceutical Knowledge
Boston Area Chapter
www.ispeboston.org



NEWSLETTER
July 2011, Volume XXI, No. 4

Return to the Table of Contents | Printing Instructions

Save page as PDF

President's Message: Looking Back on the Year and Ahead to the Future

Dear Friends of ISPE and the Boston Area Chapter:

In just a few short months we will be looking in the rear view mirror at summer, so enjoy it before we dive back into the fall, which will be full of activities for you, our loyal members.

The year will really kick off with the 20th Annual Product Show at Gillette Stadium on October 5th. This year's Keynote Speaker, Mr. Jonathan Kraft, President and Chief Operating Officer of The Kraft Group, will provide a keynote address focusing on how the Life Sciences Market may fit into the targeted development plans of Patriots Organization. This I need to hear!

We do have two options this summer for you social ISPE members (guests are welcome) - the summer social at the Baseball Tavern on June 30th and the 9th Annual Golf Outing at Indian Pond Country Club, one of the South Shore's finest private country clubs.

I am looking forward to participating in these great social events this summer; however I would be way off the mark if I did not take a look back at our year of accomplishments, particularly those activities that provided an opportunity to give back to our Chapter Membership.

This year we set some lofty goals, with the theme of "Giving Back", as we sought to take stock of our ability to create a legacy, via investment in our Chapter and, most importantly, our membership, here at the local level.

Here is a sample of our philanthropic activities since September of 2010:

- Charitable contributions resulting from each of our Social Programs: Project Place at Oktoberfest,

H.O.T. (Helping Our Troops) at the Holiday Social, and Children's Hospital Boston at the Summer Social, to name a few.

- Charitable contributions to the Japan Affiliate Chapter of ISPE and the Red Cross of Japan following the Tsunami disaster in partnership with ISPE International and the New Jersey, Delaware Valley, CASA, and San Diego Chapters of ISPE.
- Key Sponsorship of Bio Ball, a local day of competition for special needs individuals linking participants to local Biotech firms.
- Development, planning and financial support of 6 student chapters at UNH, UMASS Lowell, UMASS Amherst, Tufts, Northeastern and WPI.
- Key investments in programming for career development of area Young Professionals over the last three years.
- The launch of the Joel Goldenberg Scholarship Grant Program for deserving individuals that are pursuing degrees, advanced degrees or continuing education of subject matter relevant to careers in Life Sciences.
- Investment in CPIP Study Group II to offer assistance to those individuals interested in pursuing this credential.

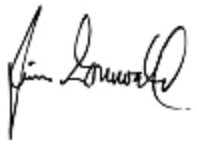
We have been able to plan and execute at a high level due to one consistent theme: Volunteers! Without our incredible community of volunteers, we could never dream up, plan and execute these incredible programs. Next year promises to present more opportunities to jump in and be part of something great.

I thank you for the opportunity to have worked towards common goals this past year and encourage all of our members to stay involved in our great local Chapter.

As always, please send us your ideas, questions and concerns to office@ISPEboston.org, or you can reach me at 617-869-8287 for all ISPE matters.

Have a great summer.

Thank you,



Jim Grunwald
President, ISPE Boston Area Chapter

Upcoming Chapter Events - Mark Your Calendar

August 15, 2011
Ninth Annual Golf Tournament

Indian Pond Country Club, Kingston, MA

While Foursomes Last! - Join fellow ISPE Members and collegues for a day of fun on a new golf course. Foursomes are on sale now and will be sold on a first come first served basis.

To register, download the flyer: Golf Flyer

September Program
"Risk Management within the Quality System"

Location: TBA

Risk is dynamic, not static. Quality Systems using a Product and Process Life Cycle approach should be designed to handle this cyclical nature of Risk Management.The current Industry State of Risk Management in the Life Cycle is shifting from a static to a dynamic approach by moving from one time ad-hoc use of assessments and tool based Risk procedures to systemic use along the Life Cycle. This session will include specific discussions and case examples of imbedding risk management in the Quality System and the Product /Process Life Cycle followed by a Panel Discussion.

Updates to this program will be posted soon at: www.ISPEBoston.org/Events

---

Sneak Preview of Upcoming Events

October 5, 2011
Annual Product Show and Educational Sessions
Gillette Stadium Clubhouse, Foxborough, MA

9:00 am - 12:00 pm Educational Sessions
12:00 pm - 7:30 pm Exhibit Floor Open
3:30 pm Keynote Address: Jonathan Kraft, President, The Kraft Group
7:30 pm After Party at CBS Scene with an appearance by Jerod Mayo, New England Patriots Football Linebacker

Registration Opens Soon!

November 15, 2011

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

Registration Opens Soon!

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

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

Introducing New Scholarship Program for Chapter Members

The Boston Area Chapter is proud to offer a new scholarship program to Members and their families. Individuals who are continuing their formal education in the life sciences or who are pursuing a degree in a life sciences field are eligible. The program has been designed with the dual purpose of contributing additional benefits to our Members and honoring Joel Goldenberg, a Chapter Past President whose wish was to support the educational pursuits of ISPE Members and their families.

Scholarship awards - up to $2,000 per individual - will be funded by proceeds from Chapter activities and are designed to help defray tuition expenses. The Chapter hopes to be able to award up to 10 scholarships each year.

The application process has been streamlined to make it as efficient as possible for both the applicants and the Scholarship Committee. Application due dates are June 15 for fall courses and November 15 for spring courses.

Full information and application can be found on the Chapter website at www.ispeboston.org/scholarship. Questions should be directed to the Chapter by email at office@ISPEBoston.org or by telephone at 781-647-4773.

Beyond E. coli & CHO - Case Studies in Alternative Host Platforms

by Lawrence Chew, Pfenex; Rachel Hoff, Percivia; and Shelly Henderson, with photos by Dan Gee, Biotech Drug Development Consultant and Barry Potts, Automatech.

On May 19th, the ISPE Boston Area Chapter presented a Process Technology Transfer and Scale Up Program entitled "Beyond *E. coli* and CHO - Case Studies in Alternative Host Platforms." The topic was

chosen in response to our members' request for presentations on novel technology. We were pleased that James Blackwell, Ph.D., former ISPE Boston Area President, offered to moderate the program, and grateful to Biogen Idec for the use of their auditorium and facilities in Cambridge. A brief summary of the program is presented below. Copies of the complete presentations are available online at the Chapter's website.

Left to right are the evening's speakers: Anna Tchoudakova, James Blackwell, Rachel Hoff, Shelly Henderson, and Lawrence Chew

Introduction by Shelly Henderson, MBA, former ISPE Vice President

The following historical tally of host cells used to produce FDA-approved recombinant therapeutics was presented to demonstrate how breakthrough the technology presented in this program truly is:

- 1982 --- first approved was in E. coli
- 1982-1991 --- 12 microbial (E. coli and yeast), 2 CHO
- 1982-2011 --- 50+ microbial (E. coli and yeast) and 50+ mammalian (~40 in CHO) total.
- 2001 --- first human cell host; since then, 2 additional by Shire.

(Note: source BioProcess International).

Pfenex Case Study - ***Pseudomonas fluorescens*** - by Lawrence Chew, Ph.D., Director of Fermentation Development at Pfenex, Inc.

The Pfenex *P. fluorescens* expression platform offers advantages similar to *E. coli*, such as simple molecular cloning, short development timelines, short cultivation time (24-48 hours), simple defined medium

and good scalability. It improves upon *E. coli* by providing the ability to generate and screen a large number of strains which support periplasmic expression of proteins that are soluble, active, with correct N-terminus, and with proper disulfide bond formation for proper folding, which allows fewer downstream processing steps. Secretion to the periplasm of proteins up to 250kDa in size at high titres (g/L) has been possible.

