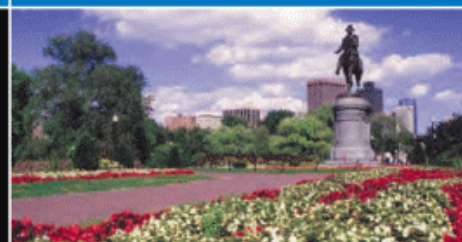
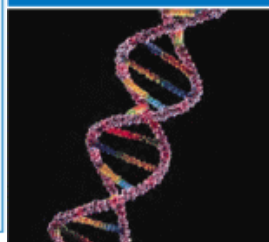




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## NEWSLETTER

May 2011, Volume XXI No. 3

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### President's Message: It's Like Orographic Lift For ISPE Programming And New Initiatives...

Dear Friends of ISPE:

If you are a skier or boarder you know there is no greater thrill than first tracks after a major snow event. Over this past winter I was lucky to hit a bunch of great days with a bounty of fresh snow. Some of the most memorable days were spent in the company of Members of the ISPE Boston Area Chapter and, I can tell you, there is no better company.



Interestingly, it seems that my exploits on the hill paralleled what has been happening within ISPE, both locally here in the Boston Area Chapter and within the larger International ISPE Community.

When you look at some of the new things we have planned and/or launched this past winter you might think that our offerings were in lock step with Mother Nature's storm cycle. It's kind of like orographic lift for ISPE programming and new initiatives; we just keep piling it on!

So here is what we have for you, fellow Chapter members:

- The Joel Goldenberg Scholarship Fund - it's official, we now offer awards to college students who are Student Chapter Members or the children of Chapter Members in good standing; and to continuing education students who are Chapter Members. Details can be found on our website at <http://www.ispeboston.org/>.
- Japan Relief - The Boston Area Chapter initiated dialog with surrounding ISPE Chapters in an effort to pool our resources and make a significant donation to the ISPE Japan Affiliate, which has been struggling mightily to recover from the disaster in Japan. It has been decided that the pooled funds will be sent to ISPE International Headquarters in Tampa. International will be expanding donations further by sending an appeal to all ISPE Chapters and Affiliates worldwide and has pledged to match all funding received. Donations will be consolidated into a single donation to the Japan Affiliate for use in the recovery effort.
- New Student Chapter - WPI promises to be our next ISPE Student Chapter. We have worked all year to support formation of their new organization and look forward to having them join our family of Student Chapters: Northeastern, UMASS Amherst, UMASS Lowell, Tufts and UNH.
- Strategic Planning - Have an idea for how to make ISPE more responsive to your needs on the local or International level? ISPE International is looking for feedback from all Members on the topic of what works for you, what does not work and what is one thing that could be changed for the better. The goal is to add value to your membership experience. ISPE International will roll out their new strategic plan this June at the Washington Conference so fire away with your ideas. Please email your ideas to [office@ispeboston.com](mailto:office@ispeboston.com).
- Extractables and Leachables - Think this might be a relevant topic with the preponderance of disposable technology platforms in use and in development? What do we need to know about the inner workings of how these products interact with the fluids they contact? Find out this June, when speakers from ELSIE (Extractables and Leachables Safety Information Exchange) join us for an informative session in Worcester jointly hosted by Abbott Bioresearch Center and the New England and Boston Area Chapters of ISPE.
- Golf anyone? - We did it! The "Golf Search Committee" has secured our newest venue for this time-honored summer outing. In August we head south to Indian Pond Country Club, a gem tucked off Route 3 in Kingston, MA. Save the date, 15 August, 2011, and have a look at



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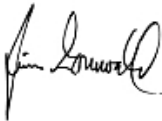
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<http://www.indianpondcountryclub.com/>.

Moving forward, I hope that the Boston Area Chapter continues to be your go to source for education, networking, career development and, of course, the occasional social program. Don't hesitate to give us a suggestion if something strikes you. We value your input and hope to see you at an upcoming event.

