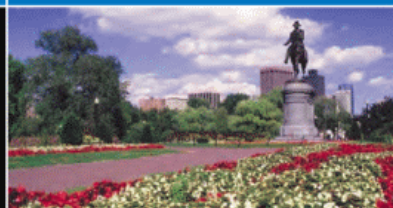




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March 2011, Volume XXI No. 2



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President's Message: We Need Your Help to Meet the Chapter's Goals for 2011

Dear Friends of ISPE:

Since our last eNewsletter things have been hopping. And we couldn't have done it without those of you who attend our programs, volunteer for our committees, write our newsletter articles, join our Chapter and in general get involved and stay involved.

Without participation and dialog, we become denizens of our cubicles, labs, conference rooms and plant floors.

The Chapter offers great resources and lots of reasons to get involved and stay current. With the help of our volunteers, here is where we have been in the past few months and where we are headed in the future. We need the continued help of our Members to fully realize our goals. Contact us at office@ispeboston.org or 781-647-ISPE (4773) and let us know how you'd like to help:



- The Social Committee hosted a Holiday Social that raised over \$2600 for Helping Our Troops and allowed 100 of our members to reconnect with old colleagues and meet new individuals, all in support of a very worthy cause. Read the article and check out www.helpingouttroops.com for more information.
- The Boston Area Chapter Young Professionals and Educational Programs Committees hosted our first-ever joint program. The topic was automation, and basic and advanced tracks were offered. This was an extremely successful event with strong attendance and a great mixer for early career and established professionals. To learn more about the ISPE Young Professionals please visit the newsletter's Young Professionals Corner.
- In a repeat of last year, the Boston Area Chapter has again made a significant charitable donation to Bio-Ball. The event - on March 26th - is still in need of volunteers. See the Chapter Bulletin Board section of this newsletter or the Bio-Ball website at www.bioball.org for more information.
- As our Committees continue to plan educational programs, socials and special events, there are many ways for Members to help. As little as an hour or two of your time once or twice a year would be a valuable contribution. Contact the Chapter at office@ispeboston.org or 781-647-ISPE (4773) to learn more.
- Our CPIP™ Study Group continues to meet, with the goal of preparing its members for the rigorous CPIP certification process. Learn more in the article by Study Group leader and CPIP candidate John Spohn later in this issue and visit the ISPE website at <http://www.ispe-pcc.org/> for more information about the CPIP credential.
- Our Committees and Board of Directors have been hard at work in an effort to define future programs and initiatives:
 - Significant improvements to our Annual Product Show
 - The launch of a Scholarship Program for ISPE Boston Area Chapter Members targeted for Spring 2011
 - The launch of a Sponsorship Program to allow vendors and operating companies access to unique Boston Area Chapter Sponsorship opportunities.
 - The formation of a Mentorship Program (still at the discovery stage) and a Charitable Actions Committee.
 - A new venue for our Annual Golf Outing August 15th: Indian Pond Country Club in Kinston, MA. Take a look at their website at www.indianpondcountryclub.com - there's no snow!
 - And something really fun: our 11th Annual Ski Outing, March 4th at Cannon Mountain where a special award will be presented to a unique individual after the day of skiing and riding.

So what's next? Lots of planning and doing as we move towards spring. We hope to see you at a future event and thank you for supporting our Chapter. And remember, if you'd like to share your ideas, questions or concerns - or would like to help us reach our goals for 2011 - contact us at office@ispeboston.org or 781 647 ISPE (4773). Or you can reach me at 617-869-8287 for all matters ISPE.

Thank you,

Jim Grunwald
President, ISPE Boston Area Chapter

Upcoming Chapter Events - Mark Your Calendar

Annual Ski Trip

Friday, March 4, 2011
Cannon Mountain, Franconia, New Hampshire



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Join your fellow ISPE Members and friends for a day of fun on the slopes of Cannon Mountain! There will be an apres ski party where you can network and socialize with your colleagues. This social is for both members and non-members.

ISPE would like to thank our Ski Trip Sponsors!

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Signer Harris Architects
Superior Controls, Inc.

If you would like to order individual tickets, or books for \$260, please contact the office at 781-647-4773 or fill out a registration form and fax it to the office at 781-647-7222.

For your convenience, a bus has been hired to take you to Cannon Mountain. It will pick up at the Newton Marriot, Newton, MA at 5:30 AM, the Chateau Restaurant, Andover, MA at 6:00 AM and will stop at LL Bean, Concord, NH at 7:00 AM. The bus will return you to your appropriate departure site at approximately 7:00 PM.

Click here to for a registration form: [Annual Ski Trip](#)

Brainstorming Session

Thursday, March 24, 2011
Genzyme Center, Cambridge, MA
Reception: 5:30 pm; Brainstorming Session: 6:30 pm

The Chapter is holding a Brainstorming Session to plan educational content for the 2011-2012 programming season. This is an ideal opportunity to share your ideas and help us plan programs of interest to you for the upcoming year. If you have ideas for programs, speakers, or locations, please join us to share your thoughts. A pre-session networking reception will let you unwind with fellow industry professionals. Then we will focus on your ideas and suggestions. All ideas will be collated and presented to the membership before being finalized for the next programming season.

Attendance is free (we want your ideas!), so please come and help us plan and brainstorm! All you have to do is RSVP today via the website or the attached form. If you have ideas but are unable to attend, please send your ideas to the office at jspe@camihq.com.

Click here to register online: [Brainstorming Session](#)

BioBall Tournament

Saturday, March 26, 2011
Buckingham, Browne, & Nichols School, Cambridge, MA

The Boston Area Chapter is once again a proud sponsor of Bio-Ball – a one-day basketball tournament and Special Olympics fundraiser which brings together teams from participating biopharma companies and partners them with Special Olympics athletes. Chapter Members can join in on the excitement as volunteers to help pull the event together and support the teams. While the opportunity to participate in this high-profile event is a “slam dunk” for Chapter Members, the Chapter will be recognized with its prominent sponsorship of the CEO Free Throw competition.

Bio-Ball organizers will provide volunteers with breakfast, lunch, and a T-shirt. All volunteering members should plan to join Sylvia Beaulieu, ISPE Past President, down at the court as the CEO Free Throw gets underway.

Bio-Ball is in its seventh year and has raised over \$400,000 for Special Olympics Massachusetts through the support of participating companies and sponsorship from service providers and suppliers to the local biopharma industry. This year's team roster includes companies such as Alnylam, Zalicus, Infinity, Momenta, Novartis, Parexel, Sunovion, Agios, AVEO, Cubist, Shire, Mass Bio Organization, Vertex and others. Please visit the Bio-Ball website (www.bioball.org) for a description of volunteer opportunities and to sign-up - click the "Volunteer Registration" link. There are various needs with varying time commitments, including assistance on Friday prior to the event. If you have any questions about the event, or have any ideas for other community events, please contact us at jspe@camihq.com.

Click here for more information: [BioBall Tournament Website](#)

INTERPHEX Bus

March 29, 30 or both, 2011
[Amtrax Parking Garage, Westwood, MA to Jacob K. Javits Center, NYC](#)

Traveling to INTERPHEX from the Boston area? Sign up for a Complimentary Roundtrip Shuttle Bus.

Buses will depart Boston on March 29 and 30 at 7am. Return trip departs from the Jacob K. Javits Center in NYC at 6pm on March 29 and 4pm on March 30. Take a one-day bus or stay over night.

Pick-up Location: The Rt 128 Parking Lot at Blue Hill Dr & University Avenue Westwood, MA. If you have any questions contact the ISPE office at office@ispeboston.org.

Click here to register online: [INTERPHEX Bus](#)

Student Leadership Career Forum

Saturday, April 2, 2011
[Royal Sonesta Hotel, Cambridge, MA](#)

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Jamie Miller | 617.475.3050
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Registration: 7:30 am; Program: 8:00 am - 5:00 pm

Discover the latest information on hiring trends, skills required and other tips to help you obtain a career in the pharmaceutical, biotech and medical device industry.

A full day workshop for students providing insights on careers in the pharmaceutical, biotech and manufacturing industry where an exchange of information, ideas and lessons learned can be shared among attendees. Some key items highlighted include resume reviews by mentors, interviewing skills, professional etiquette, and networking skills.

The event will begin at 7:30 AM and conclude at 5:00 PM. Lunch and refreshments during breaks will be served.

Presented by: Boston Area Chapter, Delaware Valley Chapter, New Jersey Chapter, and New England Chapter

Click here to register: [Student Leadership Forum](#)
Click here for more information: [Flyer and Sponsorship Information](#)

Save These Dates!