Pfenex has adopted an integrated approach to strain and process development for biopharmaceutical protein production that routinely involves good statistical experimental designs and data driven decisions. Extensive plasmid and host strain libraries that have been rationally developed using genomic data can be rapidly combined to generate thousands of unique strains that are then screened by robotically enabled sample processing and high throughput analysis methods.

Strain development is closely integrated with fermentation evaluation in mini and parallel bioreactors to ensure selected production strains are robust in scalable high cell density fed-batch cultures. The high cell density fed-batch fermentation process involves a defined, mineral salts medium with only glycerol and ammonia feeds as carbon and nitrogen sources. It requires no animal-sourced components and has been optimized to ensure excess nutrients to support high cell density of up to 100g/L of dry cell mass in a fed batch process, attainable partially because *P. fluorescens* produces minimal inhibitory acid. For scale-up considerations, oxygen transfer and heat transfer (cooling) rates optimal to support high cell density *E. coli* or yeast fermentations also apply to *P. fluorescens*.

Protein recovery and purification development also involve efficiently screening multiple options at small scale followed by further optimization with scale-up in mind. Recovery and purification of soluble expressed proteins require fewer unit operations and result in higher yields than refolding proteins produced as insoluble inclusion bodies in *E. coli*. Release of periplasmic proteins can be achieved by homogenization, osmotic shock, heat, chemical treatment or by solvent extraction. Solids separation can be achieved by continuous centrifugation, depth filtration, or tangential flow filtration. Purification steps are screened at small scale using robotic batch screening and microchip analysis, optimized at bench scale and evaluated at pilot scale. Standard as well as methods adapted to *P. fluorescens* are used to show clearance of host contaminants (such as host cell proteins, nucleic acids and endotoxins) by standard purification processes to acceptable levels for injected drugs.

A Proof of Concept Timeline was presented showing a thousand strain construction and screening by week 3 after receipt of gene, production of standard and fermentation scouting by week 5, purification to deliver 50 mg of target protein at 99% purity by week 6, and delivery of 500mg at 99% purity by week 9. A Process and Development Timeline was presented showing 5-7 months to completion of a sufficiently developed process for transfer to a manufacturing site.

An actual case study was presented of the development and transfer of a fermentation process for a vaccine protein to a disposable bioreactor at a collaborator's facility. Pfenex has also successfully transferred its *Pseudomonas fluorescens* strains and fermentation processes to several manufacturing sites of collaborators, clients, and CMOs, and produced at up to 3,000L cGMP scale. The product that is nearest to market approval is currently being tested in a Phase III Clinical Trial.

Previous Issues

September 2011, Volume... (15)

Percivia Case Studies with the PER.C6® Human Cell Line - by Rachel Hoff, Associate Scientist in the Upstream Process Development Group at Percivia, LLC.

Percivia, initially established as a joint venture of Crucell and DSM in Cambridge, MA in 2006, is focused on the development of PER.C6®-based biosimilar and biobetter protein therapeutics and monoclonal antibodies (MAbs). Additionally, Percivia outlicenses the PER.C6® cell line and provides licensees with logistical support by training and advising on methods of recombinant protein production using the technology. The origin, development, and safety testing of the PER.C6® cell line is documented in a Cell Substrate Biologics Master File submitted to the FDA. To date, approximately 40 clinical trials have been initiated world-wide with PER.C6®-based products with no adverse effects reported.

Mammalian, non-human cell lines dominate the field for manufacture of complex recombinant proteins and MAbs. Approximately 15 years ago, PER.C6® cells were created by rational design, that is, by transfecting human embryonic retina cells with adenoviral E1 transgenes which promote cell growth and inhibit apoptosis. The advantages of the PER.C6® cell line are the elimination of non-human host cell impurities, proper protein folding and "humanized" post-translational modifications, providing PER.C6®-based products with a superior safety and efficacy profile compared to non-human cell line-based products.

Additionally, Percivia has developed a tool box of high yielding cell culture production processes, including fed-batch and XD®, an Extreme Density process technology trademarked by DSM N.V. All of the processes are chemically defined, animal-derived-component free, and utilize commercially available media.

To develop a fed-batch process, a batch medium was chosen from a screen of commercial "off-the-shelf" media. Then, the feed media was developed as a concentrated form of commercial batch media components, supplemented with additional amino acids and vitamins to match relative consumption rates, and then adjusted to minimize osmolality and pH differences. To optimize the feeding strategy, a continuous feeding regimen was developed to minimize toxic nutrient spikes and the number of separate feeds was reduced to ease the operation. The improved fed-batch platform process achieved cell densities of 25 million cells/mL and a yield of 8 g/L for a MAb.

The XD® process takes advantage of the PER.C6® cell's inherent ability to withstand high shear and grow to very high concentrations. This process uses Refine's Alternating Tangential Flow (ATF) system to perfuse fresh medium through the bioreactor and remove metabolic by-products while retaining the cells and product. The constant environment of the XD® process allows PER.C6® cells to grow exponentially during the entire run, resulting in extreme cell densities of 100-200 million cells/mL within two weeks with a record yield of 27 g/L for a MAb. Since cells take up about 30% of the culture volume, the concentration of the MAb in the supernatant is actually closer to 40 g/L.

In order to minimize effort when scaling up for GMP production, a small-scale model predictive of fed-batch bioreactor performance was developed with 250mL shake flasks (50mL working volume) with once-daily feeding. It is useful for clone screening, media/process development, and process troubleshooting. A case study of the scale up and transfer of the platform fed-batch process for a MAb was presented. Performance in a CMO's 250L disposable bioreactor was nearly identical to that in a 250mL shake flask, which validated the scale down models at the 250mL, 5L, and 50L scales.

Newsletter Archive

Studies were also presented to compare three purification processes in terms of product recovery, impurity levels, cost, and scalability:

First, a protein A-based purification process was used as a benchmark, consisting of the following unit operations: clarification by sedimentation and 2-stage depth filtration, protein A column capture step, low pH viral inactivation and both CEX and AEX column polishing steps. The advantages of this process are high product yield and purity with minimal development effort. However, there are several disadvantages, such as low impurity clearance in the clarification steps, low-throughput of packed-bed chromatography steps (Protein A, CEX, AEX), high cost due mainly to protein A resins, and the extensive feed conditioning (titration/dilution) required for CEX and AEX.

Second, a high capacity cation exchange column-based purification process was developed, consisting of the following unit operations: clarification by sedimentation and optimized 2-stage depth filtration, PEG precipitation of the MAb, MF/TFF for MAb resuspension, CEX column capture step, AEX membrane polishing step, viral inactivation and HIC column for aggregate removal. This scheme provides improved impurity clearance in the clarification steps while also preparing the feed stream for loading onto the CEX column at a high product concentration. Due to replacement of protein A with a high capacity CEX capture and introduction of membranes in place of packed bed chromatography, this process results in reduced cost and process time.

Third, a process was developed using single-use membranes as replacements for all packed bed columns and consisting of the following unit operations: clarification by sedimentation and optimized 2-stage depth filtration, PEG precipitation of the MAb, MF/TFF, CEX membrane capture, AEX membrane polishing, viral inactivation, and HIC membrane polishing. The disadvantage of this option is a drop in product recovery from 90% to 70%. However, the fully disposable, membrane-based process allows for integrated, flow-through steps and reduced process time, equipment size, buffer use, and cost. In addition, the PEG precipitation step and the CEX capture membrane chromatography step were shown to be scalable over a 60-fold and 20-fold range, respectively.