In closing, I would like to take a moment and offer congratulations to Chapter Member John Spohn, CPIP, who recently studied for and passed the certification testing for the CPIP. Please take a moment to send your congratulatory wishes to John for his dedication in attaining this excellent credential. And a special thanks to him for spearheading the Chapter-sponsored CPIP Study Group 2 with Joyce Chiu and Allan MacDonald.

Thank you,



Jim Grunwald  
President, ISPE Boston Area Chapter

**Upcoming Chapter Events: Mark Your Calendar**

Process Scale-up & Technology Transfer  
"Beyond *E. coli* and CHO: Case Studies in Alternative Host Platforms"

Thursday, May 19, 2011  
Biogen Idec, Building 8 Auditorium, Cambridge, MA  
Reception: 5:30 pm; Program: 6:20 pm

We are delighted to present two lectures focusing on the challenges and successes of process scale-up and technology transfer of biopharmaceutical manufacturing processes that use emerging, novel production host organisms. Our speakers have participated in the development of cutting edge production technologies that provide new, robust alternatives to the biotechnology industry. They will provide an overview of the benefits of the following novel technologies followed by case studies:

- \* *Pseudomonas fluorescens* developed by Pfenex, and
- \* PER.C6® human cell lines developed by Percivia.

Click here to register online: [May 19 Program](#)

**Save These Dates!**

- June 16, 2011  
Educational Program
- August 15, 2011  
Ninth Annual Golf Tournament
- September 15, 2011  
Educational Program
- October 5, 2011  
Annual Product Show

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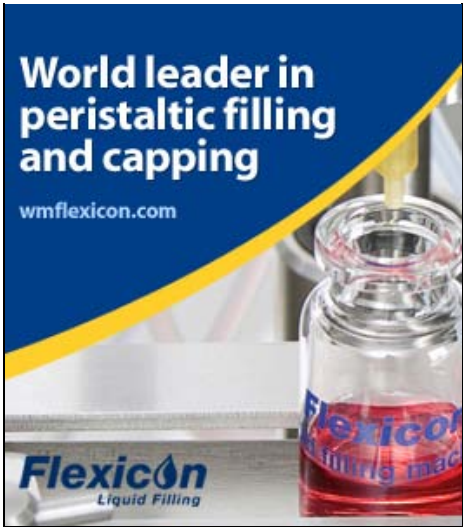
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**Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at [ispeboston.org/sponsorship](http://ispeboston.org/sponsorship),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

**Introducing New Scholarship Program for Chapter Members**

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

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

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

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

**Join Our Chapter Membership Drive & Win Valuable Rewards**

The Chapter Membership Services Committee has kicked off its membership drive for 2011 with a program of valuable incentives designed to encourage current Members to introduce a friend or coworker to the benefits of ISPE.

- Win an iPad 2 - Members who recruit a new Member by June 30 will be entered into a drawing for an Apple iPad 2. And all first-time Members who join by June 30 will be entered in a separate drawing, also for an iPad 2.
- Earn free & reduced registration for an educational program - Members who bring a non-member to an educational program will earn one free registration plus one half-price registration to an upcoming educational program; and the non-member will receive the same two rewards.

So don't delay - there's no better time to introduce a friend or coworker to the benefits of ISPE membership!

**11th Annual Ski Trip to Cannon Mountain**

*by Chris Opolski, Alexion Pharmaceuticals, with photos by the author*



Chapter President

On March 4, 51 hearty souls braved an early morning start, boarded a bus and drove north to the White Mountains. The weather prognosticators called for blue skies and seasonal temperatures. What the group didn't realize was what "seasonable" meant in the North Country. Temperatures in the single digits and 20-plus mile per hour wind welcomed this sleepy bunch to Cannon Mountain in North New Hampshire.

After getting off the bus and unpacking the ski equipment, tour guide for the day Gene Dennen passed out tickets and wished us all happy skiing. It was a typical day at Cannon, cold and windy with lots of snow. If you managed to find a part of



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Jim Grunwald presents the Golden Boot Award to Leighton Terwilliger for attending all eleven Chapter ski trips.

the mountain not buffeted by strong winds the skiing was quite good. A lot of the group chose to ride the tram for the day since a little respite from the wind allowed blood to get back into our fingers and toes.