April 21, 2011
Educational Program

May 19, 2011
Educational Program

June 16, 2011
Educational Program

Bio-Ball Needs Volunteers - A Slam Dunk for Chapter Members

By Sylvia Beaulieu, The Richmond Group and Bio-Ball Planning Committee

The Boston Area Chapter is once again a proud sponsor of Bio-Ball - a one-day basketball tournament and Special Olympics fundraiser which brings together teams from participating biopharma companies and partners them with Special Olympics athletes. Chapter Members can join in on the excitement as volunteers to help pull the event together and support the teams. While the opportunity to participate in this high-profile event is a "slam dunk" for Chapter Members, the Chapter will be recognized with its prominent sponsorship of the CEO Free Throw competition. The Bio-Ball tournament will take place Saturday, March 26th at the athletic center of the Buckingham, Browne, & Nichols school in Cambridge.

With the sponsorship, Chapter Members are eligible to participate as volunteers in this exciting event. Bio-Ball provides volunteers with breakfast, lunch, and a T-shirt - plus a great opportunity to have fun with colleagues and support a worthy cause. All volunteering Members should plan to join Sylvia down at the court as the CEO Free Throw gets underway.

Bio-Ball is in its seventh year and has raised over \$400K for Special Olympics Massachusetts through the support of participating companies and sponsorship from service providers and suppliers to the local biopharma industry. This year's team roster includes companies such as Alnylam, Zalicos, Infinity, Momenta, Novartis, Parexel, Sunovion, Agios, AVEO, Cubist, Shire, Mass Bio Organization, Vertex and others.

Please visit the Bio-Ball website at www.bioball.org for a description of specific volunteer opportunities; to sign-up just click the "Volunteer Registration" link. There are a variety of volunteer activities with varying time commitments, including assistance on Friday prior to the event. If you have any questions about the event, or have any ideas for other community events, please contact the Chapter at ispe@camihq.com.

It's Not Too Early to Start Thinking about Product Show XX!

by H. Steven Kennedy

The 20th Annual ISPE Boston Chapter Product Show will be held Wednesday, October 5, 2011 at Gillette Stadium in Foxboro. This is the biggest one-day gathering of biotechnology and pharmaceutical professionals in the Northeast. And for our 20th Anniversary, we are really going to shake it up. How? Well, we can't tell you everything this month, but here are some of the items we are working on:

- The show is being expanded dramatically to accommodate the number of exhibitors that have been waitlisted in previous years.
- For the first time, we will be offering a limited number of 10' x 10' booths to allow exhibitors to display equipment.
- The Career Fair is back and it has a new, spectacular home!
- We are going to offer a new tour this year and, for the first time, you will be able to buy tour tickets when you register for the show in advance.
- The Educational Sessions and Keynote Address has a surprising new home.
- The speaker for the Keynote Address will blow you away.
- And the after show party is shaping up to be the social event of the year! You could say it will be a great "scene."

So...if you are an exhibitor and you have not yet pre-registered, what are you waiting for? Even with the added booths, we fully expect the show will sell out again as it has for the last 19 years. If you don't want to end up on the waiting list, reserve your space today with a deposit by clicking [here](#).

Out With the Old, In With the New (eMail Address, that is)

Notice anything new? Our email address is now office@ispeboston.org for all matters related to the Boston Area Chapter. The new address is a natural extension of www.ispeboston.org. Although the old email address will continue to function for an indefinite period, we hope you'll help us "ring in the new" by using office@ispeboston.org instead.

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ISPE Northeast Regional Student Leadership Forum

Saturday, April 2, 2011
Royal Sonesta Hotel, 40 Edwin Land Boulevard, Cambridge, MA 02142
7:30am - 5:00pm

Discover the latest information on hiring trends, skills required and other tips to help you obtain a career in the pharmaceutical, biotech and medical device industry. A full day workshop for students providing insights on careers in the pharmaceutical, biotech and manufacturing industry where an exchange of information, ideas and lessons learned can be shared among attendees. Some key items highlighted include resume reviews by mentors, interviewing skills, professional etiquette, and networking skills. Lunch and refreshments during breaks will be served. There will be a \$25 charge for the event.

The Boston Area Chapter has partnered with the Delaware Valley, New Jersey and New England Chapters to sponsor this event.

[Click here](#) to register or go to www.ISPEBoston.org/Events.

If you have any questions, email the Boston Area Chapter at office@ispeboston.org or call 781 647 ISPE (4773).

Innovative Boston Area Chapter CPIP Study Group Grabs Attention

by John Spohn, Castle Hill Technologies with photos by Dana Lipp, Dana Lipp Imaging



Study Group participants work together to help one another reach the goal of CPIP certification.

Supporting the professional development of Members is what it's all about for the ISPE and the Boston Area Chapter in particular. The Chapter is now sponsoring its second consecutive CPIP Study Group to mentor Members in pursuit of the exclusive credential. The Study Group has grabbed attention and generated requests from numerous other Chapters based on the innovative approach, syllabus and materials developed by volunteer Members of the Boston Area Chapter.

The ISPE website says: "The CPIP™ (Certified Pharmaceutical Industry Professional™) credential is the first professional certification program for the pharmaceutical industry covering development through manufacturing, based on an international, knowledge and skills competency standard...and an industry and government-wide initiative to drive innovation and improve drug product quality."

What attracted me to the credential was its emphasis on professional practice in addition to comprehensive working knowledge of the pharmaceutical industry. To get the credential, one must submit a substantial application for eligibility and, once they are declared eligible, pass a 150-question exam. Having a reputable independent authority endorse your approach and accomplishments adds great meaning to the credential.



(l to r) Joyce Chiu, CPIP, Joe Maressa, Allan MacDonald, CPIP, John Spohn and Carol Bergeron worked together to design a study group format that has attracted national attention.

To obtain eligibility one must show their practice is professional, ethical and characterized by being a leader and advocate for innovation, continuous improvement and quality and that one mentors others in these best practices. A typical application comprises a college transcript, letters of recommendation and between 5 to 9 "exemplars." Exemplars are written descriptions of work experiences that demonstrate required "behavioral descriptors" witnessed by professionals with whom a given work experience was shared.

The first CPIP Study Group (SG1) took place over the summer of 2010 to prepare for the September-October exam window and consisted of nine sessions to review the 18 learning modules under the apt and affable leadership of Doyle Johnson. Doyle's innovation was to promote discussion of the material by peers from disparate corners of the Boston area pharma community, through which we all gleaned knowledge about less familiar aspects of the business.

SG1 produced one of the two fall 2010 CPIPs, our own Joyce Chiu, CPIP. Timely submission of the eligibility package hampered a number of applicants, your author among them. Unfortunately, review of my package was still incomplete as the exam window closed.

Some weeks later I encountered Doyle and told him how valuable I considered the experience and asked whether the Chapter would continue this program and if he would again lead the group. Doyle said that there could be a SG2, but that he would be unable to lead the group. At which point I remarked (without much forethought), "Maybe I should lead the group..."



All the benefits you love about your ISPE Membership are now more affordable than ever! Young Professionals, now you can enjoy a savings of more than 60% a year for the first four years you're out of school.

**Young Professionals**

Visit www.ISPE.org/YPOues to see if you qualify for the new ISPE Young Professionals Membership, or contact membership@ISPE.org

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Best of luck to these hard working Study Group participants as they prepare for the upcoming CPIP exam.

The next day a couple of emails with "CPIP" in the subject caught my eye. I opened the first to see discussion of my "interest" in leading SG2 and was seized by that peculiar feeling that occurs when one realizes they have inadvertently committed to something from which there is no graceful escape. The commitment was made on the basis of this rationalization: leading SG2 would be a great way to brush up, learn more from a new group of peers and work on my eligibility package, which was still under review.

Immediately upon crossing that Rubicon, my attention shifted to the other CPIP-related email - which notified me of acceptance of my eligibility package. (Lesson to all: maybe reading and responding to emails in chronological order is not always the best strategy.)

This episode nonetheless provided some inspiration. I enlisted two CPIPs from our Chapter, Joyce Chiu and Allan MacDonald, CPIP to collaborate on a new curriculum built on the SG1 model but with added sessions and content aimed at helping CPIP candidates develop successful eligibility packages. We investigated the application and evaluation process and created presentations on how to write effective exemplars, content for sessions dedicated to review and feedback of exemplars in small working groups and an overall plan and schedule for timely preparation for the exam.

Up to these final weeks of SG2 the feedback on the added material has been exceptionally positive from within the group. We also have strong interest from numerous other ISPE Chapters who have sought our collaboration and materials as they prepare to launch similar Study Groups.