In summary, the extensive data presented demonstrate that the PER.C6® cell line is an innovative, FDA-accepted cell line with documented origin and safety record. Percivia has developed a versatile PER.C6® technology platform for manufacture of recombinant proteins and MAbs at high yields and low cost.

(Note: PER.C6® is a registered trademark of Crucell Holland B.V., and XD® is a trademark of DSM N.V.)

A question and answer period followed each speaker's presentation. The ISPE Boston Area Chapter is grateful for the effort each made to present highly relevant, data based case studies for each of these breakthrough technologies. The authors can be reached via email as follows: Lawrence Chew at lchew@pfenex.com, Rachel Hoff at rhoff@percivia.com and Shelly Henderson at shelly_henderson@hotmail.com.

The program was conceived by Joyce Chiu, MBA, CPIP, Senior Project Leader, Honeywell Safety Products, Susan Dana Jones, Vice President and Senior Consultant, BioProcess Technology Consultants, Inc. and Shelly Henderson, MBA, Vice President, HCA.

Streamlining Extractables & Leachables Data & Plant Tour at Abbott

by Michael Levesque, Olympus Biotech, with photos by Dan Gee, Biotech Drug Development Consultant

th

The June 16 educational program, "Streamlining Extractables & Leachables Data," was held at the Abbott Bioresearch Center in Worcester. The program served to introduce the Extractables and Leachables Safety Information Exchange (ELSIE) consortium. One need look no further than recent news headlines (BPA in Baby Bottles!) to understand the timeliness and importance of this subject to our industry. This session was jointly sponsored by the Boston Area and New England Chapters.

Left to right:
Dr. William P. Beierschmitt (speaker),
Dr. Carolyn Hsu (Abbott),
Dr. Arthur Shaw (speaker)

The meeting was co-chaired by Peter Fox of RoviSys, Joshua Froimson of Abbott Bioresearch Center and Michael Levesque of Olympus Biotech Corporation. Pete and Joshua are members of the New England Chapter and Mike is a member of the Boston Area Chapter and also serves on the Chapter's Educational Programs Committee (EPC).

Over 70 attendees representing the two Chapters gathered for the event. The evening started with a sold-out, members-only tour of the Abbott Bioresearch Center facility, outstanding refreshments and an opportunity for networking.

Joshua Froimson was the host for the event. Jim Grunwald, President of the Boston Area Chapter; Kevin Chronley, President of the New England Chapter and Dan Gee, Member Service Committee volunteer for the Boston Area Chapter gave opening remarks and championed the cause for involvement in the local ISPE happenings. Did someone mention golf?

Left to right: Dr. Carolyn Hsu, Michael Levesque,
Joshua Froimson (Abbott), Dr. Arthur Shaw,
Dr. William P. Beierschmitt

Next, Joshua Froimson presented an overview of the Abbott Bioresearch Center, and Abbott as a whole. Carolyn Hsu gave some additional opening remarks, then introduced the guest speakers: Arthur Shaw, PhD, consultant to ELSIE, and William P. Beierschmitt, PhD, of Pfizer.

Dr. Shaw presented an overview of the ELSIE, including its background and purpose. ELSIE is a consortium of pharmaceutical, biotech, and medical device companies that is developing a database that

will hold safety information on extractables and leachables from a variety of materials; and controlled extraction study information from materials used in container closure systems, devices and bioprocessing. Currently, the ELSIE consortium is composed of Abbott, AstraZeneca, Baxter, Boehringer Ingelheim, Eli Lilly, GSK, Merck Serono, Novartis, Pfizer and sanofi-aventis. All pharmaceutical, biotechnology and medical device companies are invited to join ELSIE.

Left to right: Jason Nisler, Sam Fischer, Williiam Devine

Dr. Shaw noted that the primary objective of ELSIE is to provide standardized test protocols to generate extractables data for a wide variety of materials commonly used for container closure systems. Additional work will ultimately be performed on in-process materials. All of this data will be entered into the ELSIE Safety Information Database, from which it can be analyzed by toxicologists and reviewed for leachables study data.

Dr. Beierschmitt presented a demonstration of the ELSIE Safety Information Database. This is a powerful tool that will enable companies to share important safety data regarding leachables and extractables, and will save untold resources in the coming years.

Following the presentations, a variety of attendee questions were answered by the panelists. One notable closing thought was that the member companies of the ELSIE consortium have made the strategic determination that they are not in the business to compete based on safety, as any negative event is viewed as an industry-wide problem by the average consumer. ELSIE is intended to allow companies to focus their resources on the safety of their drug substances, not their containers.

YP Event - Craft Beer Tasting – IPA's and Dopplebock's and Witbier, oh my!

by Jillian Willard, Genzyme

On June 8th, more than 40 young professionals came out for a craft beer tasting at Gordon's Fine Wines and Liquors in Waltham. The tasting took the YP's around the world, as fifteen craft beers were poured, representing some of the best offerings from the US, Belgium, and Germany. From IPA's to Doppelbock's, each pour came from one of Gordon's three resident beer experts, who fielded questions from the crowd as they poured the heavenly nectars into eagerly awaiting hands holding tasting cups. The YP's left the event full of delicious and educational memories, with the additional pleasure of watching the Bruins rout the Canucks 4-0 on their way to winning the Stanley Cup. It was the perfect way to end a great evening.

Young Professionals Sampling Craft Beers

Young Professionals Corner

The Young Professionals wrapped up a year of successful events with our Craft Beer Tasting event on June 8th. The great turnout was just another indicator of how much the group has grown over the past few years „Ÿ from a small group of young ISPE members huddled around a table with some drinks at a local bar in 2008, to the organized group that it is today, offering multiple educational and social events. Thanks to everyone who has made this growth possible, from Dan Ramsey (the maverick who started it all), to all of the YP committee members past and present who have made our programs possible and volunteered their time to make YP better. And thanks also to all of the board members who have supported our mission and been our biggest advocates.

This year the young professionals put on three educational events, sponsored both educational and social events at the product show, cruised the seas with Captain Mike of the Boston Belle, took on the "seasoned veterans" of ISPE in a softball game, came together for food, drinks, and billiards at Flat Top Johnny's, and in our grand finale for the year, enjoyed some craft beer at Gordon's Fine Wines and Liquors. We hope that everyone who attended these events enjoyed themselves, and we look forward to seeing everyone (plus hopefully some new faces) at our upcoming events in the fall. Keep your eyes open for announcements for our third annual boat cruise and a rematch of the YP's vs. Seasoned Vets softball game.

If you're interested in getting involved in the YP program as a committee member, or in getting more information about our events and what we do, please email office@ispeboston.org.

Hope to see you all soon!

Jillian Willard, Rob DeCoste, and the rest of the YP Committee.

Industry News In Brief

AstraZeneca To Eliminate 145 Westborough Jobs

AstraZeneca Plc will cut about 145 jobs in Westborough by the end of the year as part of a company-wide reduction. The company, which employs about 900 people in Waltham and Westborough, said it will provide support to workers displaced from the Westborough manufacturing facility. It also said the

Westborough plant will "remain an active site."

