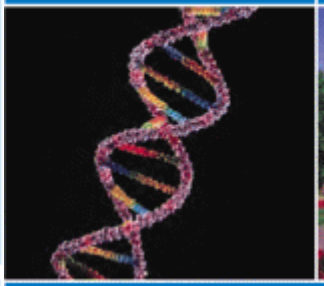
ISPE Boston Area Chapter
ENGINEERING PHARMACEUTICAL INNOVATION

www.ispeboston.org



NEWSLETTER

November 2009, Volume XIX, No. 6

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President's Message: Chapter Wins Top Award at ISPE Annual Meeting

Hello ISPE Boston Area Chapter Members,

Chapter Wins Top Award at Annual Meeting

Yes, Boston. We did it! This past week at the ISPE Annual Meeting in San Diego, the Boston Area Chapter was awarded the top honor, the North American/South American Affiliate Council "Platinum Grand Award for Excellence and Innovation."

We were awarded this recognition by a committee of judges based on the Chapter's past year's events and activities. I need to thank the entire 2008-2009 Board of Directors for their commitment to the Chapter and their extraordinary efforts during difficult times. The Chapter continued to add value to its membership by increasing the quality of the educational programs; increasing operating companies' involvement at all levels; creating a Young Professionals group; implementi a rigorous process of managing the Chapter's financial responsibilities and helping members who have found themselves with out a job.

We will be celebrating this award with our members in on December 1st at the Royal Sonesta in Cambridge. Keep an eye out for emails announcing this special event and plan to join the celebration!

Product Show Success

On October 7th we held our 18th Annual Product Show at Gillette Stadium and it was the best attended show in our history, with ove 1800 attendees. We had a wonderful Keynote Speaker and the most educational sessions, nine in all. I cannot speak highly enoug of the Product Show and Educational Program Committees, both of which worked tirelessly to put this show together. To Brian and Lee and to your committees, and to all of the other Chapter volunteers who worked together to ensure another successful Product Show - thank you from me and the Board for an outstanding day. Read on for wrap up articles and great photos.

Inaugural CEO Dinner

I am pleased to announce that our inaugural CEO/Executive Dinner Series was very successful with over a hundred members and

guests attending. The first CEO to speak was Don Kiepert, President and CEO of Lantheus Medical Imaging. He discussed Lantheu its corporate overview, just-in-time manufacturing and entrepreneurship. William Dawes, Vice President, Manufacturing & Supply Chain, discussed meeting manufacturing challenges using engineering controls. If you missed this first-ever event, the write-up and photos included in this newsletter will convince you to be at the next one!

Annual Meeting Report

For those who could not attend the conference, I want to mention a few items. On Sunday morning, there was a 5K Charity Run/Wal and some of our Boston Area Chapter Members attended. Doyle and I chose to walk and Amy and Rick ran. This was the first time this charity run took place and I am sure they will hold it again next year.

The 5K Charity Race was another chance for a winning performance by (l to r) Rick Pierro, Doyle Johnson, Sylvia Beaulieu and Amy Poole.

On Sunday night, the Boston Area Chapter hosted a cocktail reception for Chapter Members only and all who attended enjoyed som great food, drinks and networking with friends.

On Tuesday at the Members' luncheon, prior to the awards being announced, the Treasurer of the International Board spoke on the financials of the ISPE organization. Though last year was a tough year for the organization and there had to be some cuts made, including personnel, the financials are sound. But it will be a tough year moving forward. They are looking at new ways to reduce costs and increase revenue, some from the upcoming release of technical documents.

Chapter Support for Bio-Ball Special Olympics Massachusetts

This year, the Chapter has donated money and volunteers to Bio-Ball. This very special event is a one-day basketball tournament involving 16 local biotech and pharma companies and 16 Special Olympics basketball teams. The event is sponsored by all of the providers that support the local biotech community with all of the proceeds going to benefit basketball programs and activities at Special Olympics Massachusetts.

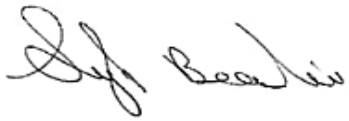
Bio-Ball had over 500 participants in this year's tournament and next year is expected to be even bigger. They have a great line-up c teams for next year including Archemix, Alnylam, CombinatoRx, Infinity, Genzyme, Momenta, Novartis, PAREXEL, Sepracor and others. The tournament will be back at the Buckingham, Browne & Nichols School on Saturday, March 27, 2010.

Most importantly, in the last 5 years Bio-Ball has raised over $310,000 for basketball programs and activities at Special Olympics Massachusetts... and they are striving for more! There are 180,000 people in Massachusetts with intellectual disabilities not involved with Special Olympics. The money they raise will allow them to reach out and offer those people a better, happier, healthier life. If yo would like to volunteer to help on the day of the event or would like to make a personal donation, please contact me at sbeaulieu@columbiacc.com or 978-222-9584.

As always, I want to thank our volunteers and our Members for supporting our Chapter. It is because of you that we were able to accomplish so much this past year and win top honors at the Annual Meeting. And we plan to continue that drive for excellence

through 2010 and beyond.

Sincerely,



Sylvia Beaulieu

President, ISPE Boston Area Chapter

Upcoming Chapter Events - Mark Your Calendar

Tuesday, December 1, 2009

Platinum Grand Award for Excellence and Innovation Celebration Social!

This past week at the ISPE Annual Meeting in San Diego, the Boston Area Chapter was awarded the top honor, the North American/South American Affiliate Council "Platinum Grand Award for Excellence and Innovation."

We were awarded this recognition by a committee of judges based on the Chapter's past year's events and activities. Thank you to t entire 2008-2009 Board of Directors for their commitment to the Chapter and their extraordinary efforts during difficult times. The Chapter continued to add value to its membership by increasing the quality of the educational programs; increasing operating companies' involvement at all levels; creating a Young Professionals group; implementing a rigorous process of managing the Chapter's financial responsibilities and helping members who have found themselves with out a job.

Help Celebrate the Success of **YOUR** Chapter!

Royal Sonesta Cambridge, Cambridge, Massachusetts

Click Here to Register!

Tuesday, December 8, 2009

Combination Products and Convergence: An overview of Clinical Benefits, Regulatory Issues and Manufacturing Challenges

Medical products, no matter how well designed, can only do so much to address many of the clinical problems today. In order to tacl the clinical problems of the future, medical devices will be used in combination with drugs and biologics (called combination products to treat a wide range of diseases from heart attack and stroke to Alzheimer's and diabetes and beyond!

Despite the controversy, the best known example of a combination product is the drug-eluting stent. However, the drug-eluting stent

also an extremely primitive example of a combination product. The quintessential example of a combination product is tissue engineering. Why? Because we have cells (biologics) producing proteins (biotech drugs) growing on polymer substrates (medical devices). It's hard to imagine more of a combination product than that - or can we? Nanotechnology also presents us with additional avenues to arrive at combination products.

During this presentation, participants will be exposed to examples of combination products on the market, under development and o the drawing board.

Royal Sonesta Cambridge, Cambridge, Massachusetts

Click Here to Register!

Tuesday, January 26, 2010

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

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

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

Click Here to Register!

Wednesday, February 17, 2010
Educational Program

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

18th Annual Product Show Attracts Record Turnout

by Mark Sitcoske, High Purity New England, Inc. with photos by Peter Teague, Boston Scientific, Inc.

The "Perfect Storm?" Maybe not quite but, with all indicators working against us, the ISPE Boston Area Chapter pulled off another outstanding success and once again enjoyed a record turnout for the 18th Annual Product Show at Gillette Stadium. Our industry ha not been immune to the economic downturn that has hit the country and the rest of the world but the Boston Area Chapter, its

wonderful volunteers, great Chapter management, supportive Board and great vendor community pulled off the unexpected. We sol out the Show two months earlier than last year, had record attendance and demonstrated that biopharm is not only alive and well bu prospering in this economic climate.

An expansive view of Gillette stadium always provides an exciting backdrop for the Show

The day began early with the half-day GAMP Forum

From Keynote Speaker Juan Enriquez to the outstanding educational program, the Boston Area Chapter is truly leading the way. Wi 278 vendors displaying their wares and over 1800 attendees buying, networking and learning, industry know-how was hard at work. Not only is this a compliment to all who worked so hard to make this event a smashing good time, it is also a testament to our cohesive, get-it-done Chapter. At times we want to pinch ourselves and ask, "Is this really happening in our back yard or am I dreaming?" No, its just darn good people doing a darn good job!

Over 275 vendor booths were a magnet for attendees

I've heard it said that the long shadow of Gillette Stadium reaches all the way to Fenway. While the Boston Area Chapter of ISPE ma not have quite that long a shadow, it has a loyal and enthusiastic following within the New England biotech community similar to the

strength of the Boston area teams - and 2009 was no exception. The outstanding array of educational offerings that included a worlc class keynote speaker, nine education seminars and a half-day GAMP Forum - not to mention the products and services on display from the full spectrum of vendors that serve the industry - attracted attendees from all over New England.

Multiple food stations ensured that visitors were kept well-fed throughout the day

The introductory level educational sessions incuded an update on ASME BPE Guidelines

And the many amenities offered at the Show sealed the deal. Some might say the Boston Area Chapter travels on its stomach and those who attended the Product Show would certainly agree. The food is always outstanding in both quantity and quality and 2009 w no exception. Comfortable seating areas for relaxed conversation completed the picture, all with an unparalleled view of the stadium Who could ask for more? (Product Show parking and admission are always free, of course. (Oh, and did I mention the food is free too?)

