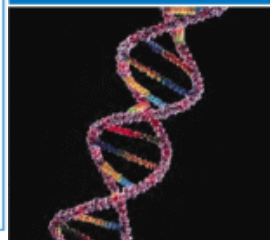




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NEWSLETTER

July 2010, Volume XX, No. 4

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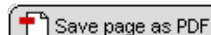
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President's Message: Thank You for a Fantastic Year!

Hello ISPE Boston Area Chapter Members,

Has it been one year already?! Sadly, this will be my last President's Message. I have really enjoyed my year as your President and hopefully I have brought the Chapter some enthusiasm and fresh ideas. I am so thankful I got the opportunity to lead the Chapter. Although it was a stressful year due to the economy, I have learned a great deal from the experience and would not trade it for anything.



I would like to take this time to thank the Board of Directors for a fantastic year. As President, I had the opportunity to work with some great people and I owe much of the success of the Boston Area Chapter to the Board and to our amazing committee volunteers.

Although I did not achieve everything I set out to do this year, I am really proud of our achievements as a Chapter. We held over 13 educational programs, two socials, the golf outing, CEO Dinner, Chapter of the Year (Platinum Award) Celebration, three Young Professionals activities and, of course, the Product Show with another nine educational tracks and a great keynote speaker. Wow, that's a lot! The Boston Area Chapter has amazing volunteers whom I would personally like to thank for their hard work in putting together all of these events. And many thanks also to our dedicated Members, who turn out for these events and help to make the Chapter successful through their participation.

I can't stress enough how important volunteering is to ISPE and to our Chapter. We rely on volunteers to help organize programs and events and contribute new ideas and fresh energy. I have been able to make new friends locally as well as internationally - all by being on one of the Chapter's committees. I hope you will consider taking advantage of this great opportunity.

Even though it sounds as if I am saying goodbye, I will still be around next year as Past President. The slate of new Officers and Directors is being planned now and ballots will be going out to Members in July, so please be sure to cast your vote.

Again, I would like to thank this year's Board - Officers Jim Grunwald, VP; Janet Tice, Secretary; Doyle Johnson, Treasurer; and Directors Brian Hagopian, Deepen Joshi, Marita King, Kevin Lynch, Christopher Opolski, Pietro Perrone, Bob Urbanowski, Jay Zaino and Lee Ward. Without the commitment and dedication of these folks, nothing would have happened.

I know I am leaving the Chapter in good hands. Jim Grunwald will be taking over as President in August. I know he will serve the Chapter well and bring it to new heights. I hope you will continue to support the Chapter by attending the many educational programs, socials and other exciting events coming up in 2010-11. And I truly hope you will find it beneficial - both personally and professionally - to be an ISPE Member. I know I have.

Sincerely,

Sylvia Beaulieu
President, ISPE Boston Area Chapter



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Upcoming Chapter Events: Mark Your Calendar

Monday, August 16, 2010 8th Annual Golf Tournament

Sign up today! Only a limited number of foursomes and sponsorships are still available.

Ferncroft Country Club, Middleton, MA
7:30 am Shot Gun Start

[Click Here to Download Registration Forms](#)

Sunday, August 22, 2010 Lowell Spinners Baseball Game and Family Fun Night

The ISPE - Social Committee is pleased to announce its 2010 Family and Friends Summer BBQ and Baseball Event!

Strike 1, Strike 2, Strike 3 you're UP - come join the ISPE Team together with your family, friends and/or colleagues to watch a winning team play ball -- The Lowell Spinners - a Class A Affiliate of the Boston Red Sox in Lowell play the Hudson Valley Renegades on Sunday August 22nd. The game starts at 1:35pm and the BBQ will begin promptly at noon. In addition to the day's festivities - after the game the kids get to run the bases on the same field that the Spinners just played and enjoy Balloon Twisting by Magic Steve.

As always, the Social Committee supports giving back to the community; therefore the Committee chose to support The Jimmy Fund Clinic. The attached link will provide you with an idea of what the children need to keep them occupied and their minds off the challenges they face with their disease. Please keep in mind that many of the patient's immune systems are not at full strength, therefore they request we collect items that are new or are already packaged. <http://www.jimmyfund.org/abo/jimmy/wishlist.html>.

LeLachur Park, Lowell, MA

Save the Date!
Registration Will Open Soon at www.ispeboston.org/events

Friday, September 17, 2010 Young Professionals Boat Cruise

Boston Belle Charters
Marina Bay, Quincy, MA

Save the Date!
Registration Will Open Soon at www.ispeboston.org/events

Tuesday, September 21, 2010 Softball Game - Young Professionals Vs. Seasoned Professionals

Boston, MA

Save the Date!
Registration Will Open Soon at www.ispeboston.org/events

Wednesday, October 6, 2010 Annual Product Show

Last Call for Exhibitors. We are down to our last 25 Tables. If you want to exhibit this year, register today.
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25 Chapter Members Take the Challenge, Join CPIP™ Study Group

by Janet Tice, GMP Piping, with photos by Joyce Chiu, Perceptive Informatics

In another first for the Boston Area Chapter and ISPE in North America, the Chapter has successfully launched its CPIP Study Group. With its kickoff meeting on May 26th, the goal of the Study Group is to make it convenient and fun for qualified Chapter Members to obtain the CPIP - Certified Pharmaceutical Industry Professional credential. Available only through ISPE, the CPIP credential establishes a "global competency standard" for industry professionals working in and supporting product development through manufacturing. It is intended to recognize those in the industry whose experience and knowledge make them outstanding leaders. Candidates are assessed through demonstrated education and experience, which involves a rigorous application process and a written examination.



CPIP Study Group leadership is ably provided by Chapter Past President Doyle Johnson.

Following several months of publicity, both formal and word-of-mouth, 25 Chapter Members stepped forward to join the Study Group, recognizing the benefit of group effort, free course materials (generously provided by ISPE), convenient and comfortable classroom space courtesy of Genzyme in Framingham and expert leadership provided by Chapter Past President Doyle Johnson as CPIP Study Group Leader. Candidates are a diverse group, representing the full spectrum of Chapter membership in terms of years in the industry, job function, company type and gender.



Study Group members represent the full spectrum of Chapter membership in terms of years in the industry, job function, company type and gender

At the first session, CPIP and Chapter veteran Allan MacDonald shared his personal experience completing the CPIP application and exam, giving candidates a good grasp of what to expect and how to approach this somewhat daunting process. The Study Group has adjourned for the summer, allowing members to independently work on their individual applications, but will resume in the fall with another round of three-hour study sessions (10 in total) in preparation for an October exam. To quote one Study Group member, "There are questions to be answered at the end of each learning objective and the class has a lot of fun with them. If everyone does as well as the class, we'll all pass the exam!"

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to Cambridge

by Keyur Doshi with photos by Viriya Shloul, both of Acceleron Pharma

They came, they saw, they learned! There is no better way to describe the level of enthusiasm exhibited by the sheer number of people who took part in the Single-Use Technology Seminar and Facility Tour at Acceleron Pharma in Cambridge on May 11th.

The evening began with a Members-only tour of the Acceleron Pharma Clinical Manufacturing Facility. This was a unique opportunity for Chapter Members to view first-hand some of the interesting approaches taken by Acceleron in its early phase, clinical GMP facility.

Following the tour, the evening's first speaker - Acceleron Senior VP of Manufacturing Bob Steininger - provided great insight into the company's pilot and GMP manufacturing strategy and how the concept of a disposable facility complements that strategy. He described the design basis of the disposable aspect of the facility which incorporates some interesting concepts like no purified water or steam system...something unheard of only a few short years ago.



Chapter Member and Meeting Manager Keyur Doshi (r) of Acceleron led one of the groups that toured the Acceleron facility.



A standing room only crowd listened attentively as a series of speakers discussed various aspects of single-use manufacturing technology.

In the second talk of the evening, speakers Paul Slaman of Shire HGT and industry consultant James Vogel provided an overview of Shire's implementation of single-use systems at their Lexington facility. The core topics they discussed were Shire's single-use business processes which include material selection, process evaluation and material/process comparison. They also emphasized a critical factor in such assessments: a successful owner-vendor partnership.

The third and final talk of the evening by Xcellerex President and CEO Parrish

Galliher was extremely informative as he reviewed the current state of industrial research in new technologies for single-use manufacturing, especially downstream processing. Some technologies, such as single-pass ultrafiltration and pre-packed chromatography, looked very promising and have already generated a lot of curiosity. Others, like simulated moving-bed chromatography and expanded-bed chromatography, though still in their nascent stage, have demonstrated significant savings - in case studies at least.

We need to thank everyone who made this event a success, not least of all the many Boston Area Chapter professionals (over 100) who turned out for the event and took part in a lively discussion on single-use systems. Beyond a doubt, this event was a huge success and managed to generate a lot of excitement among Chapter Members, demonstrating the high level of interest in this area of technology.

Members Explore Career Options with Industry Leaders at Tufts Gordon Institute

by the Membership Services Committee with photos by Joyce Chiu, Perceptive Informatics



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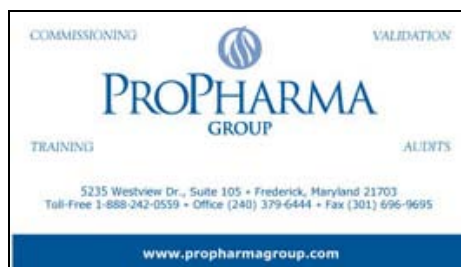
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On a warm Thursday evening on June 10th, local professionals met at Tufts Gordon Institute in Medford to see old friends, make new ones and, more importantly, learn from a panel of nine experienced industry leaders, all from different fields and companies. This unique event was organized by the Boston Area Chapter Member Services Committee to assist individuals looking for information to help them grow professionally or those interested in exploring a variety of different career options in a single evening.



Tufts Gordon Institute host Mary Viola enjoys a light moment with attendees.