Many thanks should go to Joyce and Allan for their good work on behalf of aspiring CPIPs present and future. In fact, the evolution of SG2 has been illustrative of the ethic espoused by the ISPE and exemplified by the Boston Area Chapter model: Leverage the creativity of motivated volunteers with investment of organizational resources to evolve a program of high value and national interest, in order to promote the professional development of Members, advancement of the industry and higher standards of quality.

Anyone up for leading SG3?

For more information on CPIP, please visit <http://www.ispe-pcc.org/index.cfm>.

New Year's Social Raises \$2600 for "Helping Our Troops"

by Michelle Greaney, Vanderweil P&IDC with photos by Joyce Chiu, CPIP, Sperian Protection



Volunteer Michelle Greaney congratulates lucky raffle winner.

History repeated itself on January 13th when the Boston Area Chapter once again congregated at Flat Top Johnny's Billiards in Kendall Square for our annual New Year's Social. Members and guests ventured out to into the cold to have some fun, meet with friends and colleagues, play some pool, enjoy great food and conversation and hope for a winning ticket so they could take home one of the many amazing raffle items donated by our sponsors. Even a major snowstorm the day before didn't deter attendees, with close to 100 members and guests braving the slippery sidewalks and piled-high snowdrifts to join the fun. A diverse group of Chapter members made for lively conversation, with operating companies, academic and research institutions, vendors and contractors all well represented.



Happy faces were the norm at January's successful New Year's Social.

According to tradition, there was also a serious side to the event which was a benefit for Helping Our Troops (or H.O.T.), a local nonprofit based in Stoneham dedicated to helping soldiers from Massachusetts serving in Iraq and Afghanistan. H.O.T. has a program called "Adopt-A-Box" that provides soldiers with care packages filled with goodies - everything from phone cards, to tooth brushes and toothpaste, to beef jerky and beanie

babies. You name it, any small item that can be shipped has been requested by our troops to help brighten their day, week - or even month!

The most moving portion of the evening came when H.O.T. founder and Vietnam vet Frank Geary described his organization, how it came about and its importance to our troops, followed by the proverbial "pin-dropping" moment when Sgt. John F. O'Riordan described how valuable seemingly small gifts can be. In one case, giving a beanie baby to a local child helped a truckload of soldiers find a route safe from ambush; in another case, a child led soldiers to a cache of weapons in return for a handful of beanie babies. The stories were amazing and the room grew silent as we all listened and appreciated anew our safety and security and the part played by the efforts of the brave Massachusetts men and women served by H.O.T. The message was received loud and clear - so clearly in fact that we

exceeded our fund-raising goal and collected over \$2,600 which will provide over 220 care packages for our troops. On behalf of the Social Committee and the Boston Area Chapter, thank you very much for your generous support.



Helping Our Troops representatives with Social Committee Chair & Board Member Chris Opolski.



Volunteer Gene Dennen gets thanks from Chapter President Jim Grunwald.

None of this success would have been possible without the efforts of the Social Committee, specifically, Carly Star who designed the Sponsor profiles, Paul Sullivan who assisted with additional fundraising efforts and Committee Chair Chris Opolski who coordinated our team (with help from yours truly); and Hannah and Julia from the Chapter's admin group who greeted Members and guests and efficiently managed registration. And last, but certainly not least, our exceptionally generous sponsors: R.W. Sullivan Engineering; Superior Controls; SciTech Builders; Entertainment Cruises - Odyssey Cruises | Spirit Cruises | Elite Yacht Charters; The Richmond Group; CRB Consulting Engineers; Spectra Automation; and Columbia Construction.

with Members

First "Dual-Track" Educational Program Proves Popular

In a "first" for the Boston Area Chapter, the Educational Program Committee partnered with the Young Professionals Committee to present a "dual track" educational program on January 20th at the Hyatt Regency in Cambridge. The dual-track approach was chosen to provide concurrent presentations on the same general topic - in this case, process automation and control, with each presentation geared to a different level of audience expertise. "Introduction to Automation in Life Sciences" was designed for those new to the field and "Advanced Process Control for Greater Profitability" for those who had already mastered the basics. Combined networking receptions before and after the presentations allowed both groups to meet, mingle and compare notes. This approach proved so successful that it is sure to be repeated in the future.

Introduction to Automation in Life Sciences
by Tim Schmidt, New England Controls with photos by Joyce Chiu, CPIP, Sperian Protection

Whether dealing with validation, manufacturing, R&D or other operational tasks, engineers are asked to leverage automated systems to meet the challenges before them. Understanding the terminology, fundamentals, and integration of these systems can be a daunting and difficult task. Compounding this effort is the rapid growth of automation technology on multiple platforms resulting in an abundance of information. All of this can overwhelm even the most attentive domain expert in a short amount of time.

To demystify the fundamentals of process automation, the Young Professionals developed the evening's introductory program. Young (and young at heart) attendees packed the room to hear Tim Alosi of New England Controls walk through the basics of automation technology while taking time to discuss questions and share his experiences.



Speaker Tim Alosi proves the value of a hands-on demo.

Tim started with the fundamentals of a controlled feedback loop, progressed into the essential hardware architectures and wrapped up with a high-level view of applied strategies. Of particular interest was his perspective that today's automation platforms are equally capable of performing elementary process control on a variety of scales. Differentiation does exist but is now found in specialized areas. He also presented the concept of an automation life cycle which need not be limited to capital projects but can be applied to smaller projects as engineers positively impact their process.

To finish with a bang (or a hiss), the audience asked Tim to put the laser pointer down and take a hands-on approach to create a working loop with controller, pneumatic valve, and pressure feedback device. It took him a matter of seconds to demonstrate all of the fundamentals covered in our session. In fact, many attendees stayed after to build their own loop and ask more detailed questions. Perhaps automation isn't so daunting after all!

Advanced Process Control for Greater Profitability
by Paul Doherty, CRB Consulting Engineers and Rami Mitri, Spectra Automation with photos by Joyce Chiu, CPIP, Sperian Protection

If there is one conclusion that can be drawn from this presentation, it is that the biotech field is full of innovative people. People like James Heimbach, who readily adapted new processes in order to achieve optimal results when standard control systems lack the depth to predict output based on data that is within its system

When Mr. Heimbach, a statistician for Lonza, was asked how he moved into the biotech field, given that his background was not in the industry, his response was that he created his own job. Drawing on lessons he had learned from a previous boss that were cutting edge, he understood the benefit of thinking outside the box. He believed that by bringing this kind of innovative thinking to the biotech field, he could achieve a competitive edge for Lonza.



Dual presentations offered attendees a choice of material - introductory or advanced.

The inspiration for this presentation was the partnership that was created at Lonza between Mr. Heimbach and Joseph Kauten, Director of Process Control. The result of this partnership was the concept that, by combining statistical analysis with process control, you could create a new breed of enhanced control systems.

An enthusiastic crowd was on hand to learn about Lonza's experience with "advanced" methods in controlling critical process attributes. The discussion included the use of neural networks to control titration, linear regression methods to predict harvest timing and feeding regimens, as well as Multivariate Process Control. Another key discussion point was integration of these techniques into a validated and tightly controlled automation system

One of the driving factors behind this concept was that Lonza, being a contract manufacturing company, needed to achieve a competitive edge in an industry that was moving towards commoditization. Lonza's clients needed ways to achieve higher throughput, derive more information from each batch and reduce variability so that their "time to market" would be faster than that of their competitors.

Data mining and data analysis was one way that Lonza answered their client's needs. Applying advanced control to various processes allowed Lonza to predict throughput and achieve consistent results, bringing every batch as close to the "golden batch" as possible.

Finally, Mr. Kauten discussed how advanced control in a highly regulated industry can be achieved with proper training as well as understanding cause and effect. As the two speakers demonstrated, applying advanced control, using off-the-shelf software that performs data analysis and provides concrete data, allows control system operators to refine their control schemes and achieve optimal results.

Career Transformations: Capitalizing on Your Transferable Skills

by Dan Gee, Biotech Drug Development Consultant

Along with the rest of the country, the biopharmaceutical industry has been feeling the ramifications of the Great Recession for the last few years. As a result, industry professionals have found themselves in transition and wondering about their careers and the future. For many it's more than just getting another job. It's how to leverage the valuable skills they have honed during the course of their careers while keeping their personal interests/family and ambitions in the proper perspective.

To identify the issues and provide a strategy and plan that industry professionals can apply to their specific situation, an interactive program was presented by the Member Services Committee on February 10th at the Regus Business Center in Newton. The meeting was moderated by Committee Members Ric Feldt and Bob Urbanowski in a format that consisted of an interactive discussion with audience participation and two panels, each consisting of a professional Career Coach/Counselor and several industry professionals who have capitalized on their skills and made a career transition.