Social Committee Member and event organizer Gene Dennen gets some well-deserved rest on the bus ride home.

After the long, cold day of skiing the entire group met at the Cannonball Pub to enjoy delicious appetizers and cold beverages. There was much socializing, meeting up with old friends or meeting new ones, and of course chatting about the skiing. Our President, Jim Grunwald, also presented an award to Leighton Terwilliger for having attended all 11 ISPE Boston Chapter Ski outings.

After a few stops for provisions, the bus headed south while the group enjoyed the movie Cannon Ball Run, which included a fine acting performance by Burt Reynolds. It was a long ride home back to Massachusetts (and, for some, Rhode Island) so a few took naps, especially our hard working group leader, Gene Dennen. A huge amount of thanks goes out to Gene for the great effort in organizing the event.

See you on the slopes next year!



Members meet at the top of the mountain to commemorate yet another memorable Chapter ski trip.

### Chapter Brainstorming Sessions Target Educational Program Topics

by Brian Hagopian, Mar Cor Purification

No matter how smart you think you are, there is always more to learn, particularly in this industry. As part of our effort to bring new and innovative educational programs to our members, the Boston Area Chapter recently sought out ideas from our membership on topics of interest in order to formulate plans for educational programs for the coming program year. Involving interested members in the topic generation process would open dialog and introduce new topics to the Chapter's educational mix.

First, we started with our Certified Pharmaceutical Industry Professional™ (CPIP™) Study Group, where about 30 dedicated pharmaceutical professionals were involved in a multi-week study group designed to prepare them for ISPE's CPIP certification process. The group took time from their preparations and openly shared their ideas and thoughts about programs that would be of value to them. Next, we opened this brainstorming process to everyone and invited the entire Chapter membership to participate in an open session held at the Genzyme Center in Cambridge. This session was filled with interested industry professionals and resulted in a lively session.

Frankly, I was awestruck by the diversity of topics offered up by people who participated in these sessions. I heard about topics outside of my area of expertise and came away thoroughly impressed at the collective intellectual muscle that gathered to share their ideas and help the Chapter continue in its leadership role in the local industry and in ISPE. From facilities to validation, introductory to advanced topics, close to a hundred topics were suggested for consideration.

If you want your ideas heard but missed this part of the process, no worries. You still have time to voice your opinion and share your thoughts. We have a list and, as we work to fine tune it, we will need your help

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in vetting the list and selecting the topics of greatest interest so that we can plan ahead for the next program year and beyond. Please watch for our upcoming program survey and do take a few minutes to share your ideas and thoughts with us. The Boston Area Chapter is a great Chapter, but it is also your Chapter, so share your thoughts and help make it even better!

**The Chapter Scores Again with Bio-Ball Sponsorship**

by Sylvia Beaulieu, The Richmond Group

As Chapter Past President and Bio-Ball Committee member, I am very pleased to say that once again ISPE helped our community by giving back in time and financial support to Bio-Ball. I would personally like to thank all the ISPE Boston Area Chapter Members who came out to support Bio-Ball on Friday for set-up and Saturday for the day of the event.

Bio-Ball 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. This was their seventh year and they had the biggest crowd ever - over 500 participants! More importantly, this year Bio-Ball gave a check for \$88,000 to Special Olympics, bringing the total raised in the event's seven-year history to over \$500,000.



Hundreds of enthusiastic participants and spectators crowded the stands for Bio-Ball 2011.

The Bio-Ball tournament was held on Saturday, March 26 at the Buckingham Browne & Nichols School in Cambridge. Participating industry teams included Agios, Alnylam, AMAG, AVEO, Cubist, Genzyme, Infinity, Ironwood, Momenta, Novartis, PAREXEL, Shire, Sunovion, Vertex, Zalicus and MassBio.