After a "welcome" reception (with a great array of dinner items), Gordon Institute Professor Mary Viola formally welcomed the panelists and attendees to Tufts. Her comment that one of the Gordon Institute's goals is "Helping Engineers and Scientists" struck a great opening note. Next, the nine panelists introduced themselves and opened with brief remarks in three areas: what inspires them about their jobs, how they had overcome a hurdle in their careers and one piece of advice on how to succeed in their field.

Although each of the panelists was from a different discipline, a few common themes were evident:

- be willing to try something different, something out of your comfort zone;
- recognize the virtue of having patience; and
- keep an open mind regarding new possibilities in one's career track.



Panelist Cheryl Marrotta of Genzyme with Barry Potts (left) and Ric Feldt of the Chapter's Member Services Committee.

After the welcome and panelists' introductory comments, five breakout sessions were held with the panelists, with participants able to visit with each for fifteen minutes in a friendly round-table atmosphere. The following are some of the highlights of these discussions:

Beth M. Wescott, P.E. **Operational Excellence:**
Director, Site Operations Management, Andover, Pfizer Global Manufacturing

Beth discussed issues such as how to facilitate, how to consolidate resources, the importance of "learning the ropes" in an organization and how to get people better involved in continuous improvement.

Cheryl Marrotta **Corporate Quality:**
Vice President, US Therapeutics Quality Operations, Genzyme

Cheryl hosted a lively session that spoke to points such as how important it is to find the time to make improvements, to get out of a reactive mode and become more proactive. She recommended getting out of one's comfort zone (a point echoed by several of the panelists) and described her career ladder of different companies (Millipore, Ion Pure Technologies, Genzyme) and various quality positions. She also spoke of the advantages of being able to connect to people on an individual level, person to person, rather than



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through formal positions.

Michael J. Kaufman, Ph.D. **Pharmaceutical Product Development:**
Vice President, Pharmaceutical Sciences, Millennium: The Takeda Oncology Company

Mike spoke of the day-to-day management required for his position and how this related to bringing new pharmaceuticals to market. He also answered questions regarding how he learned to plan and budget for large scale projects.

Susan Dana Jones, Ph.D. **Biotech Process Development & Tech Transfer:**
Vice President and Senior Consultant, BioProcess Technology Consultants

Susan described what her job entails on a day-to-day basis and how she started her own company, helping to shape the future with her past experience.

Bob Steininger **Biopharmaceutical Manufacturing:**
Senior Vice President, Manufacturing, Acceleron Pharma

Bob discussed his experiences at small and larger companies and the levels of expertise that can be acquired at both sizes of companies. He also gave advice to those wanting to switch from lab/office management into managing drug development projects.

Robert Mitchell, P.E. **Architecture & Engineering:**
Vice President, Engineering, SPEC Process Engineering & Construction

Rob stressed the importance of learning the history of the field you're in and described his career experiences and how they shaped his approach. He also spoke of sustainability (green engineering) and stressed that this new directive can be addressed by employing good engineering practices, that is, by doing the right thing.

Lisa Wyman **Production Engineering:**
Senior Production & Engineering Manager, Boston Scientific

Lisa discussed topics such as lean engineering, as well as how important it is to prove the connections between quality, customers and costs. Some key points of her advice included create opportunities to keep learning, take on responsibility and find mentors.

Roop Kumar **Automation Engineering:**
President & Founder, Aztec Technologies

Roop discussed some technical aspects of what his company provides and how he overcomes some common hurdles, as well as how the experiences from his past positions at such companies as Wyeth and Amgen have shaped the approaches he used at his own company.

Peter Mosgrove **Business Development, Sales & Marketing:**
Head of Marketing, Mettler-Toledo Thornton

Peter discussed how important it can be to take different avenues in one's career and how important those experiences were in his own career. After being a part of R&D, then sales, he enjoyed marketing because it allowed him to help educate people on what products can do.



Panelist Lisa Wyman of Boston Scientific with attendees (l to r) Bernadette St. John, Nancy Buczko and Cynthia Laksawana.

Attendees at this unique event - from young professionals to seasoned veterans - were offered a rare opportunity to gain personal insights from a diverse group of distinguished industry professionals, all in a single evening. One of the attendees in particular, an enthusiastic high school student, seemed especially pleased with the information she gained. We hope this event helps her formulate her future career direction.

ImprovBoston Creates a Splash at the Summer Social

by Janet Tice, GMP Piping, with photos by Joyce Chiu, Perceptive Informatics

In another "first" for the Boston Area Chapter, members and guests gathered at the Hard Rock Café in downtown Boston on June 16th for an evening of food, drink, networking and a live performance by the ImprovBoston comedy team. The Chapter used the event to honor our many hardworking volunteers, all of whom were invited to attend at no charge. In addition, they received a special thank you from outgoing President Sylvia Beaulieu for their invaluable contributions to the Chapter during the past year and a voucher for free attendance at an educational program of their choice during the upcoming 2010-11 program season. (Those volunteers who missed the event will receive their voucher in the mail.)



Outgoing President Sylvia Beaulieu thanked volunteers for their contributions to the Chapter.



Incoming President Jim Grunwald found himself in the hot seat during ImprovBoston.

As if that weren't enough, the event also acted as a benefit for Backpacks for Kids, a local nonprofit that donates backpacks complete with school supplies to Boston area children in need. Attendees who brought backpacks and/or school supplies received free tickets for raffle items generously donated by RW Sullivan (Red Sox tickets), Integrated Builders (video camera), Hard Rock Café/ImprovBoston (\$150 gift certificate),

American Plant Maintenance (autographed Celtics photo) and GMP Piping (Red Tail Golf Club, Devens - \$200 gift certificate plus private golf lesson).



Boston's Hard Rock Café provided an exciting backdrop for this year's Spring Social & Volunteer Appreciation.

All in all, attendees donated 10 backpacks, two Red Sox gym bags and tons of school supplies. Plus, the event raised over \$300 for the purchase of additional supplies by Backpacks for Kids which is now well on its way toward reaching its goal of 500 backpacks this year, thanks to generous ISPE members!

After an hour or so of socializing and snacking on a dazzling array of appetizers, members were coaxed into their chairs for ImprovBoston whose members provided entertainment custom-crafted especially for the Chapter. Comedy routines were created on the spot - that's why they call it improv! - with the life sciences industry and those who work there as the central theme. Chapter Officers Sylvia Beaulieu and Jim Grunwald



Another brave Chapter Member takes the stage...

took more than their share of ribbing - proving they each have a sense of humor equal to their leadership skills. Jim even took the stage at one point for a prolonged (and hilarious) interrogation by the Improv team. To his credit, he kept his cool throughout - good practice for the role of Chapter President!

Many thanks to Chris Opolski and his hardworking Social Committee who did a great job creating another fun and relaxing get together for Chapter members. And special thanks to all the volunteers who dedicate their time and effort to making the Chapter shine!

Millipore Tour Demonstrates Successful Sustainability Efforts

by James Koloski, RDK Engineers, with photos by Joyce Chiu, Perceptive Informatics

On Thursday, June 24th close to 100 people braved a late afternoon thunderstorm to attend a powerful program on the sustainability efforts undertaken by the Millipore Corporation. Following a lively networking reception and light refreshments, David Newman, Millipore's Senior Director for Global Sustainability, reviewed the company's vision and mission to create a more sustainable company while Paul Lukitsch, Millipore's World-Wide Energy Manager, spent close to an hour delivering an in-depth view of the tangible changes Millipore has enacted to meet the sustainability challenge. And the results he described were no less than stunning.



Millipore Corporation treated the Chapter to an upclose and personal look at their sustainability efforts.

Since implementing the program in 2006, Millipore has achieved an impressive 15 percent reduction in greenhouse gasses, a 15 percent reduction in electricity use, a 30 percent reduction in the use of gas for their boilers and cut 22 percent of their water usage, all in demanding manufacturing environments.

Paul reviewed several projects that Millipore has undertaken to achieve these goals including a building envelope project that took the insulation value of a building housing a newly constructed clean room from an R1 to an R22. He also reviewed the construction of a new clean room that gets all of its electricity from Green-e certified wind energy. This exceeds the LEED requirements by a full 35 percent.

Following the presentation, attendees divided up into smaller tour-sized groups and were led on an interactive tour of the Bedford facility. A unique "shotgun-start" approach allowed each of the groups to ask tons of questions of the Millipore staff people manning each stop. Attendees were able to view the extensive solar arrays and inverter room that provide a portion of the facility's electricity. They got an up-close view of an individual solar panel demonstration in the courtyard that powered one of Millipore's Milli-Q Integral systems.

Individual motion-controlled, energy efficient T-5 fluorescent lighting in the warehouse illuminated another stop on the tour. Not only did the new lighting save electricity, the brighter illumination significantly reduced warehouse "pick errors," an additional and totally unexpected money saver. Yet another stop described a project that analyzed the use of compressed air, then achieved a significant KWH savings by using enhanced leak detection and lowering the overall operating pressure from 110 to 90 psi.

Light was also shed on a project in the cafeteria where the meeting took place. Millipore had retrofitted the lighting fixtures with digital dimming ballasts, occupancy sensors and wall controls to create a "light harvesting" environment that reacts to the room's usage and daylight availability to obtain maximum efficiency. At another stop, this time in the boiler room, everyone was able to view the controls enhancements to the existing boilers. that realized a 29 percent reduction in gas consumed and a 0.9 year simple payback.

Given all of this, probably the most talked about stop on the tour was to review the implementation of over 1,100 plug load controllers in individual employee workstations. The controllers provide a mix of continuous power and motion detected outlets that shut down non-critical equipment in each workstation when it is



Paul Lukitsch, Millipore's World-Wide Energy Manager, described the many changes undertaken by Millipore to reduce energy use.

vacant. Everyone on the tour immediately saw a need in their own teenager's bedrooms for these controllers.

Many thanks to Dave Newman, Paul Lukitsch and their staff at Millipore. They provided extensive help in putting this program together and making it such a huge success. If you're interested in finding out more about the company's commitment to sustainability I would encourage you to visit the sustainability section on the company's website at www.millipore.com.

Tech Talk: Mechanical Polishing and Residue on Stainless Steel Surfaces

by Daryl L. Roll, P.E.