The focus of the first panel was entrepreneurs/small business owners who have departed from traditional employment to pursue entrepreneurial ventures or have become business owners. Panelists were Suzanne Gray (Self Employment Coach, The Entrepreneur's Source), Peter Antoinette (President & CEO, Nanocomp Technologies), Dr. Elizabeth Higgins (President and Founder, GlycoSolutions); and Michelle Connor (Owner, AdviCoach). The second panel was composed of professionals who have leveraged their skills and career experience to work in a different function or industry: Fred Nothnagel (Executive Director/Owner, Wednesday Is Networking Day); Shelly Henderson (Life Sciences Business Development), and Christine Gebski (Director, Applications and R&D, POROS Chromatography Resins, LIFE Technologies).

The career coaches used their specialized expertise to facilitate discussion about the soft skills, planning processes, personality profiles and values typically required for success and added their own success stories to the mix, while the distinguished panelists described what they did to be successful in their chosen careers and added personal insights gained from lessons learned along the way.

The following are a few of the questions used to frame the discussion and some of the panelists' responses:

- **Identifying Your Work/Life Goals.** What are key questions to ask yourself when considering making a change? How do you know if a specific function, industry or business is right for you? If you were starting out in your career, what would you choose to do and why?

Identify what your work and family life will look like in the future and the legacy that you want to leave. This will lead to your goals, plan and specific career/business opportunities. In other words, "avoid being a cork floating down the river and take control - add a motor." Also consider "What do you want less of?"
- **Factors to Consider.** What is the profile of a successful transitioner/business owner? What personal values and abilities do you consider to be important?

A key strategy is to "review your accomplishments - this will point to the skills that have made you successful so you can play to your strengths." Also "take off your blinders, try looking at the world in a different way" and "don't listen to too many advisors." Another piece of advice was to fully assess your skills and "get an inventory such as through Myers-Briggs or DISC."
- **Assistance Sources.** What are the most important questions, and what are the best information sources for answers? Why are informational interviews valuable? Should you enlist the support of friends and family?

The panel advised attendees to network in work and social circles and to "surround yourself with a board of advisors, formal (legal, etc.) and informal (friends, ex-colleagues, networking contacts)." For financial support, one entrepreneur recommended taking advantage of "business incubator funding that is available."

- Pathways. What knowledge and experience is applicable for a smooth transition into a different market? What are the current biopharma "extension or spinoff" technologies and industries offering a promising future? What are the steps to develop a product or service based on your idea?

One panelist advised, "maintain your mental fortitude by keeping a positive attitude" and "believe in yourself." Another said "skills can be taught, attitude must be innate." Another advised, "avoid naysayers - 'the crabs in a basket' - who pull you down with negativity."

In summary this was a very challenging topic to cover in such a short period of time and only the surface has been touched. There was enthusiastic audience participation and opportunities to network before and after the session. Nevertheless, the meeting provided a catalyst for attendees to begin pondering the many questions and answers discussed in the context of their own career and personal life. As a final take home message, these fundamental questions should be reevaluated regularly to help you to stay "on course," not just during hard economic times.

Panelists from BMS, Genzyme, Pfizer & MassBiologics Shed Light on Risk-Based C&Q

by Jack Campion, Genzyme with photos by Joyce Chiu, CPIP, Sperian Protection

Genzyme Science Center in Framingham was the site of the Boston Area Chapter's February 17th educational program. The title of the program was "Panel Discussion: Risk-Based Commissioning and Qualification." This is a hot topic in the industry currently as firms adopt the ASTM E2500 standard as well as other risk-based standards and guidance to their commissioning and qualification (C&Q) programs.



The meeting was co-chaired by Jack Campion, validation manager for purification and fill finish at Genzyme, Allston; and Aaron Jordan, IT Validation Manager at MassBiologics (UMass Medical). The meeting was moderated by Jack who also serves as co-chair of the Educational Programs Committee (EPC) for the Chapter.

The wide interest in this topic was demonstrated by the nearly 100 who registered to learn both from the panelists and each other. Three panelists, all Members of the Boston Area Chapter, generously shared their experience, giving the audience members several perspectives on the topic, with short slide presentations followed by audience participation. The three panelists were Armen Nahabedian (Director, Commissioning/Qualification, Pfizer Global Engineering), Michelle Whipple (Associate Director of QA Validation, Bristol Myers-Squibb, Devens) and Eric Felz (Validation Manager, Genzyme, Framingham). All three panelists are Members of ISPE's C&Q Community of Practice (COP) Owner's Task Team.

An overflow crowd enjoys the networking reception prior to the panel discussion.

Armen co-leads the development and roll out of the Pfizer Verification Program. Armen gave the "global enterprise" perspective, describing the differences in "adoption" by various Pfizer sites world-wide. Some are early adopters, embracing the risk-based concept broadly. For others, it is more practical to choose one project as a "pilot" for application of the risk-based approach. Armen also debunked several myths about the risk-based approach, such as the notion that "verification" means less testing. In fact, verification is "sufficient testing to show fitness for use," which may mean more or less testing than previously, depending on the associated risk.

The first presentation was given by Armen Nahabedian.



Education Program Committee chair Jack Campion (l) with panelists (l to r) Armen Nahabedian, Steven Wisniewski, Michelle Whipple and Eric Felz.

Michelle Whipple of Bristol Myers-Squibb (BMS) told the audience how the risk-based approach was applied to the new BMS biotech plant at Devens. Michelle provided details of the process by which systems and equipment were assessed for their risk to patient safety. She described how 85 systems were subjected to a three-stage assessment over two months after the process design was complete. Onsite testing requirements for each system depended upon the extent of vendor documentation, factory acceptance testing already performed, complexity and risk.

Eric Felz told "A Tale of Two Projects," two nearly identical projects involving replacement of air handling units in separate buildings. In both cases, the units and the associated cleanrooms were in scope. However, in one, the traditional approach of commissioning followed by qualification was applied. In the other, a more integrated and risk-based approach was employed. In the risk-based case, Eric

described how the Critical Quality Attributes (CQAs) were identified and associated with Critical Process Parameters (CPPs). Risks to patient safety were evaluated. When compared, the two methods showed some startling differences. The risk-based approach excluded a significant amount of what we traditionally include in validation, such as installation qualification (IQ) of all air handler (AH) components. Instead, the risk-based approach commissioned the AH, treating it as an upstream utility, and did not subject it to formal IQ. Only five key physical parameters and their associated equipment and controls required formal validation: HEPA certifications, room temperature, room differential pressures, air flow, and duct static pressure.

After the presentations, audience members asked questions about the relationship between "verification" and "validation," the panelists' experience with organizational resistance to change and a range of other topics. Attendees also received a "bonus" afforded by the attendance of Steve Wisniewski, former ISPE Chairman and founder of the C&Q Community of Practice. Steve, who is with CAI and on assignment at Genzyme, gave the audience a preview of the upcoming ISPE "practice guide" to help make the transition from traditional C&Q to a risk-based approach.

Participants all received a hefty helping of take-home information that will pay dividends as they apply them to real, everyday projects in

the pharma industry.

Young Professionals Back in Action after Holiday Break

by Jillian Willard, Genzyme Corporation

The Young Professionals are back in action after the holiday break. After co-sponsoring a successful dual-track educational program on automation with the Educational Program Committee in January, the Young Professionals are now putting together the second educational event of the new year. The session will focus on equipment cleaning and is slated for early to mid-April. The first YP Social of the year is also in the works, so keep your eyes open for more information.

Other events coming up include the Boston Area Chapter Ski Trip on March 4th and INTERPHEX in New York City, March 29 through 31. Both events are great opportunities to network and have some fun with other Young Professionals.

To receive announcements specifically for YP events, email us at office@ispeboston.org or join our Facebook group by searching for "Young Professionals - Boston ISPE Chapter."

Industry News In Brief

by Patti Charek, RF Walsh Collaborative Partners

Industry News In Brief, a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to our readers.

Sanofi-aventis to Acquire Genzyme for \$20.1 Billion

Sanofi-aventis and Genzyme Corporation have announced that they have entered into a definitive agreement under which sanofi-aventis is to acquire Genzyme for \$74 per share in cash, or approximately \$20.1 billion. In addition to the cash payment, each Genzyme shareholder will receive one Contingent Value Right (CVR) for each share they own, entitling the holder to receive additional cash payments if specified milestones related to Lemtrada (alemtuzumab MS) are achieved over time or a milestone related to production volumes in 2011 for Cerezyme and Fabrazyme is achieved. The transaction, which has been unanimously approved by the Boards of Directors of both companies, is expected to close early in the second quarter of 2011, subject to customary closing conditions.