Every year, everyone on the Product Show Committee reports someone who missed it, someone who could not get away from what or a vendor who registered too late to secure a booth. This year, the exhibitor booths sold out in August, the earliest ever. The date i already set for next year: October 6, 2010 will be another great day at Gillette. Be sure to plan ahead so you'll be there to share the excitement.

A Special Thank You to Peter Teague

The ISPE Boston Area Chapter relies on the efforts of so many volunteers. From running programs to writing newsletter articles to organizing recreational events, there are few functions that are not supported by the work of these volunteers. As many people noticed during the recent Product Show, photos were being taken. For several years we have relied on eminently capable Chapter volunteer Peter Teague for this critical contribution. Peter's photos are always memorable, interesting and many times "over the top We would like to take this opportunity to recognize Peter for applying his professional level skills on our behalf with such great enthusiasm and creativity. Thank you, Peter, for a job exceptionally well done!

Keynote Speaker Juan Enriquez Provides a Fascinating Look into the Future

by Larry Ulfik, PennTech-Tofflon LLC

The ISPE Boston Area Chapter had the pleasure of welcoming keynote speaker Juan Enriquez to the Product Show on October 7th Enriquez is widely published on the topics of life sciences and national competitiveness. His background includes positions as the founding director of the Harvard Business School Life Sciences Project, CEO of Mexico City's Urban Development Corporation and Chief of Staff for Mexico's Secretary of State. He is currently a Managing Director at Excel Venture Management, a life sciences venture capital firm, and the Chair and CEO of Biotechonomy, a research and investment firm helping to fund new genomics firms.

Keynote Speaker Juan Enriquez immediately connected with audience members

In a presentation that was both fascinating and entertaining, Enriquez used humor and a unique ability to make connections between seemingly disparate concepts. He began by describing the New England life sciences community - and the Boston area particular - as a powerful engine of innovation in a position to he the U.S. out of its financial crisis. How? Through its unique perspective on the new "language" that will carry future generations forward.

He described language as the way in which we all perceive the world, bolstered by our senses, of course. But humans are uniq no other animal can teach others by using language and the technologies of printing, the internet, etc. He said that language changing and that we are now in the fourth epoch of language, t language of the genetic code or the language of life. According t Enriquez, we will use this new language to create new life forms even robots and "genetically modified" machines.

Describing himself as an historian, not a futurist, and using sometimes humorous graphics to aid our understanding and provide entertainment, Enriquez explained that our economy produces about 13 trillion dollars annually and that our debt is now about 23 trillion dollars, equal to about 23 year's worth of taxes! He explain we need to come up with a new model of innovation to pay off this debt; that the way out is not making more Ford trucks but having many small, innovative businesses become successful by producing profitable products based on their research. Making fuels from algae, brewing beer containing the beneficial ingredients found in wine, producing kidney function using bacteria or turning yogurt green in the presence of the contaminant melamine were a few of the examples Enriquez used to illustrate his point.

He then delved into the concept of community and what is needed to sustain it: that is, a vast complex of possibilities including acce to art, educational institutions, and forums for exchanges of ideas. A map of how one progresses from one idea to another shows a circuitous path through a community that supports the arts (like Boston) and also has companies and institutions involved in a wide variety of disciplines like plant biology, music, agriculture, electronics, bio informatics, etc. (again, like Boston). Ideas travel along "pathways" as individuals meet and exchange ideas through a variety of channels including job changes and forums like those sponsored by ISPE, for example. Enriquez described the Boston area as an excellent example of a community that provides a rich a fertile ground for communication that fosters innovation.

He then turned our attention toward education, an area where he believes change is needed if the U.S. is going to continue as a world leader. There are countries like Brazil that are taking their best young athletes and training them to become world-class soccer stars. He suggested that the U.S. should follow the same model by training its best students to become world leaders in business and academia and treating education like a "varsity sport," with diplomas based on performance.

In conclusion, he looked around and remarked that it is interesting that the ISPE Product Show is being held in a sports stadium since innovation is ultimately a contact sport. The solution for the recession is to start building innovative businesses that reduce costs and are viable. He said that Boston has an advantage in this area going back to the 70s and 80s. His final comment was that

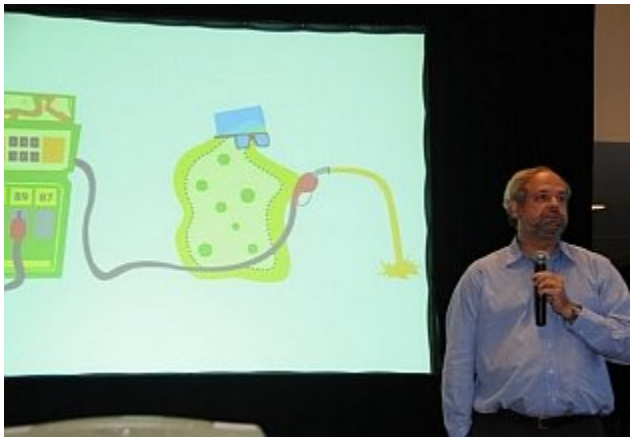
Previous Issues

future economic growth in the U.S. is on our shoulders and he urged us to get back to work!

CEO Dinner Series Opens with Lantheus Medical Imaging Execs

by Janet Tice, GMP Piping, with photos by Deepen Joshi, Sepracor

The November 3rd CEO/Executive Dinner, a first-ever event for the Boston Area Chapter, drew over a hundred interested members and guests to the Marriott Boston Cambridge for dinner and a riveting presentation by Lantheus Medical Imaging executives Don Kiepert, CEO and President, and Bill Dawes, Vice President, Manufacturing & Supply Chain.



Biofuels produced by living cells? Just one of the many innovations described during the keynote address

CEO Don kiepert introducing Lantheus to the local ISPE community

The first sign that this was a unique Chapter offering? The "formal" business attire worn by many attendees and the tables set with crisp white tablecloths and floral centerpieces in the large, well-appointed dining room. Before-dinner conversation buzz seemed above normal levels, with a sense of anticipation fueling the usual business chatter. As attendees poured in, it was evident that the Chapter's thorough preparation had achieved its goal - a great turnout of enthusiastic members and guests.

The genesis of this event materialized last year when newly-elected Boston Area Chapter President Sylvia Beaulieu learned the San Francisco Chapter had been successfully hosting a CEO's Corner on the west coast for several years. Not to be outdone, Sylvia recognized the New England area's biotechnology sector was an ideal location in which to support a similar event. During a meeting between Sylvia and Sean Brown, Director of Global Facilities & Engineering at Lantheus, to discuss Boston Area Chapter events, , t topic was raised and Sean agreed to present the idea to Don Kiepert, Lantheus Medical Imaging CEO and President. Don and his Executive Leadership Team immediately expressed interest in supporting the ISPE initiative. The CEO Dinner would be a great venu for Don to re-introduce Lantheus to the local ISPE community, while presenting a topic he is passionate about - entrepreneurial spiri

Chapter President Sylvia Beaulieu with Lantheus execs
Don Kiepert (r) and Bill Dawes (l)

Sylvia and Don then worked out the logistics and settled on a dual theme for the evening that would attract attention and ensure participation: the cultural transformation and technical innovations ongoing at Lantheus. Their goal was a presentation that would interest both ISPE members and Lantheus employees, with enough detail to interest even the most experienced engineer or executi - a goal that was met and exceeded, as the evening would soon prove.

Following the networking reception and dinner, Sylvia introduced Don, who described the transition of this Billerica-based medical imaging industry leader from its beginnings as New England Nuclear, through its growth years as a sub-division of larger companies and to its reintroduction as free-standing enterprise, Lantheus Medical Imaging. He stressed that the entrepreneurial spirit that fuele the company's success in its early years is alive and well a half-century later and comprises one of its crucial core values.

Among the many Chapter Members and guests
in attendance were (l to r) David Campanella,
Chris Opolski, Gene Dennen, Jay Zaino and Joey Buot.

Once Don had set the stage by discussing Lantheus' core values and his own leadership philosophy, he turned the microphone over Bill Dawes, Vice President, Manufacturing and Supply Chain. Bill presented a fascinating, multi-media tour through the just-in-time manufacturing process that converts raw material received from global reactors into finished product shipped from Lantheus' headquarters at the Billerica site to customers around the world - all in a single-day cycle time.

The presentations concluded with a panel discussion during which Sean joined Don and Bill on the podium to answer questions from the audience. Though the evening was no longer young, in another barometer of success, the questions were many and varied - ranging from the R&D pipeline, to healthcare reform, to emerging regulatory trends and the applications at Lantheus - and the answe insightful. The follow-on chatter and camaraderie showed no signs of wrapping up quickly.

The ISPE Boston Chapter extends its thanks to Don, Bill, Sean and the Lantheus Executive Leadership Team for an exciting evening and a successful kick-off to the CEO Dinner Series. Lantheus clearly has a bright future and is always looking to add top talent to its team. Visit them at www.lantheus.com to learn more. And be sure to contact the ISPE Boston Area Chapter at ispe@camihq.com if you would like to showcase your company at an upcoming CEO/Executive Dinner.