Have you ever wiped a vessel and found that the wipe had excessive black debris? This is common on mechanically polished vessels, especially when they have not been properly prepped and cleaned. The discoloration on the wipe is classified as polishing debris consisting of ground-in stainless steel particles and abrasive residue. The residue is a thin film not generally visible on the surface and its removal can be problematic since it consists of very fine particles (metallic debris from sanding/polishing, abrasives, and other compounds or polymers) that adhere to the surface.

Cleanliness evaluation of new equipment including vessels, process equipment and components is recommended prior to FAT testing or installation. Additionally, the condition of surfaces in equipment for pharmaceutical processing compliant with ASME - BPE requirements should be documented.

Inspection

Inspection and sampling of mechanical polished surfaces is performed with the use of a clean room wipe and alcohol. First, scrub the surface with light to moderate pressure using an alcohol wipe over approximately one square foot area. Next, inspect the wipe visually and/or under magnification to initially evaluate the severity and physical characteristics of the residue. The residue can appear white to light gray in color or, more commonly, dark gray to black.

If residue is observed, the wipe can be further evaluated with advanced analytical techniques to identify the metals or organic compounds present. ICP-MS (Inductively Coupled Plasma-Mass Spectrometry) and EDX (Energy Dispersive X-Ray) are used to identify the inorganic elements (metal oxides) present on the wipe from the surface residue. FTIR (Fourier Transfer InfraRed Spectroscopy) is used to identify any organic compounds.

Testing Results

The testing results of vessels over the past 5 years are presented below to describe the typical components found in the residue. These tests were often the result of the appearance of rouge on the surface of the vessel or the appearance of a wipe from the equipment surface that was considered excessively colored. The analyses of the wipes are summarized in Table 1, from highest to lowest average concentrations. The risk of this film on the surface can be categorized as inhibiting the cleaning and passivation treatment, potentially available for release into the process or product fluids or as a source of rouge and corrosion products.

The elemental analyses lead to the following conclusions. The most prevalent elements (iron and chromium) are from the stainless steel particles present on the surface from polishing (sanding) operations. The second most prevalent group of elements (calcium, sodium, potassium and magnesium) is from process fluids or water. Silica (silicates) is found at a similar level of concentration and is one of the more common abrasive media components used in polishing operations. Other abrasive elements including aluminum are also seen at lower concentrations. The last group of elements includes manganese, which is often present on the surface of stainless steel, and metals found in low concentrations in stainless steel such as copper, molybdenum, zinc and titanium. Phosphorus is sometimes found and generally originates from cleaners or from the stainless steel. Carbon is not quantitatively evaluated since the wiping material is largely composed of carbon.

Organic analyses of the surface residues show a low level of oils and greases, waxes, esters, phthalates and assorted polymers. These are compounds that can be found in polishing processes or in the wipe itself. As in all this testing, a blank (clean) part of the wipe is processed in addition to the colored or residue-laden section for comparison. (Note: The variance in the blank analyses, combined with the variability in the residue analyses due to the low (ppm) levels of contaminants, means only qualitative results are presented.)

Table 1 - Analysis of Wipe Sample

Element	Average Concentration	Source
Iron	Very High	Stainless steel particles / rouge
Chromium	High	Stainless steel particles

Calcium	Moderate	Water or process fluids
Sodium	Moderate	Water or process fluids
Silica	Moderate	Abrasive media
Potassium	Low	Water or process fluids
Magnesium	Low	Water or process fluids
Nickel	Very Low	Stainless steel particles
Aluminum	Very Low	Abrasive media or SS surface
Manganese	Very Low	Stainless steel surface
Zinc/Phosphorus/Copper /Molybdenum /Titanium	Trace	Water/Abrasive/Stainless steel

Very High	-	20% ± 15%
High	-	15% ± 10%
Moderate	-	10% ± 5%
Low	-	5% ± 5%
Very Low	-	2% ± 2%
Trace	-	1% ± 1%

Remediation Techniques

Removal of these films has been attempted in a number of ways, including hand wiping with an alkaline cleaner, electrochemical cleaning (flash electropolishing) and high pressure washing with particulate removal chemistries. Results vary based upon the condition of the surface and the technique employed. Electropolishing of the surface has been shown to effectively remove both the surface contamination and the damage layer often associated with mechanically polished surfaces. Hand wiping removes the majority of the residue, but can require multiple treatment efforts with hot water washing cycles between wiping efforts. Pressure washing or the use of particulate removal chemistries is generally only marginally successful, unless combined with additional mechanical cleaning efforts.

Table 2 - Removal of Debris from Mechanical Polishing

Method	Objective	Comments
Hand wiping with alkaline cleaners, followed by hot water rinsing	Effective at removing mechanical polishing residue	May require multiple applications until wipe testing results are satisfactory.
Electrochemical cleaning or flash electropolishing	Effective at removing mechanical polishing residue	Removes surface material producing clean surface
High pressure water jetting of the surface	Removes larger particles but not typical polishing debris	Generally ineffective at removal of mechanical polishing debris.

Summary

Analysis of wiping of product contact surfaces is a method to determine characteristics of potential residue or contamination. The residue from wipe samples show that it is mostly stainless steel particles and oxide compounds generated from the mechanical polishing with lower levels of abrasive compounds and water or process fluid residues. Each project presents a different level of contaminants based on existing conditions and polishing or cleaning techniques employed on the equipment surfaces. Sampling and testing of the residue will indicate the source and guide you in the proper treatment technique to be used.

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As Astro Pak's Chief Technology Officer, Daryl L. Roll serves as the primary senior technical advisor for corrosion, surface chemistry and stainless steel passivation. With over 30 years of experience in chemical processing, he is a participant on the ASME BPE Subcommittees for Surface Finish and Materials of Construction requirements and a leading contributor for the Rouge and Passivation Task Groups. Mr. Roll holds a B.A. in Chemistry and Earth Science from the California State University of Fullerton and a Professional Engineer's license from the State of California. For further information, he may be contacted at droll@astropak.com.

Industry News In Brief

by Patti Charek

Xcellerex Announces Groundbreaking for New State-of-the-Art Biomanufacturing Facility

Xcellerex, Inc. announced that it has begun construction of a state-of-the-art cGMP FlexFactory® biomanufacturing facility at its headquarters location in Marlborough, MA. Construction will be completed in September 2010. The facility, the second FlexFactory at the company's headquarters, will expand Xcellerex's capacity to provide bridge biomanufacturing services for clients that are planning or building their own FlexFactory facilities. The plant will also support Xcellerex's contract manufacturing operations.

The new facility will feature 2,000 liter Xcellerex XDR single-use bioreactors and modular single-use downstream unit operations through bulk-product. Xcellerex President and CEO Guy Broadbent commented, "This facility represents an important milestone for Xcellerex..." Xcellerex founder and Chief Technology Officer Parrish Galliher added, "This new FlexFactory facility...will be a great case study, demonstrating the power of the FlexFactory capability. We will achieve new working capacity in less than six months, at a fraction of the cost required for a conventional facility. This will also give us a hands-on educational tool to help prospective customers achieve a deeper understanding of how a FlexFactory operates." (Source: Xcellerex Website, 9 June, 2010)

Xcellerex and Collaborators Demonstrate Rapid Production of Swine Flu H1 Hemagglutinin

Xcellerex, Inc. and Pfenex Inc. announced that the companies, along with deltaDOT Ltd. and BioPharm Services have successfully demonstrated the production of purified swine flu H1 hemagglutinin (California strain) in 42 days starting from the amino acid sequence of the protein. During that period, the gene was cloned and expressed, fermentation and purification processes developed, and the quality product shown to be fully within the specifications set out by the Defense Threat Reduction Agency (DTRA) under its Accelerated Manufacturing of Pharmaceuticals contract.

The test followed completion of 24-month, \$19 million Phase 1 and Phase 2 contracts funded by both the Defense Advanced Research Projects Agency (DARPA) and the DTRA Transformational Medical Technologies Initiative (TMTI). The contracts are part of a government effort to support development of advanced manufacturing technology to address pandemic or biosecurity threats. The test results exceeded the goal for rate of production by at least 10-fold and exceeded all product quality specifications.

The test demonstrated the speed and capability of the platform in producing a real-world vaccine, in this case swine flu H1, within 12 weeks of receipt of an unknown target amino acid sequence. The team succeeded in developing a strain and bioprocess, and fully characterizing the purified product in less than six weeks and at a cost, that (scaled to manufacturing) would be less than \$0.50/dose. (Source: Xcellerex Website, 17 May, 2010)

Regulatory Affairs Workload at Drug Development Firms Shows Dramatic Increase

A growing volume of global drug development and commercialization activity during the past decade has dramatically increased the workload for regulatory affairs professionals at pharmaceutical and biotech companies, according to a study recently completed by the Tufts Center for the Study of Drug Development. The study, the first systematic assessment of global regulatory affairs performance, found that the regulatory affairs function within drug development companies has grown steadily, with most departments tending to hire from within. This comes at a time when a growing number of those companies are outsourcing more of their clinical trial work to external service providers. Findings from the Tufts CSDD analysis were reported in the March/April Tufts CSDD Impact Report.

"As more of the clinical function continues to be outsourced, regulatory affairs personnel will need to coordinate closely and communicate with external service providers. They will be challenged to handle a growing workload as their companies seek to improve R&D efficiency in an operating environment marked by ever-rising costs," said Tufts CSDD Senior Research Fellow Ken Getz, who conducted the study.

Based on data from mid-size and large pharmaceutical and biotechnology companies with global drug development operations, the study also found that:

- Regulatory affairs functions support, on average, 100 major projects per year, two-thirds of which are in clinical research phases.
- On average, 39 percent of regulatory staff has more than 10 years of experience. This compares to 9 percent for clinical staff.
- Annual average internal staff turnover for regulatory affairs groups was 6.5 percent, compared to 21 percent for clinical groups.
- Companies report that only 5 percent of staff are contract employees, who are engaged most frequently in connection with dossier compilation. (Source: Center for the Study of Drug Development, 11 March, 2010)

New Approaches to R&D May Prove Best Path for Drug Developers

Innovative approaches to drug development, including alliances and partnerships, may prove the best way to increase the rate at which the research-based drug industry brings new products to market, according to a panel of pharmaceutical and biotech industry leaders recently convened by the Tufts Center for the Study of Drug Development.