"This agreement with Genzyme is both consistent with our long-term strategy and creates significant long-term value for our shareholders," said Christopher A. Viehbacher, Chief Executive Officer of sanofi-aventis. "This transaction will create a meaningful new growth platform for sanofi-aventis while expanding our footprint in biotechnology..."

"This transaction represents a new beginning for Genzyme," said Henri A. Termeer, Chairman of the Board, President and Chief Executive Officer of Genzyme Corporation. "Genzyme has a record of innovation and a unique and pioneering approach to serving patients. We also share an exciting vision of the future, one in which Genzyme and sanofi-aventis grow and innovate by developing breakthrough treatments that change the lives of people with serious diseases. Sanofi-aventis believes in what we do, in our people and in our potential. We look forward to building a sustainable future together."

Sanofi-aventis' global footprint, significant resources and proven track record of successfully expanding franchises will create new long-term growth opportunities for the combined company, particularly in emerging markets. Genzyme will become an important new platform in sanofi-aventis' sustainable growth strategy and expand the company's presence in biotechnology. Sanofi-aventis intends to make Genzyme its global center for excellence in rare diseases and the acquisition will reinforce sanofi-aventis' commitment to the greater Boston area, where it already has a sizeable presence.

Beyond rare diseases, Genzyme has built strong Renal-Endocrinology, Hematology-Oncology and Biosurgery businesses that are complementary to existing sanofi-aventis businesses and include highly differentiated, market-leading products that provide significant benefit to patients. Sanofi-aventis will work with Genzyme through the integration process to develop plans to enhance the opportunities for these businesses going forward. Consistent with sanofi-aventis' approach in other transactions, Genzyme will retain its corporate brand.

Genzyme and sanofi-aventis will immediately begin integration planning, including the formation of a joint Integration Steering Committee. Henri A. Termeer will resign as Chairman of the Board, President and Chief Executive Officer of Genzyme following the close of the transaction, but will advise on the integration in his role as Co-Chairman of the Integration Steering Committee with Christopher A. Viehbacher. (Source: Genzyme Website, 16 February, 2011)

Pfizer Set to Add 350 Jobs in Massachusetts

Pfizer said it will add about 350 jobs in the Boston area and look for a new site to house a pair of research units it will move here from southeastern Connecticut. The news came as Pfizer, the world's largest drug company with \$67.8 billion in revenue last year, unveiled a broad restructuring plan that will slash its global research and development outlays by \$1.5 billion, resulting in the loss of thousands of jobs around the world. It was the second major research cutback since New York-based Pfizer acquired Wyeth Pharmaceuticals in 2009.

But even as Pfizer shrinks research operations globally, it will be growing in Massachusetts, where it already has about 2,300 workers at two research labs in Cambridge and a former Wyeth biotechnology plant in Andover. "We have recognized that we want to have a very significant footprint in Massachusetts," said J.C. Gutierrez Ramos, the Cambridge-based Pfizer senior vice president of biotherapeutics research and development. "This emphasizes Pfizer's commitment to increase our interactions with the academic medical centers, our interactions with the biotechnology companies and entrepreneurs, with all of the stakeholders in biomedical research."

Pfizer's decision to increase research in the Boston area follows similar recent moves by global drug makers such as Novartis AG of Switzerland and Sanofi-Aventis SA of France, which want to plug into the area's life sciences industry at a time when drug discovery has slowed worldwide. Like other companies, Pfizer is also refocusing its own research on core areas ranging from neurology and immuno-inflammation to vaccines and cancer treatments.

"It's a confirmation that, when some of these companies have to make tough decisions, they continue to favor Massachusetts," said Susan Windham-Bannister, president of the Massachusetts Life Sciences Center, a state agency created to implement Governor Deval Patrick's life sciences initiative.

Even as it eliminates 1,100 jobs in Groton, CT, about a quarter of its workforce there, the company said it will be consolidating its neuroscience and cardiovascular metabolic research operations in the Boston area. Those operations will be housed in a new site, probably in Boston, Cambridge, or Waltham, said Gutierrez. Together, they are expected to create about 450 jobs here, he said. But

Pfizer will cut about 100 other jobs in the Boston area, many at a lab it plans to close on Memorial Drive in Cambridge. That lab conducts research into regenerative medicine and other therapeutics. Pfizer will continue to be involved in those types of research, but will do less work with its own staff and more with outside collaborators, Gutierrez said.

Gutierrez said some of the projects taking place on Memorial Drive may be folded into other Pfizer operations and some researchers there may be transferred to other sites. Pfizer will still operate another lab, formerly owned by Wyeth, in the Alewife neighborhood of Cambridge.

Windham-Bannister said state government officials will work with Pfizer to assist any employees who lose their jobs as part of the restructuring, helping them to find other life sciences jobs in Massachusetts. (Source: Robert Weisman, Boston Globe, 2 February, 2011)

Vertex Drug to Get Fast-Track Review

Vertex Pharmaceuticals said regulators in the U.S. and Canada will speed their reviews of its drug candidate telaprevir, meaning the hepatitis C therapy could be approved months earlier than usual. Vertex said the FDA will do a six-month priority review on telaprevir, which means the agency expects to make a decision by May 23. Typical FDA reviews last about 10 months, starting from the date the drug maker files for approval. The Therapeutic Product Directorate of Health Canada will take six to nine months to make its decision, Vertex said. Standard reviews in Canada take about a year and a half.

Telaprevir is already receiving an accelerated review in Europe. Analysts believe Vertex could get billions of dollars in annual revenue from telaprevir, the first in what could be a series of new treatments for hepatitis C. Telaprevir and Merck & Co.'s drug boceprevir are more effective than older therapies in controlling the viral liver disease. (Source: Associated Press, 21 January, 2011)

Boehringer Ingelheim and Eli Lilly Join Forces to Develop New Diabetes Treatments

Germany's largest independent pharmaceutical firm Boehringer Ingelheim and U.S. drug major Eli Lilly announced a global agreement to jointly develop and commercialize a portfolio of anti-diabetic compounds currently in mid- and late-stage development for the fast-growing diabetes market. Included in the deal are Boehringer Ingelheim's two oral diabetes agents - linagliptin and BI10773 - as well as Lilly's two basal insulin analogues - LY2605541 and LY2963016. There is also the option to co-develop and co-commercialize Lilly's anti-TGF-beta monoclonal antibody.

Under the terms of the accord, Lilly will make an initial one-time payment to Boehringer Ingelheim of 300 million euros (\$389.4 million). The German company will be eligible to receive up to a total of 625 million euros in success-based regulatory milestones for linagliptin and BI10773. For its part, Lilly will be eligible to receive up to a total of \$650 million in success-based regulatory milestones on its two basal insulin analogues.

Should Boehringer Ingelheim elect to opt-in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, Lilly would be eligible for up to \$525 million in opt-in and success-based regulatory milestone payments. The companies will share ongoing development costs equally. Upon successful regulatory approval of any product resulting from the alliance, the companies will equally share in the product's commercialization costs and gross margin. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration.

Diabetes affects an estimated 285 million adults worldwide and more than 24 million people in the U.S. Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes costs approximately \$174 billion per year in direct and indirect medical expenses in the U.S. According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen. (Source: thepharmaletter, 12 January 2011)

Pfizer Expands Pact with RNA Drugmaker Santaris

Pfizer said it is expanding a partnership with RNA drug developer Santaris Pharma A/S in a deal that could be worth more than \$600 million. Pfizer said it will pay the Danish company \$14 million upfront for the drug candidates, which are designed to target RNA. Santaris could get up to \$600 million in milestone payments, plus royalties if any drugs from the collaboration are approved. The New York drugmaker said Santaris will deliver drugs for up to 10 RNA targets. RNA is genetic material that's produced inside cells by DNA. RNA makes proteins that control cellular operations, including disease processes.

The deal expands an agreement between Santaris and Wyeth, which is now part of Pfizer. In January 2009, Wyeth agreed to pay Santaris \$7 million upfront and make a \$10 million investment in the company. Santaris could also receive milestone payments as part of that deal. Pfizer said some programs from that partnership have been advanced and reached early milestones. (Source: Associated Press, PharmPro Website, 4 January, 2011)

Biogen Buys Drug Rights from Partner

Biogen Idec Inc. has purchased the rights to three neurodegenerative disease programs from Neurimmune Holding AG, which it had been partnering with to develop the drugs. Biogen said it will pay Switzerland-based Neurimmune \$32.5 million, and up to \$395 million more in contingent payments, for research programs focused on Parkinson's disease, Alzheimer's disease, and amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig's disease.