Again this year, the Boston Area Chapter sponsored the CEO Free Throw, one of the tournament's most popular events. Chapter President Jim Grunwald was front and center to congratulate each free throw participant and hand them a small gift on behalf of the Chapter - a whistle with an ISPE lanyard.



Chapter Past President Sylvia Beaulieu (front, right) with CEO Free Throw participants.

For those keeping score, Momenta came out on top in tournament play over Genzyme, but everyone was a winner - particularly the Special Olympics athletes with their hard work and determination - and all who participated and experienced their spirit, joy, and enthusiasm. Hope to see everyone there again next year!

**All Aboard! Next Stop INTERPHEX!**

by Barry Potts, Automatch

I'm always surprised by the floating, comfortable ride afforded by a luxury bus on a highway trip. Such was





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## Newsletter Archive

the case with the recent bus ride we took to the INTERPHEX Show on March 29. For those of you who missed the show, it ran March 29-31 at the Javits Convention Center in New York City. Let's face it, getting to NYC can be an experience, but leaving the driving to someone else (and free of cost to ISPE members!) is a great way to get to this venue.

The bus left at 7:15am from the University Ave/Route 128 MBTA Station in Dedham. (We gave a few moments to those who would be running late). In total, there were thirty-three passengers who took the bus down on the first day at the show. After a stop at a McDonalds on the Connecticut Turnpike, we arrived in NYC at approximately noontime, right by the doors to the Javits Center.

INTERPHEX was what you'd expect from the number and quality of exhibitors that were present, namely a well executed and impressive array of products and technologies. The show was clearly well-attended, with more than 11,000 attendees able to browse a myriad of exhibitor's products and services, including facilities products, packaging machinery, automation & control systems, and laboratory products, to name only a few. More than 500 exhibitors were present at the show, and many of my fellow bus passengers remarked at how large the show was.

The bus return time was set at 6pm, which gave us all ample time to walk the show, attend a conference or two, and have lunch at the Javits Center, or to walk a few blocks and experience some great nearby restaurants. As we settled in for the ride back to Boston, we all agreed it was a trouble-free way to get to the show and back and another great ISPE member benefit. I'd highly recommend it for anyone interested in attending INTERPHEX next year.

## Boston Hosts 4th Annual ISPE Northeast Regional Student Leadership Career Forum

by Dave Novak, Novak Associates, Co-chair, Northeast Regional SLCF Committee

On Saturday, April 2, ISPE Student Members from Stevens Institute of Technology, University of Massachusetts, Villanova University, Northeastern University, Rutgers University and Worcester Polytechnic University assembled at the Royal Sonesta Hotel in Cambridge for the 4th Annual ISPE Northeast Regional Student Leadership Career Forum.



UMass Amherst attendees Jennifer Duffy and Brody Stara (background) also served as hosts for the event.

The Forum, a joint effort of the Boston Area, Delaware Valley, New England and New Jersey Chapters, is a full day workshop providing insights on careers in the pharmaceutical, biotech and manufacturing industry where an exchange of information, ideas and lessons are shared among attendees and industry professionals. The day offered a series of formal presentations combined with many opportunities for attendees to network with other attending professionals and to follow up with the speakers concerning their personal and career goals.

The conference began with a personal view of ISPE by our current Chapter President, Jim Grunwald, followed by Robert Lechich, CPIP, Past President of the New Jersey Chapter. Brody Stara and Jennifer Duffy of the UMass Amherst Student Chapter were the hosts for the event and provided the speaker introductions for the majority of the day.

The first presentation of the day was "Empowerment 101 - Skills and Techniques for a Stellar First Impression" by Dave Novak of Novak Associates and ISPE Boston Area Chapter Past President. The presentation focused on sharpening observation and critical thinking skills, and the practice of social etiquette. Attendees learned techniques for networking, proper hand shaking, business cards and dining etiquette, the elevator speech, interview tips, body language, and also explored the generation/cultural gap now occurring in the workplace. This presentation was followed by a mock interview staged by UMass Amherst students to illustrate how students seeking careers in the pharmaceutical/biotechnology industry should conduct themselves at an interview, concluding with an interactive Q & A session and additional advice for successful interviews.