Process Control and Automation Expert Discusses PAT and QBD

by Lee J. Ward, Rockwell Automation, with photos by Rami Mitri, Spectra Automation

On Monday, September 14th, the Boston Area Chapter presented an educational program at Foley Hoag's attractively appointed facilities in Waltham. Presenter Glenn Restivo, Industry Manager, Life Sciences, Siemens Center of Competence, who heralds from lifetime's worth of experience in life sciences process control and automation, spent a balmy September evening educating his audience on the fine points of Process Analytical Technologies (PAT) and Quality by Design (QBD).

Speaker Glenn Restivo (l)
with Education Program Chair Lee Ward (r)

After a brief introduction by newly-elected Chapter President Sylvia Beaulieu, Glenn dove in at the deep end, submersing the audien in the business drivers which support the need for both PAT and QBD. He focused in on the challenges to modern biopharma manufacturing, both regulatory and economic, and expressed the need for change in all aspects of the industry, including social, economic, market and technological, in order that the challenges can be addressed.

So how is the industry adapting? At the forefront, as if it were the natural choice, there is new technology. This is being deployed in order to improve efficiency, yield and plant optimization. Glenn explained, "These can be easily achieved if considered at the design stage of a project and implemented through construction." However, the statement being "open" implied that such considerations are more difficult to achieve when a plant already exists and is subject to a more manual and paper-based mode of operation. This suggests, however, subject to downtime, planning and facility mobility, that such needs could be met, albeit more challenging at that time.

Then there is the subject of investment. In 2010, Glenn commented, capital expenditure is forecasted to drop by some 20 percent. H sees, therefore, that the key to wise investment would be the embrace of enabling technologies that provide plant visibility to the operation, thus facilitating agile decision-making throughout the manufacturing process. Overall this would allow the owner to make

quality decisions, almost in real time, that could affect productivity while satisfying the needs of the regulatory bodies.

Chapter Past President Dave Novak shares industry updates with colleagues

As if teeing up a golf ball, Glenn then launched the audience into the practical aspects of PAT, defined by the FDA as a mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA So the question arises: How do you achieve PAT? Glenn illustrated the technic aspects of a typical process control architecture that highlighted the sources of data (i.e. the process performance measurements) and how such information is made available to software-based systems. He noted that operators could moni deviations from the required parameters for a given process and make documented adjustments in order to maintain production quality.

In referring back to the need for QBD and how this would enable owners to lear more about what they are doing, Glenn quoted a customer who stated, "Just because you've done something in a particular way for a long time, doesn't mea its the right way to do it today." That quote highlighted and clarified the point Glenn had so eloquently conveyed: the need for a paradigm shift from "what ha always worked" to the "business drivers" when designing - or redesigning - a production process.

Glenn went on to analyze these imperatives for the benefit of the audience. For the purposes of simplification, he described PAT as a toolbox whose contents are aligned with a system of checks and balances that measure how near or far a process currently is in relation to the specific needs of the manufacturing operation. Using a key quote to illustrate his point, Glenn stated that "risk is inversely proportional to the process," which in turn focuses thinking toward employing these practices in order to follow a business-focused strategy while mitigating risk. He then drew an interesting parallel to the Department of Energy (DOE) which relies on expert leadership continuously under peer review in order that the goals are maintained within the bounds of checks and balances. To emphasize this point, he posed the question, "Would PAT, designed into a facility along the lines of the DOE model, realize a benefit?"

Attendees enjoy a light dinner during the networking reception

In conclusion, Glenn stated that, "The goal is to determine, while in the design phase, the best, predictable manufacturing process and, at the same time, build in an analysis which allows the process to actually be predictive, especially when applied to the design of a unit operation model." He commented that while the FDA is continuing to research the evolution of "demand-based manufacturing" and "personalized medicine," the need for such systems is more apparent. The question they themselves pose is, "Continuous manufacturing: is this even possible under currently accepted modes of operation?" However if you weigh the goals, objectives, challenges, and economics of continous manufacturing, then Glenn did at least touch on the fact that by employing QBD and implementing a regime of PAT, the Holy Grail of biopharma continuous process manufacturing is a possibility.

Young Professionals Launch Series of Events

by Dan Ramsey, Commissioning Agents, Inc.

The Boston Area Chapter Young Professionals (YP) have organized multiple events in the past couple of months, including the first annual boat cruise around Boston Harbor. They also partnered with the ASME's BPE Committee to organize three of the nine educational seminars presented at the Chapter's Product Show at Gillette Stadium Clubhouse. All of the events were well attended, with the End-of-Summer Harbor Cruise drawing over 25 and the educational programs at the Product Show over 250.

The Young Professionals is a new group within ISPE that has formed in order to develop and respond to the interests and needs of people new in their careers or new to the pharmaceutical, biotech and life sciences industries. The group promotes the professional development of its members through education, mentoring and networking.

The ISPE Young Professionals gathered for their first annual harbor cruise on Friday, September 11th aboard the Boston Belle. The event was co-sponsored by Commissioning Agents, Inc. and A/Z Corporation. Despite the heavy rains and winds that evening, the attendees enjoyed an evening of networking, music, dinner and drinks while taking a shoreline cruise from Quincy through Boston w Captain Mike and his crew. The evening began in Quincy Harbor where members of the Young Professionals gathered aboard the Boston Belle for a chance to make some introductions and meet some new people prior to departing. I'm happy to say the rocking of the boat did not hinder the success of the evening.

In a more serious vein, the educational events at the Product Show on October 7th were also a great success due to the efforts put forth by representatives of ASME who spoke at all three of the YP educational sessions. The lectures hosted by the YPs were "Biote 101" by Jim Vogel of Process Facilities Services; "Principles of CIP" by Marc Pelletier of CRB Consulting Engineers and Chris Pacheco of Amgen; and "ASME BPE Guidelines Update" by Jay Ankers of LifeTek Solutions. The efforts of the ASME BPE member did not go unrecognized as all three lectures were very well attended by the ISPE community.

The Young Professionals would like to recognize the support of the ISPE Boston Area Chapter for helping to foster our efforts. The support of the Board of Directors has been critical; the Board has provided guidance, financial backing and has been the sounding board for our growing group. We have also received support from other professional societies and corporations which we would like recognize as well. ASME BPE worked very closely with us to provide speakers for the YPI track of educational seminars at the Prod Show, while Commissioning Agents, Inc. and A/Z Corporation provided sponsorship for the YPI Boston Harbor Cruise.

The ISPE Young Professionals are already working on future events which include educational seminars, tours and social activities. you would like more information or would like to participate in the group, contact the ISPE Boston Area Chapter at ispe@camihq.com or Dan Ramsey at daniel.ramsey@cagents.com.

Tech Talk - Leadership in Biotechnology: Is Anyone Following You?

by Joyce Chiu with contribution from the panelists, photographs by Peter Teague

The following article is based on a panel discussion presented at the ISPE Boston Area Chapter Product Show on October 7, 2009. The article was prepared by moderator Joyce Chiu, Senior Project Manager, Perceptive Informatics, PAREXEL International, in collaboration with the panelists:

- Walt Bassett - Director, R&D, Bioprocess Technology, Pre-development and Core Research, Millipore Corporation
- Joe Maressa - Vice President, Fitzgerald, Stevens and Ford Inc./OI Partners
- Beth Wescott - Director, Site Operations Management, Pfizer
- Joyce Whitehead, PhD - Director, Manufacturing Technical Services, Shire Human Genetic Therapies
- Lesley Wood - Director of Manufacturing, Lonza Biologics

Five main aspects of leadership were examined during the panel discussion, each phrased as a question. The article explores each these questions and highlights the individual experiences and insights shared by the panelists during the live session. As there was handout, the moderator and panelists intend for the article and accompanying reference list to serve the purpose of knowledge-shari from the session, reaching beyond the immediate audience in the room to all Chapter Members.

Moderator Joyce Chiu set the stage for the panel discussion that followed

Leadership: What Is It & Why Is It Important?

Joe Maressa opened the floor and shared the distinction between managers and leaders. Leaders make decisions on destination, the course, the reason for an organization's existence and understand all stakeholders, including society, and how they benefit from the organization's endeavor. A leader crystallizes and communicates a vision, creates a new one when the original is no longer valid, and creates the compelling need for change. A leader asks questions, whereas a manager answers them. A leader provides the "what" and "why," whereas a manager provides the "how."

Joe Maressa, Fitzgerald, Stevens & Ford/OI Partners

This reminds us of the fable of the medieval traveler who happened upon a construction site and saw workers laying bricks. He asked the first worker, "What are you doing?" and got the answer, "I am laying bricks." He asked a second worker and got the answer, "I am building a wall." Finally he came upon a third worker and asked again, and got the answer, "I am building a cathedral!"

Leaders build strong teams and develop future leaders. They are strategic thinkers, not just strategic planners. They create a compelling vision that unleashes the creativity and innovation in their people, making the impossible possible. Leaders also embrace conflicts as opportunities to build strong relationships and foster innovation.

Leaders also know themselves well, their strengths and weaknesses. They then build and use a team so that the whole is greater than the sum of its parts. Leaders are people who consistently strive for maximum impact. They understand that peak performance comes from peak energy. They not only have career goals but physical and emotional health, spiritual and ethical, and often family and community goals as well. Managers implement ethics, leaders live it.