Because patents on dozens of drugs are due to expire within the next few years - paving the way for generics to compete with those products - drug developers are in a race to develop and win market approval for new medicines. "No one has yet figured out how to reliably identify early on which newly discovered compound will bear fruit," said Tufts CSDD Director Kenneth I Kaitin. "This is spurring companies across the industry to experiment with a growing range of new tools and approaches to weed out unpromising drug candidates earlier, speed development, and reduce development costs."

According to Tufts CSDD, drug development, which starts in discovery and may involve examining many thousands of compounds, takes an average of 15 years to produce a product approved for sale in the US. Industry executives, who convene several times a year at the Tufts CSDD Executive Forum Roundtable, noted that while a growing number of drug companies are developing alliances with external service providers, those approaches have not yet emerged into full-fledged partnerships, where both parties share development risks and rewards. The executives also agreed that the following new approaches, among others, may help increase R&D efficiency:

- Reducing distinctions between phases - Traditional distinctions between clinical phases is a matter of practice and not a legal requirement. Starting human trials earlier may offer a way to save money and time.
- Engaging in collaborative relationships - Agreements between sponsors, similar to the formation of the Asian Cancer Research Group, Inc. announced by Eli Lilly, Merck, and Pfizer in February, may help accelerate research.
- Using exploratory INDs - This relatively new type of pre-Phase I clinical trial lets sponsors evaluate up to five chemical entities or formulations simultaneously to identify a lead compound.

Upcoming Tufts CSDD Executive Forum Roundtable meetings in 2010 will focus on the following: Outsourcing Strategies Across the Value Chain (Sept. 16) and Strategies for Optimizing the Drug Development Process (Nov. 4). To learn more, call 617-636-2170. (Source: Center for the Study of Drug Development, 6 April, 2010)

Rising Clinical Trial Complexity Continues to Vex Drug Developers

Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs, according to a study recently completed by the Tufts Center for the Study of Drug Development. The study found that the median number of procedures per clinical trial increased by 49 percent between 2000-03 and 2004-07, while the total effort required to complete those procedures grew by 54 percent. The new study updates an analysis conducted by Tufts CSDD two years ago, which provided the first quantitative assessment of the impact of protocol design on clinical trial performance.

"More complex and burdensome protocols are extending study cycle times, increasing costs, and challenging patient recruitment and retention," said Tufts CSDD Senior Research Fellow Ken Getz, who conducted the study. "Wide observed differences in complexity and execution burden by phase and therapeutic area indicate that pharmaceutical and biotechnology companies can target their efforts to improve protocol design and improve clinical trial operating performance."

According to Getz, the rise in the number of eligibility criteria used to screen volunteers has contributed to a decline in volunteers enrolling in clinical trials. And once volunteers enroll, he said, the larger number of procedures per protocol is dissuading study volunteers from staying in trials through to completion.

The new analysis, reported in the May/June Tufts CSDD Impact Report, also found that:

- Wide variability exists in complexity and execution burden per protocol between therapeutic areas and clinical study phases, indicating opportunities to streamline design.
- Between 2002 and 2007, protocols targeting diseases in oncology, immunology, and the central nervous system saw the most rapid growth in the total number of procedures and in the burden to execute those procedures.
- Overall growth in complexity and execution burden grew at the slowest rate for protocols in Phase III studies, as companies, looking to contain costs, gathered more data in early phases of clinical research. (Source: Center for the Study of Drug Development, 5 May, 2010)

Dyax Corp. Sells Rights to Xyntha Royalties to Paul Capital Healthcare for \$12M

Dyax Corp. has sold its rights to royalties and other payments related to the commercialization of Xyntha by Pfizer, Inc., a licensee under the company's phage display Licensing and Funded Research Program (LFRP), to an investment fund managed by Paul Capital Healthcare. Under the terms of this sale, Dyax received an upfront cash payment of \$10 million and will be eligible to receive milestone payments totaling up to \$2 million based on Xyntha sales in 2010 and 2011. A portion of the upfront cash payment was applied to Dyax's debt obligations under the LFRP and, net of this and other required payments, Dyax received approximately \$6.8 million, exclusive of potential future milestone payments.

Xyntha, marketed as ReFacto AF in Europe, is a recombinant factor VIII product for patients with hemophilia A for both the control and prevention of bleeding episodes and surgical prophylaxis. The peptide ligand, used in the purification process during the manufacture of Xyntha, was discovered by Dyax

using its proprietary phage display libraries. Xyntha is distinguished as the only recombinant factor VIII treatment to utilize an entirely synthetic purification process.

The LFRP provides access to the Dyax's phage display libraries in various types of licenses and collaborations. Dyax maintains more than 70 ongoing license agreements with various research, biotechnology and pharmaceutical companies under the LFRP. To date, licensees have advanced 17 product candidates into clinical development and one product (Xyntha) has received market approval. (Source: Business Wire, 20 April 2010)

Genzyme and Carl Icahn Reach Agreement

Genzyme Corporation and Carl Icahn and certain of his affiliated private investment funds recently announced an agreement to settle their proxy contest. Under the agreement, the Icahn funds will withdraw its slate of four nominees for Genzyme's board of directors and vote its Genzyme shares in favor of the company's nominees, and Genzyme will appoint Steven Burakoff, M.D., and Eric Ende, M.D., to serve as directors immediately following its annual meeting of shareholders.

Dr. Burakoff, one of the Icahn Funds' nominees, is Professor of Medicine, Hematology and Medical Oncology at the Mount Sinai School of Medicine and Director of the Tisch Cancer Institute at the Mount Sinai Medical Center. Dr. Ende, a participant in the Icahn funds' proxy solicitation, is a former biotechnology analyst with Merrill Lynch.

"Over the past year, we have made substantial progress in enacting operational and organizational changes to return to our historical path of sustainable growth," said Henri A. Termeer, Genzyme's chairman and chief executive officer. "This agreement provides a pragmatic and constructive solution that allows us to focus on continuing to strengthen and build the company to create value for our shareholders."

Carl Icahn said: "I am always pleased when a proxy fight can be avoided. I believe Drs. Burakoff and Ende will add significant medical and financial expertise to the Genzyme board. I am also very heartened that the Genzyme board recently brought on Ralph Whitworth, a longtime activist, as a director, and announced that Dennis Fenton will shortly be added to the board as well." Mr. Icahn went on to say that the addition of these four directors represents a good outcome for shareholders, who are now better represented on Genzyme's board. "New oversight at the director level will help this great company achieve its full potential," said Mr. Icahn.

Genzyme's board currently consists of ten members, all of whom have been nominated for re-election at the company's annual meeting. Following the appointment of Drs. Burakoff and Ende and Dennis M. Fenton, Ph.D., former executive vice president of operations at Amgen Inc., the company's board will consist of 13 members. (Source: Genzyme Website)

Philips and RXi Pharmaceuticals Sign Joint Research Agreement

Royal Philips Electronics and RXi Pharmaceuticals announced that they have entered into a joint research agreement to explore the benefits of combining proprietary technologies from both companies for the targeted delivery of experimental therapeutics based on RNA interference (RNAi).

Compounds based on RNAi represent a promising new class of drugs for the targeted treatment of a number of diseases including cancer and cardiovascular disease. Currently, however, one of the greatest challenges in developing RNAi-based therapeutics is finding ways to deliver them to their target while keeping them fully active. The joint research program between Philips and RXi will address this challenge by exploring, in preclinical studies, the possibility of using RXi's sd-rxRNA (self-delivering rxRNA) in conjunction with Philips' ultrasound technology to achieve the targeted delivery and monitoring of RNAi-based compounds in cells.

"The most important technological challenges that need to be addressed in order to realize the promise of RNAi-based approaches to treating various human disorders are efficient and safe delivery of the RNAi compounds to the targeted organs, and uptake of these compounds by relevant cells," said Noah D. Beerman, President and CEO at RXi. "By combining RXi's proprietary sd-rxRNA molecules, which have unique properties of 'self delivery,' and Philips' ultrasound technologies, we will be working together to achieve targeted and specific delivery to relevant organs and tissues, which could potentially boost the efficacy of RNAi-based disease treatments."

Diseases, as well as their potential cures, are associated with specific processes at a cellular and molecular level. RNAi technology is a breakthrough in understanding how genes are turned on and off and represents a new approach to drug development. Therapeutics that leverage this breakthrough technology can potentially target the cause of specific diseases by silencing harmful genes and preventing disease-causing proteins being produced.

To realize this potential, it is important to first optimize RNAi compounds in a way that confers them with the required drug properties and second to enhance their delivery to cells that express these harmful genes. RXi's proprietary rxRNA molecules are chemically modified to provide them with important properties such as stability in biological fluids, low stimulatory effect on the immune system and high target specificity. Philips' image-guided ultrasound-mediated drug delivery platform offers researchers a unique approach to investigating the delivery of various therapeutic molecules across blood vessel barriers and facilitating their uptake in cells. It capitalizes upon Philips' existing expertise in medical imaging

technologies for diagnosis, therapy planning and minimally-invasive medical procedures. (Source: Business Wire, 3 June, 2010)

NIH Approves Advanced Cell Technology's Stem Cell Line for Federal Funding

Advanced Cell Technology, Inc. announced that human embryonic stem cell (hESC) line MA135 was unanimously approved for federal funding at the 100th Meeting of the Advisory Committee to the Director (ACD) National Institutes of Health (NIH). In addition to MA135, seven additional stem cell lines derived at ACT are currently under review by the NIH. Five of these lines were produced without embryo destruction using ACT's proprietary single-blastomere "embryo-safe" technology. The federal funding could accelerate the company's clinical activities.

There were previously only 67 hESC lines eligible for use in NIH-funded research. "We are extremely pleased with the NIH's decision to add this line to their registry," said Robert Lanza, M.D., Chief Scientific Officer of ACT. "This decision facilitates the use of embryonic stem cells as a potential source of replacement cells to treat a wide range of human diseases."