The first keynote speaker for the event was Jim Breen, Vice President of Project Management in Johnson & Johnson's Worldwide Engineering and Technical Operations Group and current President of the New Jersey Chapter. Jim discussed his

own career, using it as an example of challenges faced and accomplishments achieved. He also shared a global perspective of the pharmaceutical and biotech industry and the challenges that are ahead for engineers in the world marketplace. The second keynote speaker, Rick Pierro, President of Superior Controls and ISPE Boston Area Chapter Past President, provided his career story as an entrepreneurial adventure, highlighting the sacrifices, challenges, and decisions he made during the early stages of his career that led to his company's success in the biotech and pharmaceutical industry.



Bob Lechich of Pfizer explained that career planning begins with an assessment of one's accomplishments, skills, and education.

The afternoon sessions began with a presentation on career planning by Bob Lechich, CPIP, Director of Operational Excellence in the Global External Supply Organization at Pfizer and Past President of the New Jersey Chapter. Bob discussed the annual assessment of one's career, which involves a self-evaluation of accomplishments. Taking this annual review provides the ability to model your skills and education goals against new demands and future requirements for the biotech/pharmaceutical industry. Following a break, Meagan Driscoll, President of PharmaLogics Recruiting, provided an interactive session on the best resume format, the do's and don'ts of social and electronic networking, the best ways to apply for a job and great insights on preparing for an interview.

Members of our Young Professionals/Student Members also provided insights on their careers and described how ISPE offers a great foundation of resources, networks and opportunities that supports career growth. Included were talks by Dan Ramsey of Commissioning Agents and the Boston Area Chapter Board of Directors; Archana Sidalaghatta Nagaraja of the Delaware Valley Chapter and an ISPE International Graduate Poster Contest Winner; and Rosemary Garofalo of Stevens Institute of Technology Student Chapter and also an International Student Poster Contest Winner, in the Undergraduate Category.

As the day came to a close and many of the participants lingered to make that one final connection or obtain a business card from a mentor or speaker, I found myself reflecting on the efforts of the multi-Chapter committee that has worked so diligently to organize this annual event for the past four years: Did we do a good job? Was it a great event? Were the techniques helpful? Will the attendees be able to use what they have learned? Just then one of the students stopped to speak with me on his way out of the room. He thanked me for my time and effort and added, "Today I have learned many skills that will not only help me in gaining a job, but will continue with me for the rest of my life." Well I got my answer!

Many thanks to the ISPE Boston Area, Delaware Valley, and New Jersey Chapters, especially members of the joint committee: Bob Lechich, CPIP, Joe Manfredi, Nancy Tomoney, Chuck Clerecuzio, CPIP, William Dugary, Alex Meyers, Jennifer Duffy, Brody Stara, Jim Grunwald, and Committee Co-Chair Dan Ramsey, whose efforts and support made this event possible.

### **Young Professionals Deliver the Basics on Clean-in-Place Systems**

*by Josh Strauss, Commissioning Agents with photos by the author*

The ISPE Young Professionals group was formed to meet the professional needs of individuals who are establishing their careers in the biotech and pharma industries. Lou Traglia from Commissioning Agents delivered the Young Professionals' April educational program at Genzyme in Cambridge on the fundamentals of CIP function and design. Lou captivated the audience with down-to-earth examples of why we spent all those sober Friday evenings in college studying mind-blowing topics such as the Reynolds number and conductivity.



The Genzyme Center auditorium provides an impressive backdrop for the YP educational program on CIP fundamentals.

Referencing the parameters of TACT (Time, Action, Concentration, Temperature), Lou designed for the audience the standard CIP layout and detailed the utilities and vendor chemicals used in the industry and their purposes, mainly CIP 100 and CIP 200. Having delivered the advertised material, Lou wrapped up the evening demonstrating common pitfalls in CIP design and function.

Lou's presentation taught valuable lessons to both new and experienced engineers in the audience. As it turns out, conducting slope verifications and eliminating dead legs are essential for validating CIP cycles! The evening was very educational, entertaining, and engaging for the audience. On behalf of all members of the Young Professionals, we thank Lou for his excellent presentation.