Table I is a model that Joe has developed over the last 35 years highlighting the differences between a manager, leader, and enlightened leader.

Table I - Manager to Enlightened Leader: *Major Differences*

The Growth to Great Leadership

Manager	Leader	Enlightened Leader
• Focuses on Here and Now	• Creates Vision	• Creates New Vision
• Implements Change	• Drives Change	• Creates Change
• Works Within Culture	• Reinforces Culture	• Shapes Culture
• Manages	• Leads	• Creates a Leadership Footprint
• Tactician	• Strategic Planner	• Strategic Thinker
• Command - Control	• Aligns	• Unleashes Creativity and Innovation
• Decides How	• Decides Why	• Decides What
• Debates	• Discusses	• Dialogues
• Avoids or Suppresses Conflict	• Resolves	• Embraces
• Knows Others	• Knows Themselves	• Believes in Others and Themselves
• Overuses Strengths	• Uses Team Strengths	• Develops Team and Self Physically, Emotionally, Spiritually, Ethically
• Work Focus	• Organization Focus	• Life Focus
• Emotionally Hijacked	• Aware of Emotions	• Emotionally Intelligent
• Implement Ethics Policy	• Sets Policy	• Lives It

Joyce Whitehead offered that leading people rarely means dragging them with you to a specific destination or goal, but rather, is more like "herding cats." Diverse opinions are listened to with respect, so that the team can reach a collaborative alignment on the outcome, goal or risk. Thus leadership is the ability to get people with disparate backgrounds, experience and ideas to align behind a common goal. In the biotech business, we often need to make quick collaborative decisions on a daily basis, often with the patients in mind. Leadership is thus essential to guide, align and focus the team in getting results.

Joyce Whitehead, PhD, Shire HGT

The analogy of herding cats resonated with Beth Westcott, especially in a matrix organization where there is not a clear mandate or reporting structure. Nothing in this industry can be done independently, and people do have choices. Persuading others to follow begins with trust, integrity and willingness to support the team. In her interactions, Beth has found that people are waiting for someone to have the courage to step forward and articulate a clear business case to remove barriers. As a leader proves their willingness to support the team, the team will continue to step up to greater challenges. In the biotech industry, there are a lot of bright people, thus integrity and trust are key to building lasting relationships.

Lesley Wood emphasized having passion -- creating a culture which has a clear sense of purpose and is passionate about what it does. Leaders need to create a sense of urgency without chaos, fostering an environment where new ideas are the norm and are listened to. On the personal side, she noted it is very important to have a work life balance, as a mother of two teenage children well understanc

As a leader in a large R&D organization who is not the subject matter expert, Walt Bassett believes in motivating and encouraging others to do their best, to collectively inspire teams to work cross-functionally to achieve results, surpassing the mere sum of the individuals. A leader needs to energize, excite and empower the team.

Leadership Styles: An Exploration

Research has shown that leadership is primarily emotional intelligence and skills; effective leaders employ different styles in differen situations. There are some who provide a vision, others who build relationships, solicit input to build consensus or alignment, coach and mentor to develop others, demand excellence or even immediate compliance.[1] The panelists explored their own styles and how they used them in different situations.

Joyce is not a visionary but she has the ability to quickly develop relationships with people and influence them through these relationships, which serve as a foundation to allow other leadership styles to work, such as building consensus within teams and coaching others for high performance. She is a firm believer in leading by example. As salaried employees, her teams are not "paid the hour then go home" but rather they are paid to get a job done, no matter how long it takes. Joyce lives by that principle herself, putting in the hours needed to ensure the success of her company and the well being of its patients.

Leadership style also changes with the audience. With direct reports, Joyce rarely demands immediate compliance but if she does, means she is very serious or passionate about the issue. With peers and cross-functional teams, it is all about building collaboratior and trust. Getting teams to agree to a common goal may be hard and, on occasion, a leader may need to "trump" certain members reach a decision; it is important to remember that at that point, the entire team needs to buy into the decision and accept the risk anc reward that come with it.

Walt worked at General Electric early in his career. He has long admired the leadership style of Jack Welsh during his rise to GE President and CEO. Welsh transformed a huge company into a group of individual businesses that had enough autonomy to excel i each of their specific market segments. Welsh removed layers from the hierarchy and empowered teams to act quickly and own the ideas and their business.

Walt also likes to adopt a style exemplified by successful sports coaches, or the conductor of a symphony orchestra. In either case, the leader is a true student of the game, but not necessarily an expert in any particular area, who can rally diverse individual talents into a single-minded effort to generate success. A symphony conductor may not be the consummate player of any instrument, but they know what great music should sound like when all the instruments play in

harmony.

Leslie Wood, Lonza Biologics

Lesley's only true style is to be authentic. After that, it is important to create overall goals and, through listening and coaching, keep everyone focused on achieving those goals. When there is chaos, people cannot function. It is important to get the team aligned behi common goals for collaboration. Try to achieve some quick wins, so that the team is confident to go on. Divide and conquer - define a place for everyone immediately, not looking out 10 years. Create some order out of the chaos. The orchestra analogy is reall excellent. After the team achieves some initial success, give credit and recognition.

Joe does not lead in the traditional sense but coaches people to lead themselves and others. He uses different approaches or styles when engaged with them. When coachin leader or trying to convince someone of the benefits of leadership development, Joe establishes a foundation of trust and mutual respect. He clarifies what the individual wan as an outcome and the kind of relationship they desire. Next is to get an agreement on t development process and the steps with which to achieve the outcome. How this is achieved depends on many factors, including the level of trust, the extent of agreement o the goals and the temperament, values, life and world view, personality, learning style, et of the individual(s) involved.

Joe pointed out that the biggest problem with leaders is that very few are willing to tell a leader their weaknesses. Therefore, knowing their "blind spots" is important for leaders, especially how their leadership style hurts their effectiveness. Leaders would be fortunat to have a spouse or a close friend or associate who would be willing to share this insight with them.

Core Values for Tough Challenges

As they face tough challenges where there are no clear guidelines, what values do these leaders rely on for guidance?

Beth Wescott, Pfizer

Beth's first principle would be to walk the talk, resonating with what Lesley said about being authentic. Beth used the example of being asked to facilitate a meeting for a project. The intent was to utilize her exposure to construction and project management to create alignment on the project. Beth was unknown to the site and the team, yet within a few days of her arrival, someone on the team managed to reconstruct her entire resume. When questioned, the team member said he merely asked people about Beth as he made calls over the previous two days.

The lesson learned? Beth grew up in a small town where everyone knew your business - it doesn't hurt to treat this industry the same way. Beth found this insight served her well when she started her second career. The other value that has served Beth well is to assume the best of people and their intentions. It is the strongest place to begin relationships and brings one through tough situations. Everyone wants to perform and contribute; having a clear agreement on the goals and the path is the best way to give them the opportunity.

Joe believes an individual's values are major determinants of their leadership style, whereas leadership styles or models, when taken alone, are superficial. The three values that have served Joe well include: the dignity of every individual, conflict management and a strong desire to solve complex people issues, and to make a difference in the lives of individuals and companies.

Dignity of every individual: Joe shared a story of integrating a manufacturing plant in South Boston which had 160 employees, all wh and male, predominantly Irish. By understanding fears (with a bomb threat to his office) and anticipation of problems and strong relationships and stakeholders, Joe played a critical role and eventually the first African American, then the first woman, was hired.

Conflict is both necessary and part of work life. In most cases, it is an opportunity to create innovative solutions and build relationships. Joe was involved in a situation where there was a very poor relationship between the CEO of a startup company and board of directors and demanding investors. Through a series of interviews with all involved, people saw things from a different perspective and relationships were significantly improved, and the company received additional funding.

Joe was raised in an extended Italian American household. His father, an immigrant, instilled in him the value that America gave

everyone the opportunity to develop themselves and to succeed, and with that comes responsibility. Life is short; work life is even shorter. It behooves all of us to make the highest contribution possible for ourselves, our families, our companies and society.

Taking a different direction, Joyce said that one of the challenges in leading people is delivering the hard news - messages around performance and during layoffs. As leaders, we are obligated to our direct reports and to our company, to be timely, honest and dire during these situations.

Walt cited honesty, integrity and truth to be his values. Two early lessons came when he first stepped into management. First, bein bossy only works for a short time. He was all about telling everybody what to do and when to do it. Walt had to learn to relax and le people do their jobs and just provide direction when needed. Many first-time supervisors fall into this trap. If it continues, it shows a lack of maturity or a sign of insecurity.

Early in Walt's career, he observed a business unit manager arrive whose whole approach revolved around asking questions. He w able to get to the heart of every issue by asking good, probing questions. This stuck with Walt, especially when he is asked to lead a area where he is not the expert.

Walt shared an experience where a regulatory body came into a plant for an inspection. An old-timer had a stash of samples which provided instead of what was produced on the floor. Apparently, this had been condoned for many years and everyone turned a blir eye. Walt stopped the practice. In business, the golden rule is honesty, integrity and truth. If we cannot live with certain practices a cannot change them, then the only option is to leave.

Changes in the Biotech Industry

There are many changes occurring in the biotech industry. What are some of the changes faced by our panelists and how are they dealing with them?