Westborough Town Manager Jim Malloy said he's sorry to hear about AstraZeneca's decision, but that the job cuts are more than balanced by the addition of more than 2,000 new jobs in town over the past year. BJ's Wholesale Club moved about 1,200 positions to Westborough in January, and Bank of New York Mellon brought 315 jobs to town in recent months, Malloy said. "We've seen a lot of growth in the past year," he said. (Source: Livia Gershon, Worcester Business Journal, 20 June 2011)

Generex In Biomarker Partnership

Generex Biotechnology, a Canada-based company with operations in Worcester, is joining with Amarantus Biosciences Inc. of California in developing a biomarker test to determine which diabetic patients could respond well to an insulin spray product. Generex Oral-lyn, currently in Phase III clinical trials, is intended to provide a simple delivery system for insulin. The biomarker test would make use of a therapeutic protein that Amarantus is developing. Generex has already licensed its drug delivery technology to Amarantus for use in delivering other drugs and agreed to spend $5 million for joint research efforts on the technology.

Along with the new agreement, Amerantus announced that it has executed an agreement with the University of Massachusetts Medical School in Worcester to license intellectual property developed by the school to advance its diagnostic program. (Source: Livia Gershon, Worcester Business Journal, 9 June 2011)

WPI Partnering with Abbott, Bristol-Myers Squibb, and Shire for New Center at Gateway Park

Responding to the significant need for an expanded, well-trained workforce to help their industry grow, Abbott Laboratories, Bristol-Myers Squibb, and Shire Human Genetic Therapies (HGT) have signed on as inaugural partners for Worcester Polytechnic Institute's (WPI) Biomanufacturing Education and Training Center (BETC), a first-of-its-kind facility in the Northeast now under construction at WPI's Gateway Park.

Funded in part by a grant from the Massachusetts Life Sciences Center, the BETC (http://www.wpi.edu/+betc) will be a fully functional biomanufacturing pilot plant, providing hands-on training and educational opportunities for the multilayered workforce needed to produce medicines and research compounds using engineered living cells. Experts from the inaugural partners are working closely with WPI faculty and staff at every step of the BETC's development, from facility planning to curriculum design. They will also help deliver programs and mentor students when the center is operational.

The BETC will have industry-standard process areas of equipment preparation, buffer and media preparation, fermentation and cell culture, product capture, purification, and analytics. Content-rich programs in the BETC will give graduate and undergraduate students the chance to work on projects that are relevant to the industry, while learning the real-world business practices and workflows of life sciences companies. Biomanufacturing companies will use the BETC as a training center for new or existing employees, thereby avoiding the capital and productivity costs typically associated with in-house training programs.

For several years, WPI has worked with industry partners to deliver an entry-level biomanufacturing certificate training program at the university's small-scale bioprocessing laboratory. In contrast, the curriculum at the new BETC will cover all elements of a biomanufacturing enterprise, in the context of a 10,000-square-foot commercial-scale pilot plant.

The BETC will be located in a four-story building now under construction at Gateway Park by the O'Connell

Development Group of Holyoke, MA. Occupancy is expected in late 2012. Construction of the BETC enhances WPI's already significant presence in the life sciences; over the past seven years, the university has invested more than $100 million in life sciences education, research, and infrastructure. These investments have come in the form of outstanding new faculty, supported by the most up-to-date technology and lab space. Most notably, WPI has invested $65 million in Gateway Park, bringing to life a comprehensive urban redevelopment project that transformed a blighted and underutilized area in Worcester's core into a clean, thriving, mixed-use park that is home to a growing range of academic, research, and commercial enterprises. (Source: WPI Website, 9 June, 2011)

Proteostasis Therapeutics & Elan Form Drug Discovery Initiative

Proteostasis Therapeutics and Elan Corporation announced a strategic business relationship to advance Proteostasis' platform for the discovery and development of disease-modifying, small molecule drugs and diagnostics for the treatment of neurodegenerative disorders such as Parkinson's, Huntington's, multiple sclerosis and amyotrophic lateral sclerosis (ALS), and a broad array of dementia-related diseases including Alzheimer's. This innovative initiative will combine Proteostasis' unique discovery technology, novel targets and compounds that modulate key Proteostasis Network pathways with Elan's long-standing strength in proprietary animal models, biology, medicinal chemistry and clinical development.

Under terms of the agreement, Elan invested $20 million into equity capital of Proteostasis and will have an opportunity to provide an additional $30 million in collaboration funding over five years. As part of the agreement, Elan will become an approximate 24 percent shareholder in Proteostasis, obtained a right of first negotiation to exclusively license compounds emerging from the combined initiative and will have the right to a seat on the Proteostasis board of directors as well as its scientific advisory board. By mutual agreement, this innovative relationship can be extended for a further five years. (Source: Elan Corporation Website, 25 May 2011)

Hormone-Blocking Drug Found to Cut Breast Cancer Risk

A drug that blocks production of the hormone estrogen cut breast cancer cases by more than half in at-risk postmenopausal women, according to a team led by a researcher at Massachusetts General Hospital. Doctors said the finding that exemestane, a Pfizer drug, could prevent breast cancer will provide a new option for women who have mostly shied away from taking other drugs aimed at preventing breast cancer because of rare, but serious side effects. Today, only a tiny fraction of the women who could potentially benefit from such medications take advantage of them, and researchers said increased adoption of risk-reducing drugs could benefit millions of women.

"There was a 65 percent reduction in the risk of breast cancer - a pill that can do that to the commonest cancer that affects women globally and kills women globally; there's no such pill that I know of for any kind of cancer," Dr. Paul E. Goss, director of the breast cancer research program at Mass General and lead author of the study, said in an interview before presenting the findings at the meeting of the American Society of Clinical Oncology in Chicago.

"We haven't seen any serious toxicity that might stifle someone's decision to try and take this drug," said Goss, who has received honoraria from several pharmaceutical companies, including a one-time speaker's fee from Pfizer.

The seven-year study followed 4,560 women from the US, Canada, Spain and France who were postmenopausal and had at least one risk factor for breast cancer, which could include being over age 60 or having a breast biopsy result that showed they were at higher risk. Women were randomly assigned to one of two groups: one group received a placebo, and the other took exemestane, which is already

approved to treat women after they are diagnosed with breast cancer. After a median follow-up of three years, there were 11 invasive breast cancers among the women receiving exemestane compared with 32 in the placebo group, and there were also fewer precursor lesions found in women taking the drug.

There were some side effects: More women on exemestane than the placebo suffered hot flashes, fatigue, sweating, and insomnia. The rate of bone fractures, osteoporosis, and cardiovascular effects was the same in both groups. The study was funded by the Canadian Cancer Society and Pfizer. (Source: Carolyn Y. Johnson, Boston Globe, 5 June 2011)

Alkermes to Buy Irish Drug Maker, Move Headquarters to Dublin

Alkermes unveiled plans to buy Elan Drug Technologies of Ireland, a profitable drug formulation and manufacturing business unit of the Irish drug maker Elan Corp PLC, in a $960 million deal that will double the Waltham company's size and move its headquarters to Dublin. The merger would give the combined biotechnology company, to be called Alkermes PLC, two dozen products, including five drugs with long patent lives, under one roof.

It also will expand the Alkermes research and manufacturing workforce from about 600 to 1,200 employees at sites on both sides of the Atlantic, the majority of them in the US. Alkermes has nearly 300 employees at its headquarters in Waltham, where it recently moved from Cambridge. It also operates a production plant in Wilmington, Ohio. Elan Drug Technologies, based in Dublin, has manufacturing facilities in the central Ireland town of Athlone, and in Gainesville, GA.