"The unmet medical need among patients suffering from devastating neurodegenerative diseases is high," said Alfred Sandrock, senior vice president at Biogen. As many as 5 million Americans suffer from Alzheimer's, according to the Centers for Disease Control and Prevention (Source: Bloomberg News, 21 December 2010)

Biogen Idec Taps Industry Veteran to Lead R&D

Biogen Idec said it has lured biotechnology industry veteran Douglas E. Williams from Seattle to head its research and development operations, a critical job that had been vacant since October 2009. Williams, 52, will arrive about two months after Biogen Idec, the state's second-largest biotech company, unveiled a broad restructuring plan that shut down its research in oncology and cardiovascular medicine while intensifying its concentration on neurology, immunology, and hemophilia.

Williams, who will be an executive vice president at Biogen Idec, was most recently chief executive of ZymoGenetics Inc., a Seattle company bought last fall by pharmaceutical giant Bristol-Myers Squibb Co. Williams previously headed research at another Seattle company, Immunex Corp. He grew up in the Western Massachusetts town of Greenfield, and describes himself as "a lifelong Red Sox and Bruins fan" who is returning home.

Shortly after his predecessor, Cecil Pickett, retired from Biogen Idec, the company's then-chief executive James C. Mullen disclosed that he, too, would depart. The research job, a crucial position at any biotech firm, remained open while the board searched for a new chief executive. George A. Scangos, who assumed that role in the summer - and also came from a West Coast biotech company - said filling the research post was a priority.

Biogen Idec also said that it has named Steven H. Holtzman, 56, to the new position of executive vice president for corporate development. Holtzman will oversee corporate strategy, business development, portfolio management, program leadership, and the company's venture capital fund, all of which had previously been independent business units. He most recently had been chief executive at Infinity Pharmaceuticals Inc. of Cambridge.

With the two appointments and the restructuring announced in November, Scangos, who previously ran Exelixis Inc. in San Francisco, has begun to put his mark on Biogen Idec. The company is best known for drugs that treat multiple sclerosis and rheumatoid arthritis. (Source: Robert Weisman, Boston Globe, 6 January 2011)

Biogen Idec, Roche get OK for New Drug Use

Roche and Biogen Idec won expanded U.S. approval for use of the Rituxan medicine against a common form of blood cancer. The FDA authorized the use of Rituxan as a follow-up therapy in patients with advanced follicular non-Hodgkin's lymphoma who have received an initial primary treatment, the companies said. Rituxan, also called MabThera, won European approval in October for the same patients. The medicine is approved for use in rheumatoid arthritis, chronic lymphocytic leukemia, and non-Hodgkin's lymphoma. It generated \$1.61 billion in revenue for Basel, Switzerland-based Roche during the third quarter and \$258 million for Biogen Idec, the companies said.

Results of a study released in May showed that among follicular lymphoma patients given follow-up therapy with Rituxan for two years, 82 percent had no worsening of their condition compared with 66 percent of those who didn't get maintenance doses. (Source: Bloomberg News, 29 January, 2011)

Alexion Pharma Acquires Taligen in \$111M Buyout

There's big news for Taligen Therapeutics. Cheshire, CT-based Alexion Pharmaceuticals has bought the Cambridge, MA biotech startup for \$111 million and potential future payments, the buyer said. The deal allows Alexion to obtain Taligen's lead candidate, TT30, which Taligen had been developing as a potential rival to Alexion's drug eculizumab (Soliris) for a rare blood disease known as paroxysmal nocturnal hemoglobinuria (PNH). Alexion started selling eculizumab in 2007 and has no other products on the market.

This transaction does keep at least part of the Taligen team together. The biotech's staff is expected to serve as the core of Alexion's new translational medicines group in Cambridge, where former Taligen CEO Abbie Celniker will head research. Alexion says that Taligen's pipeline includes a potential treatment for age-related macular degeneration and other eye disease. The deal will bolster the pipeline of Alexion, one of the hot growth stories in all of biotech. Primarily on the strength of its one hit drug that has sent its stock on a bull run, Alexion is now worth more than \$7.5 billion, almost as much as Cambridge-based Vertex Pharmaceuticals.

Now Alexion controls the fate of Taligen's science, which has focused on using protein drugs to target an overactive immune activity called the complement pathway. This immune malfunction causes inflammation and harms tissue. (The company's technology initially came from the University of Colorado, and was founded there by academics Woodruff Emlen and Michael Holers.) Taligen's lead drug, TT30, might be able to target specific tissues where inflammation occurs - a big improvement from the current practice of using corticosteroids to fight such inflammation in a more generalized way, which causes side effects.

Taligen had planned to begin early clinical trials of its lead compound in late 2010 for rare blood diseases such as PNH, according to Celniker. Alexion says it's the first and only company to get FDA approval for a drug specifically for PNH, which causes immune reactions that attack and destroy red blood cells. The company says there are only 8,000 to 10,000 people in North America and Western Europe with the rare blood disorder. (Source: Ryan McBride, Xconomy, 31 January, 2011)

Amgen Buying Drug Maker BioVex Group of Woburn

Amgen is bolstering its late-stage drug pipeline by buying the privately held cancer drug maker BioVex Group, of Woburn, MA, in a deal that could be worth as much as \$1 billion. BioVex's drug candidate, OncoVex, is based on a virus that attacks cancer cells, destroying tumors and stimulating the immune system to fight cancer throughout the body. Separately, Amgen said it expects the acquisition of BioVex to close in the first quarter. It agreed to pay \$425 million at closing and another \$575 million if BioVex's products reach regulatory and sales milestones.

OncoVex is in late-stage testing as a treatment for metastatic melanoma, the most aggressive type of skin cancer, and squamous cell carcinomas of the head and neck. BioVex is also running an early stage clinical trial of the genital herpes vaccine ImmunoVex.

Sales of Amgen's drugs Neulasta and Neupogen, which are used to prevent infections in chemotherapy patients, rose 3 percent to \$1.24 billion. The increase came mostly from higher prices. Changes in inventories by wholesalers also aided its revenue, and tax credits boosted Amgen's quarterly results. Sales of Amgen's anemia drugs Aranesp and Epogen continued to slide, declining a combined 9 percent to \$1.22 billion because of lower demand, primarily for Epogen. Sales of the two drugs have dropped in recent years because of safety warnings and tighter restrictions on their use.

Amgen reported \$28 million in sales of its newest drug, denosumab. The drug is approved under the name Prolia as a treatment for osteoporosis in postmenopausal women, and it is sold as Xgeva for the prevention of bone fractures in patients with advanced cancer. Amgen said Prolia sales totaled \$20 million and Xgeva sales reached \$8 million. (Source: Marley Seaman, Associated Press, 25 January 2011)

Abbott to Cut 1,900 US Employees

Abbott Laboratories said it would eliminate 1,900 employees to keep profits up, indicating that one of the pharmaceutical industry's few success stories of recent years is not immune to cost pressures squeezing the sector. The maker of drugs and devices said the terminations involve U.S. marketing and manufacturing positions. The cuts, which represent about 2 percent of the company's workforce, are expected to save the company \$200 million annually in coming years. Abbott blamed the cuts on new fees and pricing pressures associated with the health reform law and a "challenging regulatory environment" at the FDA.

Abbott has steadily increased its revenue year after year, even as most of its pharmaceutical peers have watched sales fall as patents on blockbuster drugs expire. And while the company's multibillion dollar, anti-inflammatory drug Humira continued to deliver in the latest quarter, Abbott has stumbled in efforts to develop new therapies. Recently the company withdrew its application for a next-generation psoriasis drug after the FDA indicated additional work would be needed to win approval.

Abbott has also wrestled with safety problems in the past year. It pulled its diet drug Meridia from the market in October because of heart risks, only one month after it recalled millions of containers of its Similac baby formula because of possible contamination from insect parts. (Source: Associated Press, 27 January, 2011)

Boston Attracts Vertex from Cambridge to Fan Pier

Vertex signed a letter of intent to relocate its headquarters from Cambridge to the Fan Pier complex in late 2013. The deal is a watershed

in Boston's campaign to court a biotech industry that has largely eluded it, with most drug companies preferring to be closer to Cambridge's prestigious universities or out in massive suburban office parks that offer cheaper rents and room for expansion. "This is a jump-start for the entire waterfront," said Mayor Thomas M. Menino, who has been trying to remake the area into an "Innovation District" by offering incentives to companies to locate there. "Vertex has made the decision to be on the forefront of the Innovation District, and that decision will lead other companies to follow suit."

Terms of the deal have not been disclosed, and the company has not yet signed the lease. The lease is contingent on an unusual clause: Vertex must receive federal approval of its first major in-house commercial drug, telaprevir, a treatment for hepatitis C. US regulators are expected to act on the company's application by June.