### **Boston Area Chapter CIP Study Group 2: A Journey of Discovery, Innovation, Collaboration and Inspiration**

*by Joyce Chiu, CPIP, Honeywell Safety Products*

#### **Prologue**

I never thought it was such a big deal to attain CPIP, not that it required scaling Mount Everest or amassing the knowledge of the Library of Congress. Of course, it required planning, discipline, good writing and studying, in addition to industry knowledge.

The first Boston Area Chapter CPIP Study Group (SG1) started at the end of May 2010, ran for six consecutive weeks, took a break in the summer, resumed and ended in mid-September. The CPIP exam period started in early September and ended on October 15.

I would never have done it, had SG1 not been offered by the Chapter. I was curious and could make the class sessions, but didn't know what commitment it required. Because I didn't want to fall behind, I reviewed the study modules before each class but there were some I simply did not get to. I started the application process in early July and submitted the package with my exemplars (professional experiences that illustrate the behaviors CPIP strives for) by mid-August. After I received my "eligibility," granting me permission to take the exam, I prepared for and took the exam on the very last day it was offered.

On Monday, October 18, I learned that I had passed the exam. Then the hoopla began - first the congratulations, then the ISPE International press release, subsequently published in several trade journals. I discovered that I was the 19th CPIP in the world. At that point, I started to think, "Maybe this is a big deal." My head was still swimming in the clouds when John Spohn, a fellow SG1 classmate, asked me if I was interested in helping with the second study group (SG2), as he had somehow gotten himself involved as the study group leader.

I was feeling quite exhausted when I saw his email, having just completed another Chapter event. Nevertheless, I proposed we talk on the following Saturday. It was during that crucial one-hour phone call that I became committed to SG2. In no small part thanks to John - where we saw the challenges, how closely our philosophies matched, and how we collaborated and later enrolled others in our collaboration. Therefore, this is an account of a personal journey of discovery, innovation, collaboration and inspiration.

#### **Designing SG2**

Being engineers, our natural tendency is to solve problems. If more than 25 initially signed up for SG1, how come only one made it to the end (CPIP certification) in the time allotted? If we didn't know the root causes of this problem, how could we improve upon SG1 to achieve a better result?

Unlike scientific or technical problems, we could not easily conduct an experiment to test our hypotheses. We nevertheless quickly came up with our own - people were too busy with their professional lives, they didn't quite grasp what it required to write the exemplars needed to achieve eligibility, and they needed project management help in managing the large number of tasks. We also did not have that much time



because to take advantage of the next exam window, early March to mid-April 2011, we needed to act fast. Plus we knew we needed at least four weeks to market SG2 to Chapter Members.

We quickly went to work on the program flyer and immediately faced the question of whom to target. Would non-members be allowed to participate? As there were no formal rules for this new CPIP initiative, we approached our Chapter President and the SG1 leader for advice. The decision was made to promote SG2 as widely as possible but only ISPE Members would be able to enroll. This in fact resulted in several new Members for the Chapter.

We also decided to target SG1 veterans. After all, some might still want to attain CPIP and could also provide us with input. We emailed them and received valuable feedback. As we had hoped, a number of SG2 registrations were SG1 veterans.

SG2 began on December 7, 2010, continued for 11 sessions and ended on March 8, 2011 as planned despite several snow storms that caused cancellations. The initial enrollment exceeded 45 but some dropped out after the first few weeks.

#### SG2 Syllabus

The next challenge was the syllabus, which allowed us to achieve several objectives at once:

- a timetable of class sessions and breaks,
- a project plan for the prospective candidates, with homework assignments,
- the sequence of study modules, but more importantly,
- time for the exemplars.

In addition to education and experience, CPIP requires two competencies and code of ethics:

- Technical - seven knowledge elements with 18 modules, achieved through an exam.
- Non-Technical - three competencies including leadership/professionalism, integration/innovation/change advocacy, and quality & continuous improvement focus, achieved through five to nine witnessed exemplars.
- Code of ethics - achieved through two references.