"This approval is a watershed moment for the company, because it provides the company with the opportunity to pursue non-dilutive federally funded research programs utilizing a stem cell line derived solely by technology that we deployed," said William M. Caldwell IV, Chairman and Chief Executive Officer of ACT. "We are optimistic that we will secure approval for additional lines using our single-cell blastomere technology in the coming months as the NIH finalizes their Proposed Rule Making expanding the definition of what will constitute a stem cell line that is eligible for federal funding. We applaud the NIH for its ongoing efforts to make more stem cell lines available to the scientific community." (Source: Advanced Cell Technology, Inc., 11 June, 2010)

Genzyme to Remain Under Federal Oversight for Seven to Eight Years

Genzyme Corp. will remain under federal oversight for the next seven to eight years as it works to fix quality-control problems that have bedeviled its Allston Landing plant for 15 months. The timetable was spelled out in a consent decree struck between Genzyme and the FDA. Under its terms, Genzyme will pay a previously disclosed \$175 million federal fine, the first in its 29-year history. The agreement, filed with the US District Court in Boston, is subject to court approval.

Genzyme's plant in Allston produces drugs to treat rare genetic disorders such as Gaucher, Fabry, and Pompe diseases. The treatments can cost as much as \$300,000 a year per patient. Last summer, the company had to suspend drug production after a virus was found at the plant. The temporary shutdown delayed shipments of enzyme replacement therapies Cerezyme (for Gaucher disease) and Fabrazyme (for Fabry disease), frustrating patients and depressing sales.

Although the company said earlier this year that it expected to pay the \$175 million fine, other terms of the consent decree were not known until May. Among them, Genzyme agreed to move fill-finishing work for its domestic drug shipments out of the Allston site by November. The transfer of fill-finishing for overseas shipments will take place by Aug. 31, 2011. Late last year, inspectors found bits of steel, rubber, and fiber in some drugs during the fill-finishing process in Allston. The work will be moved to a Genzyme operation in Waterford, Ireland, and to subcontractors such as Hospira Inc., subject to approval by federal regulators. The firm faces additional fines if it fails to meet FDA deadlines.

In all, the Cambridge biotechnology giant will spend two to three years in remediation under the consent decree, and another five years under oversight by a third-party contractor, the Quantic Group, a Livingston, N.J., consulting firm focused on boosting manufacturing quality and safety. Quantic will craft a remediation plan with Genzyme, and the company could be fined \$15,000 a day for missing milestones.

"This is in line with our expectations," Genzyme spokeswoman Lori Gorski said of the consent decree. "We're focused on restoring the confidence of the FDA. And we now have a framework to achieve our goal of returning to the highest manufacturing standards and restoring a reliable product supply for our patients." (Source: Robert Weisman, Boston Globe, 25 May, 2010)

Genzyme's Lumizyme Wins FDA Approval

Genzyme Corp. recently received a significant boost by winning long-sought FDA approval for its enzyme replacement drug Lumizyme to treat Pompe disease patients in the US. The decision represents the most important US drug approval for the Cambridge biotech since 2003, when regulators signed off on Fabrazyme, a treatment for Fabry disease. Genzyme hopes Lumizyme will become a blockbuster, with worldwide sales of at least \$1 billion annually.

"This will be our fastest-growing product," said John P. Butler, president of personalized genetic health at Genzyme. The company has spent more than 10 years and \$1 billion developing Lumizyme, Butler added. "The United States is the single largest market for this product, and now we have complete access to that market," he said. No other company is marketing a drug for Pompe disease in the United States. The company plans to ship the drug from a plant in Geel, Belgium.

Most immediately, the FDA approval means Genzyme will be able to sell Lumizyme to about 200 adult patients in the US who have been receiving it for free under a charitable program. The company can also begin marketing the drug to about 1,000 adults who have Pompe disease but are not yet being treated.

Genzyme executives said the drug's price would probably be in line with what it costs in the more than 40 countries in Europe and elsewhere where it is already approved: about \$300,000 per patient annually. Most of the expense is paid by insurers or governments.

Pompe disease is a rare disorder that causes heart and skeletal muscle weakness that can progress to respiratory problems and eventually cause death from respiratory failure. The enzyme deficiency "is a devastating condition without the appropriate treatment," said Dr. Julie Beitz, a director at the FDA's Center for Drug Evaluation and Research in Silver Spring, Md. "The approval of Lumizyme will provide an important treatment for patients diagnosed late in life with Pompe disease." Genzyme currently produces another version of the Pompe disease drug, called Myozyme, in 160-liter batches at its plant in Framingham. But Myozyme has been reserved primarily for infants and children with more serious forms of the disease.

The company made Lumizyme at its Allston plant in Boston for about three years to supply US adults with Pompe under its charitable program. But production was suspended last spring after the FDA issued a warning about manufacturing shortcomings and Genzyme concluded the plant was overtaxed. (Genzyme still makes two other enzyme replacement drugs at Allston Landing: Cerezyme for Gaucher disease, its top-selling product, and Fabrazyme for Fabry disease.)

But in the past 15 months, it has struggled with a host of quality-control problems at the plant, including the discovery of a virus that caused a monthlong production halt last summer, leading to a consent agreement with the FDA. Since it stopped production in Allston, Genzyme has shipped the drug from Belgium for its charitable program.

FDA officials had approved Myozyme in smaller batches, but they required a separate approval process for Lumizyme because the agency concluded the two drugs have different carbohydrate structures. Initially, Genzyme applied to make the drug in Allston Landing. But after its manufacturing problems surfaced, it negotiated a different path to Lumizyme's approval with the FDA, including the plan to make the drug overseas. (Source: Robert Weisman, Boston Globe, 26 May 2010)

Shire Pays \$200m for Lab Buildings

Drug maker Shire Pharmaceuticals is buying four buildings in Raytheon's former Lexington campus along Route 2 for more than \$200 million, marking a major move forward for the recovering commercial real estate market. The transaction is the largest purchase of laboratory space in the region's growing life sciences sector, real estate officials said.

Shire and another biotech company are already tenants in the buildings, which made them an attractive investment to a slew of bidders. But the pharmaceutical giant won out in the end for the 435,000 square feet of laboratory space in the campus, which is known as Lexington Technology Park. The deal also includes an option for Shire to build on adjacent land that could host up to 370,000 square feet of space, according to people involved in the transaction who were not authorized to speak publicly.

The park is spread across 100 acres at the intersection of routes 2 and 128. Raytheon sold the site to Patriot Partners in 2002, and its buildings have since been renovated. In November 2009, the town of Lexington voted to support an additional 380,000 square feet of development within the park, helping to clear more room for biotechnology companies to expand there.

Shire began relocating operations from Cambridge several years ago and in 2008 launched a \$460 million campaign to build a campus there and add 750 jobs. It held a ceremony to mark the completion of a 200,000-square-foot manufacturing facility on the property. The firm has also broken ground on another 150,000-square-foot facility expected to be completed in two years. (Source: Casey Ross, Boston Globe, 28 May, 2010)

Covidien Buys Device Maker for \$2.6B

In its largest deal since it was spun out of the former Tyco International Inc. three years ago, Covidien PLC yesterday said it will buy vascular device maker ev3 Inc. for \$2.6 billion in cash and debt, a 19 percent premium over ev3's closing stock price Friday. Covidien, the former Tyco HealthCare division, is incorporated in Ireland but has its corporate headquarters in Mansfield. It has acquired more than a dozen smaller companies in the past three years, as it worked to emerge from the Tyco shadow and build its own brand in the fields of medical devices, hospital supplies, and generic drugs.

"This gives us another avenue of growth," Covidien chief executive Richard J. Meelia said yesterday. "The majority of our growth has come from our surgical and pharmaceutical franchises. We've been very interested in building out the vascular market. It's going to be one of our biggest growth opportunities."

Vascular devices are used in surgeries and procedures involving veins, arteries, and nerves. The two market segments served by ev3 - peripheral vascular and neurovascular disease technologies - together ring up annual sales of about \$3.5 billion, Meelia said. Ev3, based in Plymouth, MN, anticipated revenue of about \$525 million this year, meaning Covidien will have room to expand sales of its new line of stents, catheters, angioplasty balloons, plaque excision systems, embolization coils, and other devices.

Until last year, Covidien was only a small player in the vascular space, marketing hospital supplies such as compression sleeves and anti-embolism stockings. Then it acquired VNUS Medical Technologies of San

Jose, Calif., last May, paying \$440 million to gain a minimally invasive treatment for venous reflux disease. At that time, Covidien set up a vascular device business unit within its medical device group. That was followed in June by Covidien's smaller acquisition for an undisclosed sum of Bacchus Vascular Inc., a Santa Clara, Calif., pioneer of interventional therapies for deep vein thrombosis.

The devices sold by VNUS and Bacchus serve two of the fastest-growing niches in the vascular device business, markets expanding by estimated annual rates of 19 percent and 15 percent respectively, said Harry Glorikian, managing partner at Scientia Advisors, a Cambridge consulting firm that focuses on life sciences. Those products were "toes in the water," he said, positioning Covidien for a deeper dive with ev3, whose products compete with industry giants such as Natick's Boston Scientific and Medtronic of Minneapolis.

Covidien, which posted revenue of \$10.7 billion last year, has about 42,000 employees worldwide, including 1,300 at its sites in Massachusetts, including Bedford and Chicopee in addition to Mansfield. Its largest business group is medical devices, which generated \$6.1 billion in 2009 sales, or about 57 percent of the total. Within the Covidien medical device business, however, vascular devices accounted for less than 10 percent of revenues last year. (Source: Robert Weisman, Boston Globe, 2 June 2010)

Pfizer Set to Cut 300 jobs in Andover

Pharmaceutical giant Pfizer said it will eliminate about 300 manufacturing jobs at its Andover plant over the next five years as part of a global reduction in production capacity following its purchase of Wyeth Pharmaceuticals. The job cuts, which will be accomplished through layoffs and attrition, will leave Pfizer with just over 2,000 employees in Massachusetts, including 1,300 at the former Wyeth manufacturing plant and 750 at two research and development sites in Cambridge.