The deal, expected to close in the third quarter of this year, first needs approval of Alkermes shareholders, as well as sign-offs from US and Irish regulators. The new Alkermes would generate more than $450 million annually, according to estimates. Its portfolio would include Alkermes-produced Vivitrol, which treats alcohol and opioid dependence, and Risperdal Consta, a drug for bipolar disorder and schizophrenia, in addition to multiple Elan products.

"It's a long-term growth story," said Richard Pops, Alkermes chief executive, in an interview from Dublin, where the deal was unveiled. "We expect to be growing the business, both in Massachusetts and in Ireland. This will put us in an elite class of companies." Although the new company will be based in Ireland, it won't be moving jobs there from the Boston area, said Pops, who will be its chairman and chief executive. He said the home base in Ireland will help it sell into the European market, negotiate alliances with European companies, and more easily manage business deals overseas. (Source: Robert Weisman, Boston Globe, 10 May 2011)

Potential Parkinson's Treatment Explored

Medtronic and Eli Lilly have agreed to collaborate on an early stage research project for a potential Parkinson's-disease treatment that involves delivering medication directly to the brain-a goal that has long eluded drug makers. The pact adds to Medtronic's roster of projects aimed at using implantable drug pumps and catheters to circumvent the blood-brain barrier. The tightly packed network of cells in brain capillaries only lets certain substances through, such as key nutrients, making brain-based disorders difficult to treat with drugs. Medtronic, the largest stand-alone medical-device maker, already has a handful of other Parkinson's collaborations underway. The company is also working through home-grown efforts and collaborations on potential treatments for other brain diseases, like Alzheimer's and Huntington's.

The latest effort with Lilly is still many years from yielding a marketable treatment or even starting human testing. The companies didn't disclose terms of their agreement, but a Medtronic spokesman said it spans early research through product development and potential commercialization.

Parkinson's is a progressive, degenerative brain disorder that affects nearly one million Americans and can lead to tremors and other movement problems, according to the Parkinson's Disease Foundation. The disease, which has no cure, is thought to be caused by the death of neurons that produce the important chemical messenger dopamine. Lilly's treatment approach involves a modified form of a protein called glial cell derived neurotrophic factor, or GDNF, which is designed to protect these neurons.

Seven years ago, Amgen stopped studying a potential GDNF Parkinson's treatment delivered with Medtronic equipment because it didn't appear effective. But Lilly hopes its compound, together with Medtronic's modernized delivery system, will "overcome some prior technical hurdles," said Ros Smith, senior research director of regenerative biology at Lilly. The company believes its GDNF variant has potential to have broader distribution in the brain than prior versions. The drug may not enter human clinical trials for up to five years, Dr. Smith said.

Medtronic's system involves small catheters that are implanted in the brain and connected to a hockey-puck-size pump, which would likely be implanted in the abdomen. At this point it isn't known whether the treatment would involve short- or long-term infusion, or what specific areas of the brain might be targeted, said Steve Oesterle, senior vice president of medicine and technology at Medtronic.

The company already has experience finding and delivering treatment to parts of the brain responsible for Parkinson's through its "deep-brain stimulation" business, which makes pacemaker-like implants that deliver electrical stimulation through electrodes. That approach is used to treat Parkinson's symptoms, Dr. Oesterle said. By contrast, drug approaches from Lilly and other companies have potential to restore damaged parts of the brain, he said. The key is getting the drugs on site, rather than having them circulate through the body only to be stymied by the blood-brain barrier. (Source: Jon Kamp, Wall Street Journal, 27 April 2011)

Massachusetts to be a Key Research Hub for Sanofi & Genzyme

Two months after completing its $20.1 billion buyout of Genzyme Corp., drug giant Sanofi SA is moving quickly to integrate the two companies. Sanofi has unveiled a research and development structure that will coordinate existing Genzyme and Sanofi research operations in Massachusetts through a new innovation unit called the Sanofi Boston R&D Hub. Genzyme's own drug discovery programs, centered in Framingham, will operate within that unit as the Genzyme R&D Center.

Research at the Genzyme R&D Center will include not only the Cambridge biotechnology company's own rare diseases and multiple sclerosis programs, but also a Sanofi multiple sclerosis program, Sanofi chief executive Christopher A. Viehbacher said in an interview at Genzyme's headquarters in Kendall Square. Viehbacher is serving as Genzyme's chief executive until September to help coordinate the merging of the two companies' operations.

Genzyme will retain its name and remain a stand-alone business unit within Sanofi. The Paris-based drug maker now has about 5,000 employees in the Boston area, including 4,500 at Genzyme corporate, research, and manufacturing sites. Worldwide, Genzyme employs 10,000 people.

"We're starting to make some decisions," Viehbacher said. At meetings with Genzyme employees, he said, "The No. 1 question [was], 'What's happening to me?' And you can never answer that question fast enough. Our commitment is to try to come to these integration decisions at a 10,000-person organization across 80 countries in 90 days. Now for most people, they'll still see that as slow. But I can tell you that pretty much sets speed records." Viehbacher said his goal is to "build an even better company" by combining the strengths of Sanofi, a global pharmaceutical company with a strong position in developing

markets, with Genzyme, which built its business on expensive drugs for rare diseases, and the company's deep ties to the patients who rely on those treatments.

In May, Sanofi rolled out a new reporting structure for Genzyme's marketing and sales business units. In an employee bulletin, Sanofi said Genzyme would include personalized genetic health, the rare disease division, and multiple sclerosis operations. Other Genzyme units, including its oncology, biosurgery, and renal businesses, will be consolidated into Sanofi's own businesses in those disease areas, though they will still operate out of the Boston area.

Viehbacher said Genzyme will add about 50 jobs in the areas of personalized genetic health and multiple sclerosis work. But those new positions could be offset by jobs still to be eliminated in other parts of the company, including those that overlap with Sanofi's corporate operations. Viehbacher said it's too soon to say how many Genzyme jobs will remain after the integration is completed. (Source: Robert Weisman, Boston Globe, 15 June 2011)

Court Reverses Stem Cell Ruling, Permits Funding of Research Using Human Embryos

The Obama administration can continue to fund research that uses human embryonic stem cells, a federal appeals court ruled on April 29th, ending months of uncertainty for scientists. The ruling from the US Court of Appeals in Washington reverses a lower court's injunction that had halted new federal funding for several weeks last year.

"I am pretty excited about it," said Dr. Leonard Zon, director of the stem cell program at Children's Hospital Boston. "The issue when you're a stem cell researcher is, there's a certain level of uncertainty about whether the governmental and legal mechanisms will be in place so you can fund your research. This is not the final word but an indirect way of saying the case probably has little merit."

The White House released a statement praising the decision, as did the National Institutes of Health. "This is a momentous day - not only for science, but for the hopes of thousands of patients and their families who are relying on NIH-funded scientists to pursue life-saving discoveries and therapies that could come from stem cell research," the NIH director, Dr. Francis S. Collins, said in a prepared statement.

The ruling is the latest twist in what many predict will be a legal battle over embryonic stem cell research that could continue for months, if not longer. The initial lawsuit was brought by Dr. James L. Sherley, a former Massachusetts Institute of Technology researcher and senior scientist at the Boston Biomedical Research Institute in Watertown, and others who oppose stem cell research. The federal judge handling the case can now decide the broader legal questions in the case.

Sherley did not return a call from the Globe. But Samuel B. Casey, general counsel for Advocates International, part of the plaintiffs' legal team, said his clients plan to proceed with their case. They believe using taxpayer money for experiments that, in their view, destroy human life, violates federal law. They also argue that Sherley and others who study less controversial adult stem cells would be harmed because of the competition for federal funds that would be stoked by expansion of research into embryonic stem cells. A federal judge granted a preliminary injunction last August, halting funding. In response, the NIH decided to temporarily stop funding new grants or renewing existing grants, but said scientists who had already received grants could continue their embryonic stem cell research.