Given the economic downturn, Joe commented that it is a challenge to win people over to investing in leadership development. Trus and relationship building, and making the case that improved leadership makes a difference in how the company deals with the downturn and its future, are his approach. Such an investment is a major retention factor and once the economy turns, people will b more apt to stay because of the company's investment during hard times.

To Walt, dealing with change is exciting; however, some people are less able to deal with ambiguity. Change gets intelligent people thinking what's in it for them. The most common tasks within R&D are decisions on which projects to work and what resources to apply. Leadership needs to listen, primarily to the customer, and interpret the proper direction. Decisions are best when made with the input of strong technical talent, combined with a solid understanding of the core business strength of the company.

Joyce continued the thread with the growing pains of a development (R&D) organization being transformed into a commercial one. A a development organization, there is no real obligation to adhere to the strict cGMPs set forth by the regulatory authorities, whereas commercial organization is bound to. Thus a change in culture is necessary, where accurate SOPs and "doing it right the first time" are important. The biotech industry is also changing to new technologies with shorter cycle times; thus technical people in the indus need to adapt and embrace these changes. Working with people to bring about a new culture is a great leadership challenge.

Lesley is faced with the change of moving from engineering to operations - getting the production demand schedule and listening to people about these schedules and figuring out what makes sense. Building a new team that is realistic, feels empowered and responsible by constant coaching ... the list of challenges is endless!

The other big change is: we no longer need to build big new plants, which has been the primary goal for most engineers' careers in biotech for the last 20 years. We are building fewer plants and the plants we have are maturing, being modified for new products, th becoming more like the rest of the chemical and pharmaceutical industry. If we don't engage our engineers soon, we will lose them t another new exciting industry (sustainable energy perhaps?).

How can we get our engineers excited about new projects? These projects may sound lackluster until we put measures like dollars saved against them. At Lonza, these come under Operational Excellence - which ranks second only to customer needs - making ou plants more efficient, easier to operate, reducing energy consumption, etc.

Leadership Challenges in Biotech and Skills for Navigation

According to Lesley, the unique challenges are much fewer than they were ten years ago. The biggest is the maturing of the industr Efficiency is at least as important as science now, which requires a different mindset to get it right. Today, new improvement ideas

more often come from logistics or finance, rather than R&D. We need to learn from other industries, focus on operational excellence and show our commitment and be thoughtful about it. She recently toured a Boeing plant - an exciting opportunity. However, the rea take-away lesson for her? While a jet plane is being assembled, the operator on the floor doing the assembly is the most important person in the company; *everyone* supports them.

Walt Basset, Millipore Corporation

In Walt's view, the biotech industry is in transition. While there are still plenty of startups and small entrepreneurial companies, the maturing businesses are adjusting to the fact th earnings, shareholder value and Wall Street performance are becoming important for sustainability. Big Biotech will need to look more closely at what other industries have be doing for years. Namely, quality, cost and efficiency will become more evident as pure research is de-emphasized.

Beth concurred that the biotech industry must deal with the cost question if it is to remain prosperous: "At the Andover site, our strengths have been high quality products delivered when our patients needed them. Our weakness has been the price the patients have hac pay. Asking a family to support costs on the order of $40,000 a year is not acceptable an we are seeing the impact of these costs in restricted access across the globe. What if ou cost structure could be low enough to support broadened access to our patients?"

She continued, "We have begun tackling the inflexibility and variability in our systems, building capabilities to support a more flexible and agile manufacturing model. The engagement of our people has been astonishing, yielding surprising (and sometimes embarrassing) opportunities. Changing our culture so that visibility of barriers and proble is expected and rewarded opens the door to change. Empowering our people at all level to make these changes will be the catalyst to make it all happen."

Given the fact that patent protection will no longer exist for many drugs, Joe added, leaders will have to make the right decisions. Leaders will have to think about strategic alliances in order to have the money necessary to develop the next generation of drugs. Leaders at all levels will have to encourage and develop more creative thinking and innovative ways of developing drugs, building hi performance work systems and employment engagement, and integrating people, systems, organizational structures, and business processes and practices to maximize the talents and experience of all stakeholders.

The three key elements are: a shared focus on the results to be achieved, a strong sense of each individual's purpose and role and how that impacts others, and transparent measurements in terms of progress. High-energy, high-powered teams, with shared goals and transparent metrics, will increase the capability of individuals as well as the entire team.

Acknowledgement & Feedback

The author thanks the panelists for their collaboration on the program design and for sharing their valuable experience and insight. working together as a team, they exemplified what they preached. If anyone has any feedback on either the live session presented a the Product Show or this article, or suggestions for future topics, please send them to ISPE@camihq.com.

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Industry News In Brief

by Patti Charek, RF Walsh Collaborative Partners

What is the Impact of Sepracor-DSP Deal?

Marlborough-based Sepracor is being acquired in a $2.6 billion deal by the Japanese firm Danippon Sumitomo Pharma Co. Ltd. Tom Wellen, executive director of Marlborough 2010, the economic development corporation for the town, says the Sepracor-DSP deal is not too much of a threat. "This type of acquisition poses the least possible risk to the local workforce," he said. And that's because DSP has no operations in the US, never mind in MA. So the chances for redundancies, business code for possible layoffs, are limite

At least those are the assertions of executives at both Sepracor and DSP. Jonae R. Barnes, a spokesman for Sepracor, issued a statement staying, "We anticipate no change to the job responsibilities of most Sepracor employees for the foreseeable future. DSP committed to substantially maintaining the Sepracor organization and staff." Claims of the status quo moving forward are not unusua in merger and acquisition news, but according to one analyst that follows Sepracor, hanging on to a majority of the drug maker's sale force does make sense. "I think that this is a classic case of a deep-pocketed pharmaceutical company that is looking for a quick wa to access a sales force," said David Ansellem, principal and senior research analyst in specialty pharma for Piper Jaffray.

Sepracor made its name marketing the sleep drug Lunesta but has recently faced market speculation because it has two drugs facir generic competition because they are losing patent protection in the next three to five years. The company has more than 600 peopl working at its headquarters in Marlborough. It recently completed a $30 million property and equipment expansion, with plans for a second $20 million phase several years out. (Source: Christina H. Davis, Worcester Business Journal Staff Writer, 14 September 2009)

UMass Med To Break Ground on New Facility

The University of Massachusetts Medical School will break ground on a $400 million, 500,000-square-foot research and education facility at its Worcester campus. Dubbed the Albert "Albie" Sherman Center, the facility will house the school's Advanced Therapeuti Cluster, including the RNAi Institute, the Center for Stem Cell Biology and Regenerative Medicine, the Gene Therapy Center, the Department of Quantitative Health Sciences and the Center for Experiential Learning and Simulation. The facility is expected to be LEED Silver certified and is expected to be complete in 2012. (Source: Matthew L. Brown, Worcester Business Journal Staff Writer 17 September 2009)

Genzyme Continues Its MetroWest Expansion

The global biotechnology company recently kick started a $65 million renovation and construction project in Northborough that is expected to consolidate some of its operations, including distribution and packaging. The project adds to Genzyme's already growing presence in the region. Henry Fitzgerald, vice president of operations for Genzyme, said the Northborough location at 11 Forbes Ro is ideal due to its proximity to other Genzyme locations and major arteries. In addition to distribution and packaging, there will also b some quality control staff at the facility. In total it will host about 165 workers who will come from various Genzyme locations in the region. In the future, Genzyme expects to hire another 35-50 people to work in Northborough.

The decision to move forward with the project was mostly driven by space crunches at other Genzyme facilities. But the depressed real estate market certainly didn't hurt the budget, according to Fitzgerald. "We would have needed this had the market been good o bad, but the timing of the market happened to work for us," he said. Genzyme has approximately 1 million square feet of space in Framingham alone, and the new Northborough facility, when completed, will add another 211,000 square feet. In addition to its operations in Framingham and Cambridge, Genzyme also has locations in Westborough, Waltham, Boston, and Allston.

Fitzgerald said the Northborough project's total budget includes about $40 million in construction costs, with another $25 million in equipment and other costs, bringing to final price tag to $65 million. The cost is driven by the exacting requirements that Genzyme operates under. Because the building will process Genzyme drugs, it will have to be certified by the FDA. The building will need specialized temperature and humidity controls as well as holding areas for chemicals and finished products.

Genyzme has a long-term lease on the property. The owner is Leggat McCall Properties of Boston. The architect on the project is Signer Harris Associates of Boston and the construction company is AZ Corp. of Franklin. Fitzgerald said the project should be completed by the fourth quarter of 2010. He estimated that 150 to 200 construction workers will be on site each day during the peak construction.

Genzyme just opened a $125 million, 180,000-square-foot R&D center in Framingham in September 2008. The company is also building more manufacturing space in Framingham and is expanding its manufacturing space in Allston. (Source: Christina H. Davis Business Journal, 17 September 2009)

AstraZeneca to Cut 113 Jobs in Massachusetts

AstraZeneca PLC has said it plans to cut 113 jobs at its manufacturing plant in Westborough beginning in November, largely becaus the company faces increased competition for the asthma medication it makes there. In March, the FDA approved rival Apotex's request to market a generic version of AstraZeneca's Pulmicort Respules asthma drug. "We have to be cognizant of what will be happening in the market and plan according to that,"said AstraZeneca spokeswoman Kate Klemas. The company also makes some other medications at the plant, including a liquid version of Nexium, the popular "purple pill" used to treat heartburn.