Wyeth had nearly 1,900 production and research workers at its Andover plant in the fall of 2007, two years before Pfizer completed its blockbuster \$68 billion purchase of the drug maker. Since then, Pfizer has been working to scale back manufacturing capacity.

The new round of cuts in Andover is part of a broader move to reconfigure the Pfizer production network worldwide. As part of that effort, the company said it will shut down eight plants in the United States, Puerto Rico, and Ireland, while reducing operations at another six - including the Andover plant - in the United States, Puerto Rico, Germany, Ireland, and the UK. Those moves will pare 6,000 jobs in all. Despite the Andover rollback, Pfizer remains committed to Massachusetts, where it is developing and manufacturing drugs and collaborating with academic labs and smaller biotech partners, said Liz Power, spokeswoman for the New York-based drug maker.

Pfizer's Power said that, even with the staffing cutback, the company plans to continue its three existing production lines in Andover. Workers there make BeneFix, an injectable medicine that treats hemophilia B, a bleeding condition also known as Christmas disease; bone morphogenetic protein, which stimulates bone growth for people with spinal degeneration and is marketed by Pfizer partner Medtronic as part of a drug-device combination known as Infuse; and a component of the pneumonia vaccine Prevnar. Pfizer plans to consolidate global production of the Prevnar component - polysaccharides that target certain strains of pneumonia - in Andover as part of its overall consolidation, Power said. (Source: Robert Weisman, Boston Globe, 19 May 2010)

Pfizer to Pay Academics to Find Uses for Molecules

Pfizer Inc. said that it has agreed to pay \$22.5 million over five years to researchers at the medical school of Washington University in St. Louis in a bid to breathe new life into existing compounds developed for other uses. The researchers will be able to check out about 500 Pfizer molecules targeting a range of diseases and study new uses for those molecules that the researchers believe are promising, said Jeff Gordon, director of the medical school's Center for Genome Sciences & Systems Biology.

The Pfizer molecules were approved for a different use, are in development for a separate indication or failed during clinical testing for another use, said Don Frail, chief scientific officer at Pfizer's Indications Discovery Unit. The unit was established in 2007 to enlist outsiders for help finding additional uses for compounds that Pfizer already had in various stages of development.

The project marks the latest effort by a big drug maker to share valuable intellectual property in a bid to replace aging pipelines. Companies have established joint ventures with rivals and signed agreements with scientists overseas, and rely heavily on outside companies called contract research organizations to share the risks and reduce the costs of developing new medicines.

Pfizer and Washington University's medical school said their collaboration is unusual in that industry and academia have teamed up in drug development. Drug makers have normally paid universities for basic research into diseases or enlisted their help during clinical testing of promising drugs. "What we are looking for is the intersection of their academic interest and disease knowledge with a mechanism we have a compound for," Mr. Frail said. Should a compound win approval for a use pursued by a university researcher, the medical school could get rights to the discovery and negotiate a licensing agreement, according to Dr. Gordon and Mr. Frail. (Source: Jonathan D. Rockoff, Wall Street Journal, 18 May, 2010)

Huge Biotech Center Gets Green Light

Cambridge officials approved development of what would be the region's largest biotech complex, a 1.7 million-square-foot research center near Kendall Square. The \$1 billion development, planned by Alexandria Real Estate Equities Inc., will include five new buildings as well as restoration of several historic buildings on 11 acres along Binney Street. The city's planning board signed off on the project.

"The Binney Street project is one of the most important developments of its kind and will further enhance Cambridge's position as a world-leading center for life-science research and development," said Tom Andrews, regional market director for Alexandria. Alexandria has not announced a starting date for construction and is still looking for a main tenant. The project is also slated to include two acres of public parks and a new transportation center for buses, bicycles, and vans. (Source: Casey Ross, Boston Globe, 4 June, 2010)

Vertex Says Hepatitis Drug Meets Goal

Vertex Pharmaceuticals Inc. said its potential hepatitis C drug met a key goal of curing the hard-to-treat virus in a late-stage study. The company said 75 percent of patients receiving telaprevir for 12 weeks experienced a sustained response, or viral cure.

Hepatitis C is a virus that can cause severe liver damage. In the study, telaprevir was followed by a combination of pegylated interferon and Ribavirin, which is considered the standard of care. Patients on that telaprevir combination were compared with those receiving only pegylated interferon and Ribavirin. After 48 weeks, 44 percent in that arm of the study experienced a sustained response. The company expects to ask for FDA approval during the second half of 2010. (Source: Associated Press, 26 May 26, 2010)

Abbott Labs to Become Number One Drugmaker in India

Abbott Laboratories has declared its intention to acquire Indian branded generics drugmaker Piramal Healthcare's Solutions business (Domestic Formulations), for an up-front payment of \$2.12 billion, plus \$400 million annually for the next four years (for a total of \$3.72 billion), and will result in Abbott gaining number one position in the Indian pharmaceutical market.

There had been strong speculation that France's Sanofi-Aventis and US behemoth Pfizer were vying to buy Piramal. Abbott says that the transaction will not impact on its earnings outlook for 2010, and the company's plans to fund the deal with cash on its balance sheet. This deal is subject to shareholder approval of Piramal Healthcare and other customary closing conditions, and is expected to close in the second half of 2010.

The announcement is further evidence of the growing importance to multinational drug majors of generics and emerging markets, and further accelerates Abbott's growth in such sectors. The US company recently completed its buy of Belgian firm Solvay Pharmaceuticals for \$6.6 billion and revealed a collaboration with India's Zydus Cadila, as well as the creation of a new stand-alone Established Products Division to focus on expanding the global markets for its leading branded generics portfolio.

"This strategic action will advance Abbott into the leading market position in India, one of the world's most attractive and rapidly growing markets," said Miles White, chairman and chief executive of Abbott. "Our strong position in branded generics and growing presence in emerging markets is part of our ongoing diversified pharmaceutical strategy, complementing our market-leading proprietary pharmaceutical offerings and pipeline in developed markets." He continued, "Emerging markets represent one of the greatest opportunities in health care - not only in pharmaceuticals - but across all of our business segments. Today, emerging markets represent more than 20 percent of Abbott's total business."

India is one of the world's fastest-growing pharmaceutical markets, due in large part to branded generics, noted Abbott in a statement. The market will generate nearly \$8 billion in pharmaceutical annual sales this year, a number that is expected to more than double by 2015. Abbott estimates the growth of its Indian pharmaceutical business with Piramal to approach 20 percent annually, with expected sales of more than \$2.5 billion by 2020.

Branded generics have significant brand equity in many international markets, providing durable, sustainable franchises for future growth. Piramal markets the products in its Healthcare Solutions business in India only and does not market traditional generic products. Today, says Abbott, branded generics account for 25 percent of the global pharmaceutical market, have the majority of market share in the largest emerging markets, and are expected to outpace growth of patented and generic products.

The Mumbai-based Piramal Healthcare Solutions business has a comprehensive portfolio of branded generics with annual sales expected to exceed \$500 million next year in India, and market-leading brands in multiple therapeutic areas, including antibiotics, respiratory, cardiovascular, pain and neuroscience. This business grew 23 percent in the 2010 fiscal year, faster than the market in India. The business will become part of Abbott's newly-created, stand-alone Established Products Division. (Source: thepharmaletter, 21 May, 2010)

Study Finds Bristol-Myers Squibb Melanoma Drug Improves Survival Rate

Researchers have scored the first big win against melanoma, the deadliest form of skin cancer. An experimental drug significantly improved survival in a major study of people with very advanced disease.

The results, reported at a cancer conference, left doctors elated. "We have not had any therapy that has prolonged survival" until now, said Dr. Lynn Schuchter of the Abramson Cancer Center at the University of Pennsylvania, a skin cancer specialist.

The drug, ipilimumab, works by helping the immune system fight tumors. The FDA has pledged a quick review and doctors think the drug could be available by the end of this year.

Melanoma is the most serious form of skin cancer. Last year in the US, there were about 68,720 new cases and 8,650 deaths from the disease. Worldwide, more than 50,000 people die of melanoma each year. "The incidence is rising faster than any other cancer," said one of the study's leaders, Dr. Stephen Hodi of Dana-Farber Cancer Institute in Boston. "When it spreads to vital organs, it's almost always fatal."

The skin cancer study involved 676 people around the world with advanced, inoperable melanoma who had already tried other treatments - a very grim situation. They were given one of three treatments: ipilimumab by itself, with another immune-stimulating treatment, or the immune-stimulating treatment alone. After two years, 24 percent of those given the drug alone or in combination were alive, versus 14 percent of those given just the immune-stimulating treatment.

Average survival was 10 months with ipilimumab versus just more than six months for the others, which worked out to a 67 percent improvement in survival for those on the drug, said one of the study's leaders, Dr. Steven O'Day of the Angeles Clinic and Research Institute in Los Angeles. Doctors hope the drug can provide more benefit if given earlier in the course of the disease and to less sick patients. Ten percent to 15 percent of patients on ipilimumab had serious side effects related to the drug's actions on the immune system. Most were treatable with high doses of steroids, but 14 deaths were thought to be related to the treatment. That's still far fewer than deaths due to the cancer.

The study was funded by Bristol-Myers and Medarex Inc., a company that co-developed the drug and was bought by Bristol-Myers last year. A spokeswoman said Bristol-Myers has not yet set a price for the drug, but similar treatments for other cancers cost several thousand dollars a month or more. Results were reported at the American Society of Clinical Oncology's annual conference in Chicago and published online by the New England Journal of Medicine. (Source: Marilynn Marchione, Associated Press, 5 June 2010)

Regulatory & Legislative Highlights

by Deepen Joshi

FDA Launches Medical Device and Radiation-Emitting Product Website

The FDA has launched the Center for Devices and Radiological Health (CDRH) Transparency Website as part of the agency's transparency initiative. The site will provide information about medical device and radiation-emitting product regulatory processes and decisions, and summaries of data that provide the rationale for agency actions.