Vertex would occupy about 1.1 million square feet, filling a pair of 18-story buildings at Fan Pier, with an option to expand into a third to be built there. Vertex's portion of the \$2 billion Fan Pier complex is estimated at \$800 million, according to state officials. State and city leaders are providing Vertex with a substantial tax break and other inducements to help close the deal. Vertex's lease will require it to pay real estate taxes on the new buildings. Boston will provide Vertex with an \$11.8 million reduction in property taxes through 2018.

The state, meanwhile, will provide \$10 million in tax breaks in exchange for Vertex creating 500 additional full-time jobs by 2015. Massachusetts will also borrow \$50 million for roads, water and sewer, and other necessary infrastructure, to be repaid with tax revenues generated from Vertex's buildings. Any shortfall in revenue needed to pay off the state's bonds would come from the City of Boston or from the developer.

The relocation will allow Vertex to consolidate its 1,300 workers, now divided among 10 buildings across Cambridge, into a single location. The decision to relocate comes at a critical juncture for the biotech, which has recently hired 300 employees in anticipation of selling telaprevir, a drug it has been developing for 15 years. If it gets a regulatory nod this spring, Vertex will be the first approved, commercially available treatment for hepatitis C. (Source: Casey Ross, Boston Globe, 25 January 2011)

Novartis Will Assume Full Control of Alcon in Deal Worth \$12.9 Billion

Novartis AG will take full control of Alcon, the world's largest eye-care company, after agreeing to pay about \$12.9 billion for the stock it doesn't own to end an 11-month dispute with minority shareholders. Alcon will become the eye-care division of Novartis, which will also include CIBA Vision contact lenses and eye medicines. The unit would have had sales of \$8.7 billion last year.

Novartis chief executive Joseph Jimenez is looking to Alcon to help the Swiss company diversify away from pharmaceuticals, a model also pursued by New Jersey-based Johnson & Johnson, which sells prescription drugs, medical devices, and consumer products such as Tylenol. The purchase values Alcon at about 25 times net income, compared with an average multiple of 26 for past eye-care acquisitions, according to data compiled by Bloomberg. Based on the new terms, the Swiss company will have paid a total of about \$51.6 billion for Alcon.

Jimenez, a former executive at ConAgra Foods Inc. and H.J. Heinz Co. named to the top job at Novartis in January, is finishing a deal started in 2008 by predecessor Daniel Vasella. Novartis expects the deal to close in the first half of 2011. Vasella, who is still the chairman, struck an agreement in 2008 to buy a 25 percent stake in Alcon from Nestle SA for \$143 a share. The Swiss drug maker in January this year exercised an option to buy Nestle's remaining 52 percent for an average \$180 a share.

Alcon, based in Switzerland, got 87 percent of its revenue last year from surgical equipment for ophthalmology and prescription drugs for the eye, with 13 percent from consumer products such as contact-lens solutions. (Source: Eva von Schaper, Bloomberg News, 16 December 2010)

Citing Slow Pace of New Drugs, US to Open \$1 Billion Development Center

The Obama administration has become so concerned about the slowing pace of new drugs coming out of the pharmaceutical industry that officials have decided to start a billion-dollar government drug development center to help create medicines. The new effort comes as many large drug makers, unable to find enough new drugs, are paring back research.

Promising discoveries about such illnesses as depression and Parkinson's that once would have led to clinical trials are instead going unexplored because companies have neither the will nor the resources to undertake the effort, and pharmaceutical companies have typically spent twice as much on marketing as on research, a business model that is increasingly suspect.

The initial financing of the government's new drug center is relatively small compared with the \$45.8 billion that the industry estimates it invested in research in 2009. The cost of bringing a single drug to market can exceed \$1 billion, according to some estimates.

The National Institutes of Health has traditionally focused on basic research, such as describing the structure of proteins, leaving industry to create drugs using those compounds. But the drug industry's research productivity has been declining for 15 years, "and it certainly doesn't show any signs of turning upward," said Dr. Francis S. Collins, director of the institutes.

The job of the new center, to be called the National Center for Advancing Translational Sciences, is akin to that of a home seller who spruces up properties to attract buyers in a down market. In this case, the center will do as much research as it needs to do so that it can attract drug company investment. In other cases, the center may need to not only discover the right chemicals but also perform animal tests to ensure that they are safe and even start human trials to see if they work. All of that has traditionally been done by drug companies, not the government.

Whether the government can succeed where private industry has failed is uncertain, officials acknowledge, but they say doing nothing is not an option. The health and human services secretary, Kathleen Sebelius, sent a letter to Congress on Jan. 14 outlining the plan to open the new drug center by October - an unusually rapid turnaround for an idea first released with little fanfare in December.

Under the plan, more than \$700 million in research projects already underway at various institutes and centers would be brought together at the new center. But officials hope that the prospect of finding new drugs will lure Congress into increasing the center's financing well beyond \$1 billion.

For the plan to go into effect by October, the administration must by law get rid of one of the 27 centers and institutes already in existence at the NIH. The administration plans to downgrade the National Center for Research Resources, in part by giving some of its functions to the new center. (Source: Gardiner Harris, Boston Globe, 23 January 2011)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights, a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech and device industries, and related fields.

FDA Launches Website to Help Industries Save Time, Resources

The FDA has introduced a new online resource called FDA Basics for Industry available at www.fda.gov/FDABasicsforIndustry to help companies and others save time and resources in their interactions with the agency. The website includes basic information about the regulatory process, including information that is frequently requested by industry.

Part of the agency's ongoing transparency initiative, the site is one of the 19 action items contained in a 46-page report titled "FDA Transparency Initiative: Improving Transparency to Regulated Industry." The report also contains five draft proposals to improve FDA's transparency to regulated industry. The draft proposals, available for public comment for 60 days, include publishing a timeline on the FDA website for high priority guidance documents in development. The FDA would disclose dates for publication of the draft guidance, receipt of public comments, and publication of the final guidance.

The agency also has established an online performance program for FDA offices nationwide. Called FDA-TRACK, the program features monthly metrics for more than 100 agency offices and provides insight for the public into the FDA's decision-making and regulatory activities. (Source: FDA Website, 6 January, 2011)

FDA to Improve Most Common Review Path for Medical Devices

The FDA has unveiled a plan containing 25 actions it intends to implement during 2011 to improve the most common path to market for medical devices. Key actions include streamlining the "de novo" review process for certain innovative lower-risk medical devices, clarifying when clinical data should be submitted in a premarket submission, and establishing a new Center Science Council of senior FDA experts to assure timely and consistent science-based decision making.

Before marketing most lower-risk medical products such as certain catheters or diagnostic imaging devices, manufacturers must provide the FDA with a premarket notification submission. These submissions are known as 510(k)s for the section of the Federal Food, Drug, and Cosmetic Act that describes this notification requirement. Generally, 510(k)s must demonstrate that a proposed product is substantially equivalent to another, legally marketed medical device that is also lower-risk.

In September 2009, CDRH set up two internal working groups to address concerns relating to the premarket notification process -- industry argued that the 510(k) process was unpredictable, inconsistent and opaque, while consumers and health care professionals argued that the review process wasn't robust enough. At the same time, CDRH also asked the independent, nonprofit Institute of Medicine to study the program. That review is still underway. (Source: FDA Website, 19 January, 2011)

FDA Approves Drug to Reduce Risk of Preterm Birth in At-Risk Pregnant Women

The FDA has approved Makena (hydroxyprogesterone caproate) injection to reduce the risk of preterm delivery before 37 weeks of pregnancy, in pregnant women with a history of at least one spontaneous preterm birth. The drug is not intended for use in women with a multiple pregnancy, such as a twin pregnancy, or other risk factors for preterm birth. Makena is sponsored by Hologic, Inc., based in Sunnyvale, California.

The FDA approved Makena under the agency's accelerated approval regulations that allow promising drugs to be approved based on a surrogate endpoint benefit (here, reducing the risk of delivery before 37 weeks of pregnancy) that is reasonably likely to predict a clinical benefit. Under these regulations, the manufacturer must conduct additional studies after the product is approved to demonstrate that the drug does, in fact, have a clinical benefit.

An international trial is ongoing to learn if there is also improvement in the outcome of babies born to women given Makena. Such outcomes include reducing the number of babies who do not survive or who suffer serious health problems shortly after birth. (Source: FDA Website, 4 February, 2011)

FDA Clears First Diagnostic Radiology Application for iPhone, iPad

A new mobile radiology application cleared by the FDA will allow physicians to view medical images on the iPhone and iPad. The application is the first cleared by the FDA for viewing images and making medical diagnoses based on computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine technology, such as positron emission tomography (PET). It is not intended to replace full workstations and is indicated for use only when there is no access to a workstation.