Coincidentally, the drug company plans to hold a ribbon-cutting ceremony in November to formally mark the expansion of its researc facilities in Waltham. The expansion increased the size of the plant by 132,000 square feet to 514,000 square feet. Despite the job cuts in Westborough, Klemas said the company will continue to add jobs gradually in Waltham. Overall, AstraZeneca has about 1,0(employees in Massachusetts, split roughly evenly between Waltham and Westborough. (Source: Todd Wallack, The Boston Globe, September 2009)

Genzyme Expects Shortages of Two Drugs to End by 2010

Genzyme Corp. has cut its 2009 sales forecast for Fabrazyme, a treatment for a rare genetic disorder, and said it expects to correct shortages of the drug and of Cerezyme, its top-selling product, by next year. Genzyme said it has successfully restarted its Allston Landing plant, which was closed by viral contamination in June, but initial supplies of Fabrazyme will be "lower than anticipated." Genzyme still expects to meet worldwide demand for both medicines by the first quarter of 2010, it said.

Genzyme started rationing Cerezyme, used for Gaucher disease, and Fabrazyme, for Fabry disease, after discovering the virus. Cerezyme generated $1.24 billion last year, 27 percent of total revenue. Fabrazyme was Genzyme's third-biggest drug, generating $494 million, or about 11 percent of sales. "We have reached a point in this process where we can anticipate with greater confidence the timing and amount of the first finished product to be shipped from the Allston plant," Henri A. Termeer, Genzyme's chairman and chief executive, said in a prepared statement.

Genzyme said it expects 2009 Fabrazyme sales of about $450 million, down from its earlier forecast of $510 million to $520 million. Cerezyme sales will be about $800 million, narrower than the prior forecast of $750 million to $1 billion. Fabrazyme production was delayed partly for preventive maintenance and for sanitizing the Allston plant, the company said. Genzyme said it is asking patients and doctors to continue conserving their supplies of the drug. If the restart of the plant continues as planned, Genzyme expects new produced Cerezyme to be available in November and December, and new Fabrazyme in mid-December, the company's statement said. Gaucher and Fabry disease are inherited disorders caused by low levels of certain enzymes needed to break down fatty substances. (Source: Alex Nussbaum, Bloomberg News, 24 September 2009)

Two Biotechs Moving Operations to Boston

A pair of Massachusetts biotechnology companies will be moving their operations to Boston with the assistance of the city's LifeTech initiative, which provides financing, site location, and permitting assistance to life sciences companies. Ginkgo BioWorks of Cambrid a synthetic biology company founded by five PhDs from MIT, plans to move to Marine Industrial Park on the South Boston Waterfror The company received a $150,000 LifeTech innovation fund loan through Boston Local Development Corp. Eutropics Pharmaceutic of Woburn, a Harvard Medical School spinoff that develops small molecule treatments for blood cancers, will relocate to 609 Albany Ave. on the BU Med School campus at BioSquare. Eutropics has been approved for an unspecified loan by the LifeTech advisory committee. (Source: Robert Weisman, The Boston Globe, 26 September 2009)

Eli Lilly to Cut 5,500 Jobs by 2011

Drugmaker Eli Lilly & Co. says it will eliminate thousands of jobs and reorganize into five business units in an effort to slash costs an speed up development of potential new drugs. The Indianapolis company says it will reduce its work force to 35,000 by the end of 2011. It has about 40,500 now. Lilly hopes to cut annual costs by $1 billion per year over the same time, and will organize itself into five units: cancer, diabetes, established markets, emerging markets, and Elanco, its animal health business. Key Lilly products like tl anti-psychotic drug Zyprexa will lose patent protection starting in 2011. CEO John Lechleiter believes the company's best path to pro growth involves focusing on its early and mid stage drug candidates. (Source: The Herald Bulletin Online, 14 September 2009)

Epizyme Gets $32M for Gene Regulation Research

Biopharmaceutical start-up Epizyme Inc. of Cambridge said it landed $32 million in venture capital to develop drugs to treat cancers and other diseases through gene regulation. Epizyme, which last year received a $14 million first round of funding from venture capi heavyweights MPM Capital of Boston and Kleiner Perkins Caufield and Byers of Menlo Park, CA, will use its new money to run "pro of-concept" studies with its lead compounds, said Kazumi Shiosaki, cofounder and chief executive. Shiosaki said the goal is to identi a drug candidate that the two-year-old company can take into clinical trials. The company currently has 16 employees, all in Cambridge. "It's a fundamentally new area of biology," she said. "And we believe this could have applications not only in oncology bu also in inflammatory conditions and certain neurological disorders."

The company is one of a handful, including another Cambridge firm, Constellation Pharmaceuticals Inc., working in the emerging fiel of epigenetics, which seeks to control how genes are read by molecules that convert them into proteins. The goal is to be able to produce inhibitors for enzymes involved in cancer and other diseases. "What we're trying to do is inhibit enzymes that can regulate certain genes, turning them on and off," Shiosaki said. "There are tumor suppressor genes that are turned off, and this mechanism c turn them back on. And it can turn off genes that activate tumors."

Epizyme's latest venture round was led by a new investor, Bay City Capital of San Francisco. Joining it were two other new investors Astellos Venture Management of Los Altos, CA, and Amgen Ventures, a financing arm of biotechnology giant Amgen Inc. in Thousa

Oaks, CA, along with MPM Capital and Kleiner Perkins. (Source: Robert Weisman, The Boston Globe, 9 October 2009)

Paratek and Novartis Strike Licensing Deal

Paratek Pharmaceuticals Inc. said it has entered into an exclusive worldwide licensing agreement with Novartis AG. Headquartered Boston, Paratek is a privately held company that employs about 50 people. The agreement covers Paratek's lead drug candidate PT 0796, an antibiotic that the company hopes is broad enough for single-agent treatment of life-threatening infections, such as complicated skin infections and moderate to severe bacterial pneumonia. The drug candidate is in phase 3 clinical trials, according t Paratek, which has no products on the market at this time.

"Under the terms of the agreement, Novartis and Paratek will share responsibility and costs for worldwide development of PTK 0796, while Novartis will have the exclusive right to commercialize PTK 0796 on a worldwide basis," Paratek said in a press release. Paratek will be eligible to receive up to $485 million in payments, which include upfront and future milestone payments. The company will also receive a royalty on net sales of PTK 0796 around the world. (Source: The Boston Globe, 9 October 2009)

Regulatory & Legislative Highlights

by Deepen Joshi, Sepracor Inc.

Accelerated Approval of Hiberix to Help Sustain Adequate Vaccine Supply

The FDA has approved GlaxoSmithKline's Hiberix, a *Haemophilus influenzae* Type b (Hib) vaccine, as a booster dose for children 1 months through 4 years old. A nationwide shortage of Hib vaccine began in December 2007 due to a voluntary recall by the manufacturer and subsequent production suspension of PedvaxHIB and COMVAX, both manufactured by Merck, two of four vaccine licensed in the United States for primary and booster immunization against invasive disease due to Hib. This shortage resulted in a recommendation by the Centers for Disease Control and Prevention to temporarily defer the Hib vaccine booster dose for children w were not at high risk for infection until the vaccine supply could be restored.

Although current vaccine supply is sufficient to reinstate the booster dose and begin catch-up vaccination, it is not yet ample enough support mass vaccination of all children whose boosters were deferred. Before the availability of Hib vaccines, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. (Source: FDA Website, 19 August, 200

FDA Proposes Mandatory Electronic Postmarket Safety Reporting

The FDA is proposing to amend postmarket safety reporting regulations for three of its centers to require that manufacturers and oth facilities subject to current reporting requirements submit their reports in an electronic format. The agency has issued two proposed rules - one that applies to electronic medical device adverse event reporting and one that applies to electronic drug and biologic product adverse experience reporting. Today's rules would not change what types of incidents are required to be reported to the FD it would require that the incidents be reported in an electronic format that the FDA can process, review and archive. (Source: FDA Website, 20 August, 2009)

FDA Conducting Safety Review of Weight Loss Drug Orlistat

The FDA has announced that it is reviewing adverse event reports of liver injury in patients taking the weight loss drug orlistat, marketed as the prescription drug Xenical (by Roche) and the over-the-counter medication Alli (by GlaxoSmithKline). Between 1999 and 2008, the FDA received 32 reports of serious liver injury in patients taking orlistat. Of those cases, 27 reported hospitalization ar six resulted in liver failure. Thirty of the adverse events occurred outside the United States. The most commonly reported adverse events included yellowing of the skin or whites of the eyes (jaundice), weakness, and stomach pain.