The new website is part of an ongoing effort within CDRH, across the FDA and across the Department of Health and Human Services to enhance public communication and transparency. CDRH's previous site provided information about approved products, industry guidance, medical device safety, and adverse event reports. On the new site, this and additional information are displayed in a more user-friendly format. The site includes information related to the following topics:

- Premarket submissions for approved and cleared products
- Postmarket performance and safety
- Compliance and enforcement
- Science and research
- Educational resources
- CDRH performance data

The site also features a searchable Total Product Life Cycle database, which integrates premarket and postmarket medical device information from multiple data sources into a single snapshot. In the coming months, FDA will expand the CDRH Transparency Web site to include premarket approval and clearance reviews. (Source: FDA Website, 19 April, 2010)

FDA Approves a Cellular Immunotherapy for Advanced Prostate Cancer

The FDA has approved Provenge (sipuleucel-T), a new therapy for certain men with advanced prostate cancer that uses their own immune system to fight the disease. Provenge, manufactured by Seattle-based Dendreon Corporation, is indicated for the treatment of asymptomatic or minimally symptomatic prostate cancer that has spread to other parts of the body and is resistant to standard hormone treatment.

Prostate cancer is the second most common type of cancer among men in the US, behind skin cancer, and usually occurs in older men. In 2009, an estimated 192,000 new cases of prostate cancer were diagnosed and about 27,000 men died from the disease, according to the National Cancer Institute.

Provenge is an autologous cellular immunotherapy, designed to stimulate a patient's own immune system to respond against the cancer. Each dose of Provenge is manufactured by obtaining a patient's immune

cells from the blood, using a machine in a process known as leukapheresis. To enhance their response against the cancer, the immune cells are then exposed to a protein that is found in most prostate cancers, linked to an immune stimulating substance. After this process, the patient's own cells are returned to the patient to treat the prostate cancer. Provenge is administered intravenously in a three-dose schedule given at about two-week intervals. (Source: FDA Website, 29 April, 2010)

FDA Approves Genzyme's Lumizyme for Treatment of Late-Onset Pompe Disease

The FDA has approved Genzyme's Lumizyme (alglucosidase alfa) for patients ages 8 years and older with late-onset (non-infantile) Pompe disease, a rare genetic disorder that occurs in an estimated 1 in every 40,000 to 300,000 births. Its primary symptom is heart and skeletal muscle weakness, progressing to respiratory weakness and death from respiratory failure. Lumizyme is manufactured at Genzyme facilities in Ireland and Belgium.

In Pompe disease, a gene mutation prevents the body from making an enzyme, or making enough of the enzyme called acid alpha-glucosidase (GAA), necessary for proper muscle functioning. GAA is used by the heart and muscle cells to convert a form of sugar called glycogen into energy. Without the enzyme action, glycogen builds up in the cells and, ultimately, weakens the heart and muscles. Lumizyme is believed to work by replacing the deficient GAA, thereby reducing the accumulated glycogen in heart and skeletal muscle cells.

Lumizyme is being approved with a risk evaluation and mitigation strategy (REMS). It will only be available through a restricted distribution system called the Lumizyme ACE (Alglucosidase Alfa Control and Education) Program to ensure that it is used by the correct patient group. Lumizyme will carry a Boxed Warning because of the risk of anaphylaxis, severe allergic reactions, and immune-mediated reactions.

Currently, the only other treatment for Pompe disease available in the US is Myozyme, which is also manufactured by Genzyme at its manufacturing facilities in Framingham and Allston. Myozyme has been in short supply due to limited manufacturing capacity. The manufacturer reserved Myozyme to treat infants and children with Pompe disease because younger patients generally have a much more aggressive form of the disease. (Source: FDA Website, 25 May, 2010)

FDA Approves Amgen's Prolia for Treatment of Osteoporosis

The FDA has approved Prolia, an injectable treatment for postmenopausal women with osteoporosis who are at high risk for fractures. Prolia is manufactured by Amgen Manufacturing Limited, a subsidiary of Amgen Inc.

Osteoporosis is a disease in which the bones become weak and are more likely to break. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, 80 percent of the people in the US with osteoporosis are women. One out of every two women over age 50 will break a bone in their lifetime due to osteoporosis.

People with osteoporosis at high risk for fracture include those that have had an osteoporotic fracture, or have multiple risk factors for fracture; or those who have failed or are intolerant to other available osteoporosis therapy. Prolia works to decrease the destruction of bone and increase bone mass and strength. An injection of Prolia is recommended once every six months.

Prolia was approved with a risk evaluation and mitigation strategy (REMS) that includes a Medication Guide for patients and communications to health care providers that explains the risks and benefits of the drug. (Source: FDA Website, 1 June, 2010)

FDA Revises Recommendations for GlaxoSmithKline and Merck Rotavirus Vaccines

The FDA has revised its recommendations for rotavirus vaccines for the prevention of the gastrointestinal disease in infants and has determined that it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq. The vaccines are manufactured by GlaxoSmithKline and Merck, respectively.

In March, the FDA advised doctors to stop using Glaxo's vaccine after researchers found evidence of a porcine circovirus known as PCV1 in the vaccine. Those tests did not find the same pig virus in Merck's Rotateq, which has stayed on the market. However, more sensitive tests subsequently conducted on Rotateq found a low level of the same PCV1 virus, as well as a related porcine circovirus known as PCV2. Neither virus is known to cause illness in humans.

The agency reached its current decision based on a careful evaluation of information from laboratory results from the manufacturers and the FDA's own laboratories, a thorough review of the scientific literature, and input from scientific and public health experts, including members of the FDA's Vaccines and Related Biological Products Advisory Committee that convened on May 7, 2010 to discuss these vaccines. The FDA also considered the following in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of vaccine recipients.
- The FDA has no evidence that PCV1 or PCV2 pose a safety risk in humans, and neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of death in some

parts of the world and hospitalization for severe rotavirus disease in the US. These benefits outweigh the risk, which is theoretical. (Source: FDA Website, 5 May, 2010; and Jennifer Corbett Dooren, The Wall Street Journal, 8-9 May, 2010)

FDA Approves Sanofi-Aventis' Treatment for Advanced Prostate Cancer

The FDA has approved Sanofi-Aventis' Jevtana (cabazitaxel), a chemotherapy drug used in combination with the steroid prednisone to treat men with prostate cancer. Jevtana is the first treatment for advanced, hormone-refractory, prostate cancer that has worsened during or after treatment with docetaxel, a commonly used drug for advanced prostate cancer.

In prostate cancer, the male sex hormone testosterone can cause prostate tumors to grow. Drugs, surgery, or other hormones are used to reduce testosterone production or to block it. Some men have hormone refractory prostate cancer, meaning the prostate cancer cells continue to grow, despite testosterone suppression. Different treatments are needed for men with this type of cancer.

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

Prostate cancer, which usually occurs in older men, is the second most common cancer among men in the United States, behind skin cancer. In 2006, the most recent year for which numbers were available, 203,415 men developed prostate cancer and 28,372 men died from the disease, according to the Centers for Disease Control and Prevention. (Source: FDA Website, 17 June, 2010)

FDA Approves New Indication for Novartis' Tasigna

The FDA has approved a new indication for Novartis' Tasigna (nilotinib) for the treatment of a rare blood cancer when it is first diagnosed. The cancer, called Philadelphia chromosome positive chronic phase chronic myeloid leukemia (Ph+ CP-CML), is a slowly progressing blood and bone marrow disease linked to a genetic abnormality.

Tasigna is believed to work by blocking a signal that leads to leukemic cell development. The new indication expands the use of Tasigna to adult patients in earlier stages of the disease. The FDA originally approved Tasigna in October 2007 for the treatment of Ph+CP-CML in adult patients whose disease had progressed or who could not tolerate other therapies, including Gleevec (imatinib).

When Tasigna was originally approved in October 2007, the FDA identified that the therapy placed patients at risk of an abnormal heart rhythm called QT prolongation. In March 2010, the FDA approved a Risk Evaluation and Mitigation Strategy (REMS) for Tasigna to help patients and health care professionals to better understand this risk. The REMS includes an updated Medication Guide and a communication plan to help reduce medication errors involving drug-food interactions and incorrect dosing intervals.

In CML, too many blood stem cells develop into a type of white blood cell called granulocytes. These granulocytes are abnormal and do not become healthy white blood cells. These cells can build up in the blood and bone marrow so there is less room for healthy white blood cells, red blood cells, and platelets. When this happens, infection, anemia, or unexpected bleeding may occur.

The FDA granted Tasigna a priority review for Ph+ CP-CML. The agency completed the review in six months. The new indication for Tasigna was approved under the FDA's accelerated approval program, which allows FDA to approve a drug to treat serious diseases with an unmet medical need based on an endpoint thought to reasonably predict clinical benefit. The company is required to collect additional long term efficacy and safety information data confirming the drug's benefit. The accelerated approval program provides earlier patient access to promising new drugs while the confirmatory clinical trials are being conducted.

Other FDA-approved drugs to treat CML include Gleevec and Sprycel (dasatinib). Tasigna and Gleevec are marketed by Novartis Pharmaceuticals; Sprycel is marketed by Bristol-Myers Squibb. (Source: FDA Website, 17 June, 2010)

FDA Approves First Diagnostic Assay to detect both HIV Antigen and Antibodies

The FDA has approved the first assay to detect both antigen and antibodies to Human Immunodeficiency Virus (HIV). It is approved for use in the diagnosis of HIV-1/HIV-2 infection in adults including pregnant women and children as young as two years old.

Manufactured by Abbott Laboratories, the highly sensitive assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. Since it actually detects the HIV-1 virus (specifically the p24 antigen) in addition to antibodies to HIV, the assay can be used to diagnose HIV infection prior to the emergence of antibodies. Most tests used today in the diagnostic setting detect HIV antibodies only. Although direct detection of the virus itself by nucleic acid testing is available, it is not widely used in diagnostic settings.

The Centers for Disease Control and Prevention report that approximately 18 million people in the United States are tested for HIV each year. Most recent CDC estimates are that there are about 56,000 new HIV infections in the United States each year. In addition, there are more than 1 million people living with HIV in

the United States, according to CDC.