The US Justice Department appealed the injunction, and Collins warned that if the decision was upheld, it would jeopardize a fast-moving area of science that offers potential treatments for spinal cord injury, diabetes, and Parkinson's disease, as well as help in screening new drugs. (Source: Liz Kowalczyk, Boston Globe, 30 April 2011)

Regulatory & Legislative Highlights

FDA Approves Genentech's Actemra to Treat Rare Form of Juvenile Arthritis

The FDA has approved Genentech's Actemra (tocilizumab), given alone or in combination with methotrexate, for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in children ages 2 years and older. SJIA, or Still's disease, is a rare, potentially life-threatening disorder in children that causes severe inflammation throughout the body. SJIA is distinguished from other forms of juvenile idiopathic arthritis (JIA) by the prominence of systemic and inflammatory features, including spiking fevers; rash; swelling and inflammation of lymph nodes, liver, and spleen; and high white blood cell and platelet counts. The prevalence of JIA is an estimated 1 to 2 per 1,000 children, and SJIA affects about 10 percent of all JIA patients.

Actemra carries a Boxed Warning for serious infections. Patients treated with Actemra who develop a serious infection should stop Actemra treatment until the infection is controlled. A Boxed Warning is a brief, concise summary of the information that is critical for a prescriber to be aware of, including any restriction on distribution or use, which is included in a black box at the beginning of the drug label. (Source: 15 April, 2011, FDA Website)

FDA Approves New Medical Device for Form of Brain Cancer

The FDA has approved the NovoTTF-100A System, a new device to treat adults with glioblastoma multiforme (GBM) that recurs or progresses after receiving chemotherapy and radiation therapy. The NovoTTF-100A System is made by Novocure of Portsmouth, New Hampshire. According to the National Cancer Institute, each year about 19,000 people in the United States are diagnosed with primary brain cancers. In 2010, there were 13,140 deaths from brain and other nervous system cancers in the US. GBM is the most common primary brain cancer. The brain tumor is highly resistant to standard treatments such as surgery, radiation and chemotherapy.

When using the NovoTTF-100A System, a health care professional places electrodes on the surface of the patient's scalp to deliver low-intensity, changing electrical fields called "tumor treatment fields" (TTFs) to the tumor site. The unique shape and electrical characteristics of dividing tumor cells make them susceptible to damage when exposed to TTF, which could stop tumor growth.

The device is portable and can be powered with batteries or plugged into an electrical outlet. Patients can use the device at home, allowing them to continue their normal daily activities. (Source: 15 April, 2011, FDA Website)

FDA Approves Genentech's Rituxan to Treat Two Rare Disorders

The FDA has approved Genentech's Rituxan (rituximab), in combination with glucocorticoids (steroids), to treat patients with Wegener's granulomatosis (WG) and microscopic polyangiitis (MPA), two rare disorders that cause blood vessel inflammation (vasculitis). Rituxan is an antibody that is manufactured through biotechnology methods. The drug works by greatly reducing the number of specific immune cells in the blood, known as B cells.

Vasculitis in patients with WG and MPA can lead to tissue damage. WG mostly affects the respiratory tract (sinuses, nose, trachea, and lungs) and kidneys, while MPA commonly affects the kidneys, lungs, nerves, skin, and joints. Both of these diseases affect people of all ages and ethnicities, and both genders. The

causes of these disorders are unknown, and both are considered orphan diseases because they each affect less than 200,000 people in the US.

Rituxan carries a Boxed Warning for infusion reactions, which can occur during infusion or within 24 hours afterwards. Other Boxed Warnings for Rituxan include rashes and sores in the skin and mouth (severe mucocutaneous reactions); and progressive multifocal leukoencephalopathy, a brain infection that generally is fatal. Rituxan is not recommended for use in patients with severe, active infections.

Rituxan, which has been marketed since 1997, is also indicated for the treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, and rheumatoid arthritis. (Source: 19 April, 2011, FDA Website)

FDA "Strategic Priorities 2011 - 2015" Now Available

The FDA has released the final version of a strategic priorities document outlining the goals that will guide the agency and its 12,000 employees through 2015. Titled "Strategic Priorities 2011 - 2015: Responding to the Public Health Challenges of the 21st Century," the 50-page document provides a vision of the FDA that includes: a modernized field of regulatory science that draws on innovations in science and technology to help ensure the safety and effectiveness of medical products throughout their life cycles; an integrated global food safety system focused on prevention and improved nutrition; and expanded efforts to meet the needs of special populations.

The document contains four sections: Introduction, Cross-Cutting Strategic Priorities, Strategic Goals and Long-Term Objectives, and Implementation. Senior staff from the FDA's seven product and research centers and two major offices contributed to the document. A Federal Register notice that invited public comment in October 2010 generated more than 200 comments and the final document includes that input.

The FDA commissioner stated that she would continue to act as an advocate for advancing the field of regulatory science and innovation, one of five cross-cutting areas that serve as strategic priorities at the agency over the next five years. (Source: 20 April, 2011, FDA Website)

FDA Approves First Vaccine to Prevent Meningococcal Disease in Infants & Toddlers

The FDA has approved the use of Menactra in children as young as 9 months for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is manufactured by Sanofi Pasteur and is already approved for use in people ages 2 through 55 years.

Meningococcal disease is a life-threatening illness caused by bacteria that infect the bloodstream (sepsis) and the lining that surrounds the brain and spinal cord (meningitis). *Neisseria meningitidis* is a leading cause of meningitis in young children. Even with appropriate antibiotics and intensive care, between 10 percent and 15 percent of people who develop meningococcal disease die from the infection. Another 10 to 20 percent suffer complications such as brain damage or loss of limb or hearing.

Although the rates of meningococcal disease are low in the United States, infants and toddlers are more susceptible to getting this serious illness. Meningococcal disease is particularly dangerous because it progresses rapidly and can cause death within hours. Early symptoms are often difficult to distinguish from influenza and other common illnesses. (Source: 22 April, 2011, FDA Website)

FDA Approves Zytiga for Late-Stage Prostate Cancer

The FDA has approved Zytiga (abiraterone acetate) in combination with prednisone (a steroid) to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have received prior docetaxel

(chemotherapy). Zytiga is marketed by Centocor Ortho Biotech.

In prostate cancer, the male sex hormone testosterone stimulates prostate tumors to grow. Drugs or surgery are used to reduce testosterone production or to block testosterone's effects. However, sometimes prostate cancer can continue to grow even when testosterone levels are low. Men with these cancers are said to have castration-resistant prostate cancer.

Zytiga is a pill that targets a protein called cytochrome P450 17A1 (CYP17A1) which plays an important role in the production of testosterone. The drug works by decreasing the production of this hormone that would stimulate cancer cells to continue growing. (Source: 28 April, 2011, FDA Website)

FDA Approves New Treatment for Type 2 Diabetes

The FDA has approved Tradjenta (linagliptin) tablets, used with diet and exercise, to improve blood glucose control in adults with Type 2 diabetes. Tradjenta is marketed by Boehringer Ingelheim Pharmaceuticals and Eli Lilly Co.

People with Type 2 diabetes do not produce or respond normally to insulin, a hormone that regulates the amount of glucose in the blood. Over time, high blood glucose levels can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney damage.