Because one must first receive eligibility before taking the exam, the first four sessions were designed to be heavily focused on eligibility preparation, in particular, writing exemplars. The latter sessions concentrated on the study modules.

While SG1 emphasized technical knowledge exchange and discussion, it covered the preparation of the non-technical competencies only in an introduction. Thus this was fertile ground for strengthening SG2. We again enlisted the aid of Allan MacDonald, CPIP, who agreed to provide the same overview he did for SG1 and I proceeded to prepare two new presentations for SG2.

#### SG2 Eligibility Coaching

Our assumption going in was that everyone has worthy professional experience. However they would need help describing this experience in writing, in other words, writing "exemplars" that would meet the CPIP criteria and thus make them "eligible" to take the CPIP exam.

It was one thing to know what I did to attain CPIP, yet quite another to teach others how to do it. I asked myself and reflected on these questions:

- How did I know the requirements?
- How did I organize my activities to meet the timeline?
- What skills did I rely on that helped me?
- How did I acquire these skills?
- How can we teach these skills to the class in the time we had?
- What other resources can we tap into?

I realized there were two sets of skills I relied on. First was project and time management. Before one could properly manage a "CPIP project," however, one must first understand the requirements. It was the second epiphany that shed light for me.

In the past decade, I have acquired and honed many job search and networking skills such as talking about my accomplishments, relating my skills to job needs, marketing myself, and mentoring and coaching others. The exemplars came naturally to me because I knew they were nothing more than writing about my experiences with a subtle yet important difference: The exemplars were not asking for my accomplishments (although they would certainly help) but rather, they were asking for concrete examples that illustrated the desired behaviors!

With those insights, I put together two presentations: "Planning for Success" and "Writing Good Exemplars." For the latter, I further decided to share all of my exemplars with the class. I wrestled the most with this decision because of concern for privacy. In the end, I trusted my intuition which then inspired John to share all of his exemplars as well.

#### SG2 as a Community

One of the first things we emphasized with the class was confidentiality. Because we worked with

professional experiences, we set the rule that "Whatever happens in Vegas stays in Vegas." This freed everyone to talk about their experiences and gave John and me the assurance that our exemplars were in good hands.

Yet presentations, as one-way street, were insufficient in coaching. CPIP is a long and arduous road, so why should anyone have to do it alone? Why wouldn't we tap into professional career coaches? Most of all, why couldn't we help one another?

Toward that end, we first broke the class into small groups of five to seven people each. They were to work together in the classroom (and outside as well if they so chose), to provide feedback and mutual support to one another on their exemplars. Second, I approached two professional career coaches, Joe Maressa and Carol Bergeron, whom I had worked with in previous Chapter events, to help us with a coaching workshop.

Class number four, the first of the New Year, was chosen for this workshop. John, Allan and I conferenced with Joe and Carol to plan it. After a brief introduction, the class broke into their small groups and the five of us sat with them in a group critique of the exemplars they had prepared. Halfway through the session, Joe was so inspired that he got up to the front of the room and shared further insight. The group I sat with had many good exemplars and gave one another excellent feedback. To my delight, I saw the makings of a genuine community.

#### Assisting Other Chapters

While we were still heavily involved with SG2, in mid-January, our reputation had preceded us through our collaboration with Michael Phelan, ISPE Director of Professional Certification, as we received several inquiries from other Chapters. They were either starting or preparing to start their own study groups for the first time.

This presented somewhat of a challenge because there was little precedent for working directly with other Chapters, study group leader to study group leader. We engaged our Chapter leadership and, after much discussion, decided to share the materials we had prepared for SG2, with permission of all authors. It is in the CPIP spirit to assist other Chapters, especially since our Chapter had started its efforts about nine months before any other North America Chapter, had already completed SG1 and had applied "lessons learned" in the design of SG2, already underway.

It was very gratifying to Allan, John and me to be able to assist other Chapters in this way, not only as validation of our efforts but also because it furthered our desire to see a critical mass of CPIPs, so that such a rigorous credential would be more widely acknowledged.