Radiology images taken in the hospital or physician's office are compressed for secure network transfer then sent to the appropriate portable wireless device via software called Mobile MIM. Mobile MIM, manufactured by Cleveland-based MIM Software Inc., allows the physician to measure distance on the image and image intensity values and display measurement lines, annotations and regions of interest.

In its evaluation, the FDA reviewed performance test results on various portable devices. These tests measured luminance, image quality (resolution), and noise in accordance with international standards and guidelines. The FDA also reviewed results from demonstration studies with qualified radiologists under different lighting conditions. All participants agreed that the device was sufficient for diagnostic image interpretation under the recommended lighting conditions. (Source: FDA Website, 4 February, 2011)

FDA Launches Medical Device Innovation Initiative

The FDA has proposed the Innovation Pathway, a priority review program for new, breakthrough medical devices and announced the first submission: a brain-controlled, upper-extremity prosthetic that will serve as a pilot for the program. The new proposed Innovation Pathway program for pioneering medical devices, highlighted in a report published on the FDA's website today, is part of a broader effort underway in the FDA's Center for Devices and Radiological Health (CDRH) designed to encourage cutting-edge technologies among medical device manufacturers. The initiative will also seek to strengthen the nation's research infrastructure for developing breakthrough technologies and advancing quality regulatory science.

In addition, CDRH intends to engage in formal horizon scanning - monitoring medical literature and scientific funding in a systematic way to predict where technology is heading. CDRH will include public input in this process to prepare for and respond to transformative innovative technologies and scientific breakthroughs.

Because of the transformative nature of the devices that would be eligible for this pathway, CDRH expects them to generally be approval pathways intended for either high risk or novel products. The FDA could conduct premarket reviews of products in the Innovation Pathway within 150 days, nearly half the time it currently takes the FDA to review most premarket approval applications. (Source: FDA Website, 8 February, 2011)

AstraZeneca Receives Complete Response Letter from FDA for BRILINTA

AstraZeneca announced that the FDA has issued a complete response letter (CRL) for the New Drug Application (NDA) for ticagrelor (BRILINTA). In the CRL, the FDA requested additional analyses of the PLATO data. The agency did not request that additional studies, including clinical studies, be conducted as a prerequisite for approval of the ticagrelor NDA.

AstraZeneca is evaluating the contents of the CRL and will respond to the agency's request for additional analyses of the PLATO data as soon as possible. The company remains confident in the NDA submission for ticagrelor and in its ability to respond to the agency's

questions. (Source: AstraZeneca Website, 17 December 2010)

FDA Approves Eisai Drug for Treatment of Metastatic Breast Cancer

Eisai has announced that the FDA approved the company's novel anticancer agent Halaven (eribulin mesylate) injection for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included two common chemotherapy treatments, an anthracycline and a taxane, for early or advanced breast cancer. Discovered and developed by Eisai, Halaven is a non-taxane, microtubule dynamics inhibitor and a synthetic analog of halichondrin B, a natural product isolated from the marine sponge Halichondria okadai.

Halaven is the first and only single-agent therapy to demonstrate a significant overall survival benefit in patients with late-stage metastatic breast cancer. Many women with metastatic breast cancer see their disease progress after receiving multiple therapies. With the approval of Halaven, Eisai can now offer a new option that has been shown to improve survival in women with metastatic disease. (Source: Eisai Website, November 16, 2010)

Merck's Gardasil Vaccine Approved to Prevent Anal Cancer

The FDA has approved the vaccine Gardasil for the prevention of anal cancer and associated precancerous lesions due to human papillomavirus (HPV) types 6, 11, 16, and 18 in people ages 9 through 26 years. Gardasil is already approved for the same age population for the prevention of cervical, vulvar, and vaginal cancer and the associated precancerous lesions caused by HPV types 6, 11, 16, and 18 in females. It is also approved for the prevention of genital warts caused by types 6 and 11 in both males and females.

Gardasil will not prevent the development of anal precancerous lesions associated with HPV infections already present at the time of vaccination. For all of the indications for use approved by the FDA, Gardasil's full potential for benefit is obtained by those who are vaccinated prior to becoming infected with the HPV strains contained in the vaccine. (Source: FDA Website, 22 December, 2010)

New Members

- Mr. David Baldiga, *Project Manager*, CRB Builders
- Tammy S. Bishop, *Director of Sales & Marketing*, Caligor Rx, Inc.
- Megan E. Blewis, *Process Engineer II*
- Phillip B. Carpenter, *Principal Quality Systems Analyst*, Genzyme Biosurgery
- Mr. James Cole, *Quality Systems Manager*, Alexion Pharmaceuticals
- Ms. Nayla Doumit, *Principal Validation Engineer*, Genzyme
- Mr. Marc B. Fleischman, *Engineer*, Genzyme
- David Gallagher, , University of New Hampshire
- James Godbout, *Process Controls Engineer*, Alexion Pharmaceuticals
- Mr. Glen R. Gonthier, *Senior Maintenance Technician*, Genzyme Corporation
- Mrs. Erika Hanley-Onken, *Sr. Product Manager*, MKS Instruments
- Tom Kohl, CCO, Itrica
- Mr. Salvatore LaFauci, *Controls Manager*, Interstate Electrical Services, Inc.
- Mr. Gary Lavine, *Consultant*, Waltham Consulting
- Scott Martin, *Sales Rep.*, DL Thurrott
- Michael A. Molinario, *Process Engineer*, Organogenesis Inc
- Mr. Nick Pirog, , CPU Automation, Inc.
- Mr. Brian Stonelake, *Architect*, Signer Harris Architects
- Mr. Raymond C. Terrell, *Senior Engineer*, OPK Biotech, LLC
- Mr. Yan Wang, *Sales/Applications Specialist*, Bruker Optics
- Mrs. Laura J. White, *QA Manager*, Pfizer
- Mr. Lawrence Wong, *Student*, Northeastern University

Member Anniversaries

20+ Years of Membership

- Mr. Michael A. Boenitz, DUSA Pharmaceuticals Inc
- Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation
- Mr. Cesar B. Daou, PE, Daou Engineers Inc
- Ms. Greta W. Davis, Lantheus Medical Imaging
- Mr. George C. Enos, Hart Design Group
- Mr. John H. Evers, Lantheus Medical Imaging
- Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz
- Mr. David C. Hardy

Mr. Stephen R. Higham, PE, Genzyme Corp
Mr. David L. Hyde, Mount Wachusett Community College
Mr. Thomas R. Jerome
Mr. Robert W. Juffras, MS, Stryker Biotech
Dr. Richard V. Levy, PDA
Mr. Frank J. Manning, VNE Corp
Mr. Hank Moes
Mr. Thomas W. Moss, Applied Process Solutions, Inc
Mr. Armen J. Nahabedian, Pfizer
Mr. Richard D. Priestester, Strategic Facility Planning LLC
Mr. Pasquale M. Sacco, Shire HGT
Mr. Alexander E. Smith, Jr., Parsons
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

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Mr. John R. Butterfield, Hallam Associates Inc
Mr. Eugene S. Dennen, UltraFiltrionics Corp
Mr. George R. Skillin, Pfizer

[10 Year Anniversary](#)

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Mr. Eric Ammondson, Ammondson Architects Inc
Mr. Herve F. Berdou, AstraZeneca
Mr. Douglas Brenner, Superior Controls Inc
Mr. Eric D. Felz, Genzyme Corp
Mr. David E. Greenberg, Saint-Gobain Performance Plastics
Mr. William A. McWilliams, Boehringer Ingelheim Pharma
Mr. Colin M. O'Sullivan, D L Thurrott
Mr. Graham L. Skidmore, Vertex Pharmaceuticals
Mr. Curtis W. Steenstra, Pfizer

[5 Year Anniversary](#)

Mr. Gary Barbin, Lantheus Medical Imaging
Mr. Leo T. Bedard, Genzyme Corp
Ms. Asel K. Beisekulova, Genzyme Corp
Mr. Peter Canisius, Jr., Abbott Bioresearch Center
Mr. Jan-Marc Featherston, Weed Instrument Inc
Mr. Craig M. Griffin, TRG Builders LLC
Mr. Timothy M. Hillios, Pfizer, Specialty/Biotechnology
Mr. Brian D. Lapietra, ATR Inc
Mr. Sheldon M. Lathrop, Celsius Technologies
Milan N. Madani, Pfizer
Mr. William T. Mallonee, Non-Metallic Solutions Inc
Mr. Brendan R. O'Donnell, Mylan Technologies Inc
Mr. Wayne K. Pearson, Castle Hill Technologies
Mr. Jim A. Rice, Genzyme Corp
Mr. Cory Siddons, CRB Consulting Engineers, Inc.
Mr. Adam Sokolnicki, Millipore Corporation
Mr. Robert Wilkie, TRG Builders LLC

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