The FDA is reviewing additional data submitted by orlistat manufacturers on suspected cases of liver injury, and the issue has been discussed at the FDA's CDER Drug Safety Oversight Board. The FDA's analysis of these data is ongoing, and no definite associatio between liver injury and orlistat has been established at this time. Consumers taking Xenical should continue to take it as prescribed and those using over-the-counter Alli should continue to use the product as directed. Consumers who have used orlistat should cons a health care professional if they experience symptoms possibly associated with development of liver injury, particularly weakness o fatigue, fever, jaundice, or brown urine. (Source: FDA Website, 24 August, 2009)

FDA Authorizes Emergency Use of H1N1 Test for US Troops Serving Overseas

The FDA has announced it has issued an Emergency Use Authorization (EUA) that allows a 2009 H1N1 influenza virus test to be us to detect the virus in troops serving overseas. The EUA allows the Department of Defense to distribute the H1N1 test to its qualified laboratories that have the required equipment and trained personnel to perform the test and interpret its results. An EUA authorizes use of unapproved medical products or unapproved uses of approved medical products during a declared public health emergency. The Centers for Disease Control and Prevention (CDC) developed the test, which is called the CDC swH1N1 (swine) Influenza Real Time RT-PCR. (Source: FDA Website, 24 August, 2009)

FDA Study Indicates Most Industry Postmarketing Studies Meet Timelines

Makers of approved drugs and biologics generally are meeting their regulatory obligations and complete their postmarketing studies a timely manner, according to a study recently released by the FDA. A review of 1531 open postmarketing studies indicated that ove 80 percent are proceeding according to the established timelines, have been submitted for FDA review, or have been determined by the FDA to have met their goals or are no longer needed. The study also recommended changes designed to improve the quality of the information submitted to the FDA, the timeliness of the FDA review, and the accuracy of the FDA's databases.

Under the Food and Drug Administration Amendments Act of 2007, the FDA must undertake such a review annually. The review showed that the industry has been initiating most studies on time and submitting final reports for many studies, as required. Many o these reports are pending completion of a thorough FDA review. Manufacturers of drugs and biologics are also required to report to the FDA in a timely manner any serious safety issues that are identified from studies or other sources. (Source: FDA Website, 3 September, 2009)

FDA Clears a Test for Ovarian Cancer

The FDA has cleared a test that can help detect ovarian cancer in a pelvic mass that is already known to require surgery. The test, called OVA1, helps patients and health care professionals decide what type of surgery should be done and by whom. OVA1 identifie some women who will benefit from referral to a gynecological oncologist for their surgery, despite negative results from other clinical and radiographic tests for ovarian cancer. If other test results suggest cancer, referral to an oncologist is appropriate even with a negative OVA1 result. OVA1 should be used by primary care physicians or gynecologists as an adjunctive test to complement, not replace, other diagnostic and clinical procedures.

OVA1, developed by Vermillion Inc. of Fremont, CA in conjunction with researchers at The Johns Hopkins University in Baltimore, uses a blood sample to test for levels of five proteins that change due to ovarian cancer. The test combines the five separate results into a single numerical score between 0 and 10 to indicate the likelihood that the pelvic mass is benign or malignant. (Source: FDA Website, 11 September, 2009)

FDA Approves Vaccines for 2009 H1N1 Influenza Virus

The FDA has approved four vaccines against the 2009 H1N1 influenza virus. The vaccines will be distributed nationally after the initi lots become available and are made by CSL Limited, MedImmune LLC, Novartis Vaccines and Diagnostics Limited, and sanofi paste Inc. All four firms manufacture the H1N1 vaccines using the same processes, which have a long record of producing safe seasonal influenza vaccines.

People with severe or life-threatening allergies to chicken eggs, or to any other substance in the vaccine, should not be vaccinated. with any medical product, unexpected or rare serious adverse events may occur. The FDA is working closely with governmental and nongovernmental organizations to enhance the capacity for adverse event monitoring, information sharing and analysis during and after the 2009 H1N1 vaccination program. In the Department of Health and Human Services, these agencies include the Centers for Disease Control and Prevention.

Vaccines against three seasonal virus strains are already available and should be used. However, they do not protect against the 20 H1N1 virus. (Source: FDA Website, 15 September, 2009)

FDA Approves Blood Donor Screening Test for Antibodies to HIV

The FDA has announced approval of Abbott Laboratories' Prism HIV O Plus assay, as a screening tool designed to detect the presence of certain antibodies to HIV. The assay is one of five assays that run on the fully automated Abbott Prism System.

There are two types of HIV. HIV type 1 consists of various subgroups, including group M, the most common subgroup of the virus in the United States, and group O, found primarily in Cameroon and other areas of West Africa. HIV type 2 is found mostly in West Afri Both types have been detected in the United States and Europe. The Abbott Prism HIV O Plus assay detects antibodies to HIV type groups M and O, and HIV type 2. It is the second donor screening test licensed for the detection of antibodies to HIV type 1, group C

The Abbott Prism HIV O Plus assay is licensed to screen donated blood and blood specimens from other living donors for these specific types of HIV and subgroups of HIV type 1. The assay is also licensed to screen specimens from organ donors when specimens are obtained while the donor's heart is still beating and from cadavers. Positive results from the screening test require confirmation from supplemental tests. (Source: FDA Website, 18 September, 2009)

FDA Awards Grants to Stimulate Development of Pediatric Medical Devices

The FDA has awarded three grants designed to stimulate the development and availability of medical devices for children. A panel o six experts with experience in medicine, business, and device development reviewed 16 applications for the grants, which will be administered by the FDA's Office of Orphan Products Development.

Development of medical devices for children lags up to a decade behind similar devices intended for use in adults. Children differ in terms of size, growth and body chemistry and present unique challenges to device designers. In addition, the activity level and ability to manage some implantable or long-term devices may vary greatly among children.

Each of the grant recipients will coordinate among the FDA, device companies, and the National Institutes of Health's Eunice Kenne Shriver National Institute of Child Health and Human Development to facilitate research and any necessary applications for device approval or clearance. (Source: FDA Website, 21 September, 2009)

Institute of Medicine to Study Premarket Clearance Process for Medical Devices

The FDA has announced that it has commissioned the Institute of Medicine (IOM) to study the premarket notification program used t review and clear certain medical devices marketed in the United States. The IOM study will examine the premarket notification program, also called the 510(k) process, for medical devices. While the IOM study is underway, the FDA's Center for Devices and Radiological Health (CDRH) will convene its own internal working group to evaluate and improve the consistency of FDA decision making in the 510(k) process. Established by the National Academy of Sciences, the IOM provides independent, objective, evidence based advice to policymakers, health professionals, the private sector, and the public.

The FDA classifies medical devices into three categories according to their level of risk. Class III devices represent the highest level risk and generally require premarket approval to support their safety and effectiveness before they may be marketed. Class III devic include heart valves and intraocular lenses.

Class I and Class II devices pose lower risks and include devices such as adhesive bandages and wheelchairs. Most Class II device and some Class I devices can be marketed after submission of premarket notifications - also called 510(k) applications -that support their substantial equivalence to legally marketed devices that do not require premarket approval.

Devices that present a new intended use or include new technology that presents new questions of safety or effectiveness may not b found substantially equivalent and require premarket approval. (Source: FDA Website, 23 September, 2009)

FDA Approves First Drug for Treatment of Peripheral T-cell Lymphoma

The FDA has approved Folotyn (pralatrexate), the first treatment for a form of cancer known as Peripheral T-cell Lymphoma (PTCL) an often aggressive type of non-Hodgkins lymphoma. Folotyn, manufactured by Allos Therapeutics Inc. of Westminster, CO, was approved under the FDA's accelerated approval process, which allows earlier approval of drugs that meet unmet medical needs. It is approved for patients who have relapsed, or have not responded well to other forms of chemotherapy.

Lymphoma is a cancer of the lymphatic system, which is part of the immune system. There are many types of lymphoma: one type is called Hodgkin's disease, and the rest are called non-Hodgkin's lymphomas. PTCL involves a type of white blood cell called T-cells. is a relatively rare disease, occurring in less than 9,500 patients each year in the United States.

To speed the drug's availability, Folotyn was granted priority review, ensuring a review within six months rather than 10 months for a standard review. The drug was also designated as an orphan drug, which provides a variety of financial incentives to manufacturers that develop drugs for a small number of patients with a rare disorder. (Source: FDA Website, 25 September, 2009)

FDA Approves New Drug to Treat Psoriasis

The FDA has approved Stelara (ustekinumab), a biologic product for adults who have a moderate to severe form of psoriasis. Stelar is manufactured by Centocor Ortho Biotech of Horsham, PA, a wholly-owned subsidiary of Johnson & Johnson of New Brunswick, N

Plaque psoriasis is an immune system disorder that results in the rapid overproduction of skin cells. About 6 million people in the United States have plaque psoriasis which is characterized by thickened patches of inflamed, red skin, often covered with silvery scales. Stelara is a monoclonal antibody, a laboratory-produced molecule that mimics the body's own antibodies that are produced a part of the immune system. The biologic treats psoriasis by blocking the action of two proteins which contribute to the overproductior of skin cells and inflammation.

The FDA is requiring a risk evaluation and mitigation strategy or REMS for Stelara that includes a communication plan targeted to healthcare providers and a medication guide for patients. (Source: FDA Website, 25 September, 2009)

FDA Transparency Task Force to Hold Second Public Meeting

The FDA sought comments on how to ensure that information on FDA activities and decision-making is useful, understandable, and accessible to the public, during a daylong public meeting on Nov. 3, 2009.

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

Wyeth Sues FDA to Block Generic Rival of Antibiotic Zosyn

Wyeth has sued the FDA to block the sale of a generic rival to its intravenous antibiotic Zosyn, claiming the generic is not an equivalent product and could harm critically ill patients.Wyeth filed the lawsuit in US District Court in Washington, D.C., seeking a temporary restraining order and a preliminary or permanent injunction.