The assay is not intended to be used for routine screening of blood donors. However, it is approved as a donor screening assay for HIV-1/HIV-2 infection in urgent situations where licensed blood donor screening tests are unavailable or their use is impractical. (Source: FDA Website, 21 June, 2010)

Pfizer Voluntarily Withdraws Cancer Treatment Mylotarg from US Market

Pfizer has announced the voluntary withdrawal from the US market of the drug Mylotarg (gemtuzumab ozogamicin) for patients with acute myeloid leukemia (AML), a bone marrow cancer. The company took the action at the request of the FDA after results from a recent clinical trial raised new concerns about the product's safety and the drug failed to demonstrate clinical benefit to patients enrolled in trials.

Mylotarg was approved in May 2000 under the FDA's accelerated approval program. This program allows the agency to approve a drug to treat serious diseases with an unmet medical need based on a surrogate endpoint - a laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that directly measures how a patient feels, functions, or survives.

Under accelerated approval, the company is required to conduct additional clinical trials after approval to confirm the drug's benefit. If those trials fail to confirm clinical benefit to patients, or if the company does not pursue the required confirmatory trials with due diligence, the FDA can withdraw the drug from the market using expedited procedures.

Mylotarg was approved to treat patients ages 60 years and older with recurrent AML who were not considered candidates for other chemotherapy. The initial approval was based on the surrogate endpoint of response rate (i.e., the percentage of patients whose leukemia decreased or disappeared in laboratory tests), observed in 142 patients with AML across three clinical trials.

A confirmatory, post approval clinical trial was begun by Wyeth (now Pfizer) in 2004. The trial was designed to determine whether adding Mylotarg to standard chemotherapy demonstrated an improvement in clinical benefit (survival time) to AML patients. The trial was stopped early when no improvement in clinical benefit was observed, and after a greater number of deaths occurred in the group of patients who received Mylotarg compared with those receiving chemotherapy alone.

At initial approval, Mylotarg was associated with a serious liver condition called veno-occlusive disease, which can be fatal. This rate has increased in the postmarket setting.

As a result of the withdrawal, Mylotarg will not be commercially available to new patients. Patients who are currently receiving the drug may complete their therapy following consultation with their health care professional. Health care professionals should inform all patients receiving Mylotarg of the product's potential safety risks.

Following the withdrawal, any future use of Mylotarg in the United States will require submission of an investigational new drug application to FDA. (Source: FDA Website, 21 June, 2010)

FDA Pushes Orphan Drug Research

Roche Holding AG, Johnson & Johnson, and Biogen Idec are being urged by US regulators to see whether existing medicines may help neglected disorders, after an incentive program failed to spark research on new therapies.

The FDA has published a list yesterday of 235 treatments that may have benefit in rare disorders and already have marketing clearance for other uses. Identifying "low-hanging fruit" may compel large drug makers to look beyond common ailments with guaranteed consumer demand, said Tim Cote, head of the agency's Office of Orphan Product Development. The list includes Roche's hepatitis drug Pegasys, J&J's leukemia medicine Leustatin, and Biogen Idec's multiple sclerosis drug Avonex.

About 30 million Americans have one of 7,000 rare diseases, defined by the FDA as conditions affecting fewer than 200,000 people in the US. Medicines developed to treat these conditions are called orphan drugs, under rules that encourage their development.

Roche's Pegasys has orphan status for chronic myelogenous leukemia. Roche is no longer studying Pegasys in cancer, said a spokeswoman for the company's Genentech unit.

Leustatin, made by J&J, is approved for hairy cell leukemia but has had orphan drug designation since 1990 for chronic lymphocytic leukemia and acute myeloid leukemia. J&J decided not to further develop Leustatin in part because there are other drugs available for leukemia, Ernie Knewitz, a spokesman, said. J&J is studying products for other types of neglected diseases, he said.

Also on the list is Biogen Idec's top-selling MS drug Avonex, which has had orphan designation since 1991 as a treatment for cutaneous t-cell lymphoma. While Biogen Idec initially pursued Avonex in "several indications," it now has no plans to develop it for cutaneous t-cell lymphoma, said Kate Weiss, a company spokeswoman. (Source: Catherine Larkin, The Boston Globe, 19 June, 2010)

IRS Accepting Applications for Qualifying Therapeutic Discovery Project

The IRS has announced that small firms may now begin applying for certification for tax credits or grants available under the Qualifying Therapeutic Discovery Project Program, created by the Affordable Care Act. These credits or grants are available for projects that show significant potential to produce new cost-saving therapies, create US jobs and increase US competitiveness.

Form 8942, Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program, and its instructions are now available. Companies may submit applications for certification beginning immediately. Applications must be postmarked no later than July 21, 2010.

The Qualifying Therapeutic Discovery Project Program is targeted to projects that show potential to produce new therapies, reduce long-term health care costs, or significantly advance the goal of curing cancer within the next 30 years. The credit or grant covers up to 50 percent of the cost of qualifying biomedical research, up to a maximum credit of \$5 million per firm and \$1 billion overall, and is only available to firms with no more than 250 employees. Credits and grants are available for investments made in 2009 and 2010.

As part of the review process for research projects, the Department of Health and Human Services (HHS) will evaluate each project for its potential to produce new therapies, reduce long-term health care costs or cure cancer within 30 years. Only projects that show a reasonable potential to meet these goals will be certified as eligible for the credit or grant. The IRS will issue certifications by the end of October, based on the determinations made by HHS. More information on this program, can be found at http://grants.nih.gov/grants/funding/QTDP_PIM/index.htm. (Source: IRS Website, 18 June, 2010)

New Members

- Mrs. Geetanjali Abbi, *Validation Engineer*, Genzyme Corporation
- Mr. William A. Apruzzese, *Health Science Specilist*, Department of Veterans Affairs
- Dr. Kumar Dhanasekharan, *Principal Scientist-Engineer*, Genzyme Corporation
- Mr. Herbert L. Dukeshire, *Sales Representative*, Meriden Cooper Corp.
- Mr. Ryan E. Ferguson, *Associate Center Director*, Epidemiology Research and Information Center
- Joe Fish, *Production Engineer*, AMAG Pharmaceuticals
- Mr. Robert F. Flynn, *Plant Engineer*, Genzyme Corp
- Mr. David Mark Fourman, *Lead Consultant*, Unify Consulting
- Mr. Kyle Haraldsen, *Assoc Director - Contract Manufacturing*, AMAG Pharmaceuticals
- Mr. William L. Hearn, *CEO*, Effervescent Inc
- Ms. Jennifer L. Higgins, *Validation Scientist*, Commissioning Agents Inc.
- Ms. Hsiu-Yin Hsiao, *Student*, Regis College
- Ms. Penny Kaufman, *Documentation Specialist Lead*, Genzyme Corporation
- Mr. Steven J. Krausert, *RSE*, Genzyme
- Lutfiye Kurt, *Graduate Student*, Northesatern University
- Mrs. Michele Laudenslager, *Validation Specialist*, Strategic Maintenance Solutions
- Mr. Steven Liechti, *Project Engineer*, Whiting-Turner Contracting
- Mr. Joseph G. Liscouski, *Executive Director*, Institute for Laboratory Automation
- Mr. Cory R. Loder, *Facilities Technician*, Acceleron Pharma
- Mr. John R. Marzilli, *District Director*, US Food and Drug Administration
- John Nevill
- Mr. Paul J. Nicholson, PE, *VP of Engineering*, The Beacon Group
- Mr. John S. Nikopoulos, *Continuous Improvement Specialist*, Genzyme
- Mr. Michael Noonan, *Consultant*, Valsource
- Emily Petrelis, *Validation Engineer II*, Genzyme
- Mr. Grant N. Pierce, *Pharmaceutical Market Manager*, BS&B Safety Systems Inc
- Ms. Meghan Reed, *Validation Specalist Associate*, Genzyme Corp

Mr. Scott Reese, *Associate Director*, Genzyme Corp
Mr. David J. Sartorius, *Assoc. Director Lean Transformation*, Genzyme Corporation
Mr. Hirdesh Singh, *Validation Engineer*, Genzyme
Valentin Splett, *Business Development Manager*, Bioengineering, Inc.
Mr. Steve Taliadouros, *Sr Plant Engineer*, Genzyme
Mr. Navin Tiwari, *Process Engineer*, Genzyme
Mr. Kevin Trottier, *Director, Facilities & Eng*, Celldex Therapeutics, Inc

Member Anniversaries

20+ Years of Membership

Mr. David C. Hardy
Mr. Thomas W. Moss, Applied Process Solutions, Inc
Mr. Hank Moes
Mr. Stephen R. Higham, PE, Genzyme Corp
Ms. Sandra Illich, Wyeth BioTech
Mr. Armen J. Nahabedian, Pfizer
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises
Mr. Michael A. Boenitz, DUSA Pharmaceuticals Inc
Dr. Richard V. Levy, PDA
Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz
Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation
Mr. Cesar B. Daou, PE, Daou Engineers Inc
Mr. Thomas R. Jerome
Mr. Robert W. Juffras, MS, Stryker Biotech
Mr. Frank J. Manning, VNE Corp
Mr. Alexander E. Smith, Jr., Parsons
Ms. Greta W. Davis, Lantheus Medical Imaging
Mr. John H. Evers, Lantheus Medical Imaging
Mr. David L. Hyde, Indpendant Contractor

15 Year Anniversary

Ms. Patricia J. Charek, RFWalsh collaborative partners
Mr. Steven Kennedy, PE, Xcellerex

10 Year Anniversary

Mr. Mark J. Keegan, Selecta Biosciences, Inc.
Mr. Anthony J. Meenaghan, Serono Laboratories Inc
Mr. Christopher J. Opolski, Alexion Pharmaceuticals
Mr. Matthew E. Teal, New England Laboratory Casework Co Inc

5 Year Anniversary

Mr. Michael S. Curry, NNE Pharmaplan US Inc
Mr. Christopher H. White, Eisai, Inc.

Mr. Rexford Hayes, ImmunoGen Inc
Mr. David Truex, Commissioning Agents

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