Tradjenta has been studied as a stand-alone therapy and in combination with other Type 2 diabetes therapies including metformin, glimepiride, and pioglitazone. Tradjenta has not been studied in combination with insulin, and should not be used to treat people with Type 1 diabetes or in those who have increased ketones in their blood or urine (diabetic ketoacidosis). (Source: 2 May, 2011, FDA Website)

FDA Approves New Treatment for Rare Type of Pancreatic Cancer

The FDA has approved Afinitor (everolimus) to treat patients with progressive neuroendocrine tumors located in the pancreas (PNET) that cannot be removed by surgery or that have spread to other parts of the body (metastatic). Afinitor is marketed by East Hanover, N.J.-based Novartis.

Neuroendocrine tumors found in the pancreas are slow-growing and rare. It is estimated that there are fewer than 1,000 new cases in the United States each year.

Afinitor is also approved to treat patients with kidney cancer (advanced renal cell carcinoma) after they fail treatment with Sutent (sunitinib) or Nexavar (sorafenib); and patients with subependymal giant cell astrocytoma (a type of brain cancer) associated with tuberous sclerosis (a disease that causes tumors in various parts of the body), who cannot be treated by surgery.

Afinitor has another trade name, Zortress, and is approved to treat certain adult patients to prevent organ rejection after a kidney transplant. Zortress has a different safety profile in these patients. (Source: 6 May, 2011, FDA Website)

FDA Requests Input on User Fee Program for Biosimilar And Interchangeable Biological Products

The FDA is requesting input from stakeholders and the public relating to the development of a user fee program for biosimilar and interchangeable biological product (351(k)) applications. The Biologics Price Competition and Innovation Act of 2009, a provision of the Affordable Care Act, creates an abbreviated approval pathway for biological products that are demonstrated to be highly similar (biosimilar) to, or interchangeable with an FDA-licensed biological product. It directs the FDA to develop recommendations

for a 351(k) user fee program for fiscal years 2013 through 2017. The recommendations must be presented to Congress by January 15, 2012. (Source: 9 May, 2011, FDA Website)

FDA Approves Merck's Victrelis for Hepatitis C

The FDA has approved Victrelis (boceprevir) to treat certain adults with chronic hepatitis C. Victrelis is used for patients who still have some liver function, and who either have not been previously treated with drug therapy for their hepatitis C or who have failed such treatment. Victrelis is approved for use in combination with peginterferon alfa and ribavirin.

According to the Centers for Disease Control and Prevention, about 3.2 million people in the United States have chronic hepatitis C, a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Victrelis is a pill taken three times a day with food. The therapy is part of a class of drugs referred to as protease inhibitors, which work by binding to the virus and preventing it from multiplying. (Source: 13 May, 2011, FDA Website)

FDA Approves New HIV treatment

The FDA approved Edurant (rilpivirine) in combination with other antiretroviral drugs for the treatment of HIV-1 infection in adults who have never taken HIV therapy (treatment-naïve). Edurant is manufactured by Tibotec Therapeutics, a division of Centocor Ortho Biotech.

Edurant is a pill taken once a day and belongs to a class of HIV drugs called non-nucleoside reverse transcriptase inhibitor (NNRTI). The drug works by blocking HIV viral replication. Edurant is to be used as part of a highly active antiretroviral therapy (HAART) regimen that is designed to suppress the amount of HIV (viral load) in the blood. Edurant does not cure HIV infection. Patients must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses. (Source: 20 May, 2011, FDA Website)

FDA Approves Sutent for Rare Type of Pancreatic Cancer

The FDA has approved Pfizer's Sutent (sunitinib) to treat patients with progressive neuroendocrine cancerous tumors located in the pancreas that cannot be removed by surgery or that have spread to other parts of the body (metastatic).

Neuroendocrine tumors found in the pancreas are slow-growing and rare. It is estimated that there are fewer than 1,000 new cases in the United States each year. This is the second new approval by the FDA to treat patients with this disease; the agency approved Afinitor (everolimus) earlier.

Sutent is also FDA-approved to treat patients with late-stage kidney cancer (metastatic renal cell carcinoma) and to treat patients with GIST (gastrointestinal stromal tumor), a rare cancer of the stomach, bowel, or esophagus. (Source: 20 May, 2011, FDA Website)

FDA Approves Vertex Pharmaceuticals' Incivek for Hepatitis C

The FDA has approved Incivek (telaprevir) to treat certain adults with chronic hepatitis C infection. Incivek is used for patients who have either not received interferon-based drug therapy for their infection or who have not responded adequately to prior therapies. Incivek is approved for use with interferon therapy made up of peginterferon alfa and ribavirin. The current standard of care for patients with chronic hepatitis C infection is peginterferon alfa and ribavirin taken for 48 weeks. Less than 50 percent of patients respond to this therapy.

According to the Centers for Disease Control and Prevention, about 3.2 million people in the United States

have chronic hepatitis C infection, a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure.
Most people with hepatitis have no symptoms of the disease until liver damage occurs, which may take several years.

Incivek is a pill taken three times a day. It should be taken for the first 12 weeks in combination with peginterferon alfa and ribavirin. Most people with a good early response to the Incivek combination regimen can be treated for 24 weeks rather than the recommended 48 weeks of treatment with the standard of care. Incivek is part of a class of drugs referred to as protease inhibitors, which work by binding to the virus and preventing it from multiplying. (Source: 23 May, 2011, FDA Website)

FDA to Make Enforcement and Compliance Activities Accessible Online

The FDA has announced that it is disclosing more information about inspections and court actions, and has a web portal on its enforcement activities as part of Phase II of the agency's Transparency Initiative. These actions are being taken to make FDA's enforcement and compliance-related activities more accessible, downloadable, and searchable online.

The information includes a summary of the most common Inspectional Observations of objectionable conditions or practices made during inspections and a searchable Inspections Database that includes the names and addresses of inspected facilities, inspection dates, type of FDA-regulated products involved, and final inspectional classification.

FDA Commissioner Margaret A. Hamburg M.D. launched FDA's Transparency Initiative in June 2009 in response to the Obama administration's commitment to openness in government. After holding public meetings and inviting written comments, FDA issued a report proposing 21 actions to increase disclosures about agency activities. The actions announced today stem directly from that effort and are among the first of the proposals to be implemented. (Source: 26 May, 2011, FDA Website)

FDA Outlines Roadmap for Discussion on Nanotechnology in Regulated Products

The FDA has released draft guidance to provide regulated industries with greater certainty about the use of nanotechnology, which generally involves materials made up of particles that are one billionth of a meter in size. The guidance outlines the agency's view on whether regulated products contain nanomaterials or involve the application of nanotechnology.

Nanotechnology, the science involving manipulation of materials on an atomic or molecular scale, is an emerging technology with a broad range of potential applications, such as increasing bioavailability of a drug, improving food packaging and in cosmetics.

For products subject to premarket review, the FDA intends to apply the points contained in the draft guidance, when finalized, to better understand the properties and behavior of engineered nanomaterials. For products not subject to premarket review, the FDA will urge manufacturers to consult with the agency early in the product development process so questions related to the regulatory status, safety, effectiveness or public health impact of these products can be adequately addressed.

The FDA has a robust regulatory science agenda to develop the tools, methods and expertise necessary to evaluate products that contain nanomaterials or otherwise involve the use of nanotechnology. The FDA's regulatory science portfolio focuses on generating data needed to ensure the safety and effectiveness of products using nanomaterials, with an emphasis on products the use of which could present the greatest

potential risk to public health. (Source: 9 June, 2011, FDA Website)

FDA Approves Potiga to Treat Seizures in Adults

The FDA has approved Potiga (ezogabine) tablets for use as an add-on medication to treat seizures associated with epilepsy in adults. Potiga was developed by Valeant Pharmaceuticals North America of Durham, NC and will be distributed by GlaxoSmithKline of Research Triangle Park, NC.