The lawsuit seeks to prevent Orchid Chemicals & Pharmaceuticals Ltd. of Chennai, India, from selling a generic version of Zosyn tha the FDA approved last week. The suit also asks the court to order the FDA to withdraw its approval of Orchid's products or any gene versions that are not exactly the same as Zosyn.

Many of the patients receiving Zosyn are critically ill with very serious infections, so hospital workers often rush to set up an intravenous line to rapidly feed in both Zosyn and, often, a standard IV solution to boost blood volume and pressure. With an older formulation of Zosyn, which Wyeth says is what Orchid would be selling, if the same IV line is used Zosyn can mix with the intravenc solution and cause a chemical reaction that inactivates the antibiotic, limiting how much patients get. That could mean the patient doesn't get enough antibiotic to stop the infection in time. (Source: Linda A. Johnson, Associated Press, Boston Globe, 24 Septembe 2009)

FDA Panel Backs Glaxo Cancer Vaccine Cervarix & Merck's Gardasil

Merck is likely to face US competition for its vaccine Gardasil, after federal experts recommended rival GlaxoSmithKline's Cervarix also be approved to prevent the virus that causes most cervical cancers. The FDA's panel of vaccine experts voted overwhelmingly yesterday that Cervarix appears safe and effective for girls and women ages 10 to 25. If the FDA follows the group's advice as it usually does, Glaxo would begin competing against Merck's Gardasil, which has controlled the US market since 2006.

But Merck won its own small victory at the meeting, as the same panel recommended Gardasil be expanded to prevent genital warts boys, a new use for a vaccine that already posts sales of more than $1 billion. While panelists favored the expanded approval, they questioned how widely the vaccine would be used, since genital warts are not a serious medical condition.

Glaxo has already won approval for Cervarix in Europe but its US launch was delayed in 2007 when the FDA said it needed more data. Panelists said newer studies suggest the vaccine is safe, but they recommended follow-up studies to monitor miscarriages and inflammatory-muscular problems reported by a small number of patients.

Gardasil and Cervarix both defend against HPV strains 16 and 18, which cause about 70 percent of cervical cancer cases. But Merc vaccine also defends against two other HPV types that cause 90 percent of genital warts, something Cervarix does not target.

(Source: Matthew Perrone, Boston Globe, 10 September, 2009)

FDA Approves New Hologic Therapy

Hologic Inc., based in Bedford, MA, announced that the FDA has approved a new version of its MammoSite system, which delivers radiation seeds to prevent recurrences of breast cancer. The agency approved the MammoSite ML radiation therapy system, which allows physicians to better target specific areas of tissue than the original MammoSite system, the company said.

MammoSite devices include balloon catheters that are inserted into the body after a tumor has been removed. Inside the catheter is pellet of radioactive material.

The radiation seed is left inside the body for five days, delivering radiation to the areas the cancer is most likely to return, Hologic sa The treatment is intended to prevent a recurrence while not harming healthy tissue.

Hologic, which makes medical diagnostic products for illnesses affecting women, said the new version of the device will allow therapists to treat patients who are not otherwise good candidates for radiation seeding. It said it will also be usable in more typical cases.

(Source: Associated Press, Boston Globe 2 September, 2009)

Shire Submits Gaucher Drug to FDA

British drug maker Shire PLC said it submitted a new drug application with the FDA for velaglucerase alfa, its enzyme replacement treatment for the rare genetic disorder Gaucher disease. FDA approval would put the drug in head-to-head competition with Cerezyme, the market leader for treatment of Gaucher, made by Genzyme Corp. Genzyme has been rationing Cerezyme because c a virus found in its Allston plant. In a statement, Sylvie Gregoire, president of Shire's human genetic therapies division in Lexington, said her company filed its application earlier than it previously had planned. She called it "an important milestone" for Shire. (Source Robert Weisman, Boston Globe, 2 September, 2009)

FDA Seeks New Trial of Genzyme Leukemia Drug

The FDA's oncology panel recently voted 9 to 3 that Genzyme should be required to conduct a larger, comparison study to prove its drug Clolar is safe and effective for older patients. Clolar already is approved for a form leukemia in patients younger than 21. Genzyme is seeking approval for adults with leukemia who are older than 60, but are not healthy enough to undergo chemotherapy.

The FDA asked Genzyme to conduct a randomized controlled study, which compares patients taking the drug to those taking alternative treatments. Such studies are commonly used to gauge a drug's effect. However, Genzyme said doctors were unwilling to put cancer patients on the alternative treatment recommended by the FDA. Panelists complained that without a comparison it was difficult to say whether patients would truly do better taking Clolar than drugs already in use.

Genzyme researchers said it was too soon to decide whether the company would go back and conduct the recommended trial. (Source: Associated Press, Boston Globe, 2 September, 2009)

New Members

Mr. Ryan J. Adams, *Student,* WPI

Ms. Denise Aronson, *President,* Safety Partners Inc

Ms. Kelli Y. Barrett, *Validation Engineer,* Genzyme Corp

Mr. Steve Bellanti, *MFG Supervisor,* Shire HGT

Kristen Benoit,

Ms. Gayla J. Berg, *Student,* University of Massachusetts Amherst

John E. Bigelow, *Student,* University of Massachusetts Amherst

Mr. Jeffrey Bruno, *Director Process Engineering,* Genzyme Corp

Mr. Nicholas A. Cadirov, *Student,* University of Massachusetts Amherst

Mr. Francis A. Callahan, *Product Validation Manager,* Millipore

Corinne L. Carpenter, , University of Massachusetts Amherst

Rick Carroll, *Sr. Dir. Quality Operations,* Genzyme

Ms. Jennifer Cauley, *Computer Validation Engineer,* Sepracor Inc

Kevin V. Chen, *Student,* University of Massachusetts Amherst

Mr. Mark W. Clark, *Principal,* Clark Consulting Services

Mr. Ryan T. Colombo, *Student,* University of Massachusetts Amherst

Tawn Darrow

Ms. Michelle A. Daunais, *Validation Consultant,* Ceiba Solutions

Mr. Paul Esteves, *EM,* AMAG Pharmaceuticals

Mr. Roger H. Fairbanks, *Sr Project Mgr,* Xcellerex

Mr. William T. Frantz, *Student,* University of Massachusetts Amherst

Dr. Larry A. Gatlin

Mr. James J. Gikas, *Managing Principal,* Vanderweil Engineers

Mrs. Jennifer Grimley, *Sales,* Spectra Automation Ltd.

Mr. Frank R. Guardabasciu, *Process Engineer III,* Massachusetts Biologic Laboratories

Mr. Alfonso Guarracino, *Validation Specialist,* Valsource

Mr. Fredric Halsall, *Account Manager,* Donnegan Systems, Inc.

Dongwon Han, *Student,* University of Massachusetts Amherst

Mr. Patrick Harold, *President,* Harold Brothers Mechanical

Mr. Christopher J. Harrington, *Student,* Villanova University

Andrew M. Hashkes, *Student,* University of Massachusetts Amherst

Amber L Kane, *Student,* University of Massachusetts Amherst

Mr. Alan Karner, *Associate Director Engineering,* Shire HGT

Mr. Steve Kassack, *VP Global Engineering,* Novartis Vaccines & Diagnostics

Prateek Katti, *Student,* University of Massachusetts Amherst

Mr. Arthur Kyle Kennedy, *Sr. Validation Manager,* Stryker Biotech

Mr. James Koloski, *Business Development Manager,* RDK Engineers

Ms. Anna Lai, *Validation Engineer,* Organogenesis Inc

Danielle N. LeBlanc, *Student,* University of Massachusetts Amherst

Mr. Joseph H. Letlow, Jr., *Maintenance Engineer,* Bristol Myers Squibb

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Mr. Timothy J. McFaden, Jr., *Student,* Great Bay Community College

Mr. Adam F. Morrone, *Process Piping Engineer,* Genzyme

Mr. Stephen Mountain, *Manufacturing Technician,*

Besufekad A. Negewo, *Associate Dir. IT,* Massachusetts Biologic Laboratories

Mr. Russell L. Newton, *Senior Consultant,* BioPharm Services Inc.

Mr. John Nguyen, *Validation Engineer,* Organogenesis Inc

Mr. Joe O'Brien, *Automation Engineer,* Wyeth

Mr. Daniel O'Connell, *Facilities Supervisor,* Shire HGT

Mr. Michael O'Rourke

Nicholas Palumbo, CPC, LEED AP, *Project Engineer,* Skanska USA Building inc.

Mr. Srini Paluri, *Business Leader,* New England Controls

Mr. Matthew J. Pond, *Assoc. Validation Specialist,* Genzyme Corp

Mr. Albert J. Porras, *Consultant,*

Anthony B Preteroti, *Electrical Engineer / Project Mgr,* R.W. Sullivan Engineering

Mr. Anthony C. Primo, *Project Manager,* Parsons

Mr. Jonathan P. Rayla, *Student,* University of Massachusetts Amherst

Mr. Kyle W. Reagan, *Vice President,* DECCO, Inc

Mr. Richard A. Renehan, *President,* Renco Corporation

Lily Reynaert, *Principal Capital Project Manager,* Genzyme

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Daniel B. Ross, *Student,* University of Massachusetts Amherst

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