Potiga was approved for the treatment of partial seizures, the most common type of seizure seen in people with epilepsy. Epilepsy is a brain disorder in which there is abnormal or excessive activity of nerve cells in the brain. Partial seizures affect only a limited or localized area of the brain, but can spread to other parts of the brain. Seizures cause a wide range of symptoms, including repetitive limb movements (spasms), unusual behavior, and generalized convulsions with loss of consciousness.

Potiga is the first neuronal potassium channel opener developed for the treatment of epilepsy. Although the mechanism of action is not firmly established, the drug may act as an anticonvulsant by reducing excitability through the stabilization of neuronal potassium channels in an "open" position. (Source: 13 June, 2011, FDA Website)

FDA Approves New Test to Determine Whether Breast Cancer Patients are Candidates For Herceptin Treatment

The FDA has approved a new genetic test that will help health care professionals determine if women with breast cancer are HER2-positive and, therefore, candidates for Herceptin (trastuzumab), a commonly used breast cancer treatment. The test, called Inform Dual ISH, allows for measurement of the number of copies of the HER2 gene in tumor tissue. The HER2 gene is located on chromosome 17 in human cells. An excessive amount of the protein produced by the gene is found in some types of cancer cells, including breast cancer cells. Arizona-based Ventana Medical Systems manufactures the Inform Dual ISH test. Herceptin is marketed by Genentech. (Source: 14 June, 2011, FDA Website)

New Members

Angel Adrovet, *Validation Engineer,* Genzyme

Mr. Robert G. Andrews, Jr., *Partner,* AHA Consulting Engineers, Inc.

Dr. Sunil Anklekar, *Associate Director,* Lantheus Medical Imaging

Brent A. Arbogast, *Chemist,* Critical Process Filtration

Eric D. Briggs, *Account Executive*

Gary Broberg, *Sr. Chem. Engineer,* Practical Applications, Inc.

Mr. Ronald J. Calo, *Sales Manager,* Mar Cor Purification

Jonathan Chan, PE, LEED AP, *Associate,* Bard, Rao + Athanas Consulting Engineers, LLC

Mr. John F. Coolidge, *Biorepository Manager,* Masy Systems

Mr. Michael DePesa, *Sales Representative,* Crosspoint Engineering

Mr. Patrick J. Donahue, *President,* Blackthorn Associates, LLC

Mr. Jarrod M. Dore, *Construction Management/ Project Manager,* Robert White Sons, Inc

Steven W. Dunsford, *Sr. Director,* Lantheus Medical Imaging

Ms. Carly Evans, *Principal Associate,* Genzyme Corp

Roberto Facendola, *,* University of Massachusetts Lowell

Mr. David Feria, *Regulatory and Clinical Compliance Officer,* Department of Veterans Affairs

Thomas Fernberg, *,* University of Massachusetts Amherst

Margaret Grace, *Student,* University of Massachusetts Amherst

Dr. Ellen Gualtieri, *Applications Engineer,* Formulatrix

Mr. Antonio Hernandez-Cardoso, *Senior Scientific Liaison,* United States Pharmacopeial Convention

Ms. Rachel F. Hoff, *Associate Scientist II,* Percivia, LLC

Ms. Joanna Ioannides, *Field Process Control Engineer,* CrossPoint Engineering

Mr. R Scott Jennings, *Director of Quality,* Integra Companies, Inc.

Mr. Josh Jones, *Manager Process Engineering/Development,* Genzyme Corp

Mr. Adam P. Keane, *Construction Management/Sr. Project Manager,* Richard White Sons, Inc

Keith Kelly, *VP Quality,* Masy Systems, Inc.

Mr. Daniel Kuhl, *Process Engineer,* Genzyme

Mr. Sean Marnane, *Process Engineer,* Genzyme

David Marsocci, *Inside Sales Consultant,* High Purity New England

Dr. Jesse D. McCool, *Associate Director,* Lonza Biologics Inc.

Mr. Thomas J. Montgomery, *Manager, Inst. & Metrology,* Momenta Pharmaceuticals

Ms. Lisa-Marie Nesbitt, *CLSSMBB,* Shire HGT

Karen A. OConnell, *Project Manager,* Genzyme Corp

Fasha Onorato, *Marketing,* R.W.Sullivan Engineering

Mr. Ryan Petrarca, *Student,* Northeastern University

Khoa Pham, *Student,* University of Massachusetts Lowell

Cheryl Poole, *Student,* Middlesex Community Collete

Amit Prasad, *Global Cam Administrator,* Genzyme Corp

Gil Salzman, *, G*enzyme Corp

,

Matthew J. Schneiderhan, University of Conneticutt

Ms. Linda M. Schocken, *Manager, Training & Compliance,* Shire

Mr. Greg Snell, *District Sales Manager,* MKS Instruments

Ms. Jennifer Staffin, *Lead Automation Engineer,* Bristol-Myers Squibb

Mr. Michael S. Tetreault, *Student,* University of New Hampshire

Mason A. Turner, *Student,* University of Massachusetts Amherst

Fredrick Wafula, *EHS Associate*

Mr. Steven M. Wieners, *Senior Process Engineer,* DUSA Pharmaceuticals Inc

Mr. Wendell W. Yee, *Sr. Compliance Specialist,* ShireHGT

Member Anniversaries

20+ Years of Membership

Mrs. Janice Abel, ARC Advisory Group

Mr. Michael A. Boenitz, DUSA Pharmaceuticals Inc

Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation

Ms. Greta W. Davis, Lantheus Medical Imaging

Mr. George C. Enos, Hart Design Group

Mr. John H. Evers, Lantheus Medical Imaging

Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz

Mr. David C. Hardy

Mr. Stephen R. Higham, PE, Genzyme Corp

Mr. David L. Hyde, Lantheus Medical Imaging, Inc.

Mr. Thomas R. Jerome

Mr. Robert W. Juffras, MS, Stryker Biotech

Mr. Jerome Justin, Shire HGT

Dr. Richard V. Levy, PDA

Mr. Frank J. Manning, VNE Corp

Mr. Hank Moes

Mr. Thomas W. Moss, Applied Process Solutions, Inc

Mr. Armen J. Nahabedian, Pfizer

Mr. Richard D. Priester, Strategic Facility Planning LLC

Mr. Thomas Ramundo, New England Controls, Inc.

Mr. Thomas Ransohoff, BioProcess Technical Consultants Inc.

Mr. Pasquale M. Sacco, Shire HGT

Mr. Alexander E. Smith, Jr., Parsons

Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

15 Year Anniversary

Mr. John C. Masiello, Masy Systems Inc

Mr. Daniel J. Mathien, Behringer Corporation

10 Year Anniversary

Mr. Michael A. Benedetto, Skanska

Mr. Dino J. Farina, MS, EME, Proveris Scientific Corporation

5 Year Anniversary

Ms. Maria E. Baca, Pfizer

Mr. Mark D. Kehrer, Commissioning Agents Inc

Mr. Harry E. MacNeil, Skanska USA

Ms. Kristin S. Murray, Pfizer

Mr. Rodney L. Renn, Commissioning Agents

Mr. Stephen Runge, nanoCLEAN

Mr. Charles J. Selig, IMA Nova Packaging Systems

Mr. Kinnar Shah

Mr. Lee Ward, Rockwell Automation

Back