#### Inspiration from Personal Coaching

After the Coaching Workshop, with actual data in hand (finally as an engineer, I had gathered real data - other people's exemplars), I was able to gain further insight as to how they could be improved and wrote a 'Tip Sheet' for the class.

A thank you note came from Michael Atchue for the tips. I offered to help with his exemplars and he accepted. He sent me his drafts, I reviewed and we discussed them by phone. At the time, I thought I was helping him. But when I got to his Professional Development exemplar, where he talked about going after his bachelor's degree part time, how he developed good study habits and how his family made sacrifices to accommodate his efforts, I was greatly moved and inspired!

I realized here was a person who exemplified the very best of CPIP - continuously improving, striving, sharing, collaborating and helping others. Even so, the exemplars didn't come naturally to him. He needed coaching on what experience would be appropriate for which exemplar, and how best to write them in a way that would meet the CPIP requirements, but all the raw material was there.

Michael and I worked together from mid-January to early March. At times, it was hard on him and on me but we kept each other on track. I was embarrassed when at first I could not put a face to his name and told John. John sent the class photo to me with a red arrow pointing to Michael. So at the next chapter event, held at where Michael works, we spoke and had a good time. This was an unexpected gift as I didn't realize the experience of coaching someone could inspire and benefit me!

#### Epilogue

As of this writing, John Spohn has passed the exam and become a CPIP. Others have submitted their applications although the number is not anywhere near what we had hoped for. In a way, we are disappointed in that all this effort did not result in more applications. On the other hand, sometimes things may take longer than we expect and the journey itself, rather than the destiny, is worthy of the experience.

I am grateful for this experience where we conceived of and implemented innovative ideas, spurred one another on, got many involved and created a community that together learned and shared great industry knowledge and also had fun. I have learned a good deal from this journey, one filled with discovery, innovation, collaboration and inspiration, not to mention friendship. It may still bring pleasant surprises and gifts in ways I can not envision!

### Industry News In Brief

*by Patti Charek, RF Walsh Collaborative Partners*

## Licensing Deal Settles Cubist Fight with Teva

Cubist Pharmaceuticals has reached an agreement to settle a two-year patent dispute with Teva Pharmaceutical Industries. Under the deal, Cubist will grant Teva a license to sell a generic version of daptomycin - an antibiotic Cubist markets under the brand name Cubicin - starting in 2018 if Cubist wins an exclusivity extension from the FDA. Without the extension, Teva will start selling its generic in 2017.

Teva agreed to buy its supplies of daptomycin, an injectable treatment that fights bacterial infections in the bloodstream and skin, exclusively from Cubist. Michael Bonney, chief executive of Cubist, said the Lexington company decided to give up 21 months of patent life for Cubicin, its only drug currently on the market, in exchange for an end to the patent litigation and the guarantee of a revenue stream from the licensing deal with Teva, the world's largest maker of generic drugs. "This is an extraordinarily good outcome for Cubist," said Bonney, who projected Cubicin will generate \$1 billion in revenue before Teva enters the market with its generic product later in the decade. "We've removed the uncertainty from this litigation. It will allow us to continue our work finding new antibiotics for resistant bacteria."

The patent dispute began in February 2009 when Teva, based in Israel, challenged multiple Cubist patents protecting Cubicin under a US law encouraging lower-cost generic competition for branded drugs. Cubist responded with a patent infringement lawsuit against Teva the following month. The suit was scheduled to go to trial in Delaware this month.

As part of the settlement, Teva acknowledged the patents asserted in the Cubist lawsuit are valid and enforceable and would have been infringed by Teva's proposed generic product. The settlement between Cubist and Teva must still be approved by the Justice Department and the Federal Trade Commission. (Source: Robert Weisman, Boston Globe, 5 April 2011)

## Sanofi Selling Dermatology Business

Sanofi-Aventis SA, France's biggest drug maker, is seeking a buyer for its US dermatology business in a sale that may fetch as much as \$433 million, according to two people with knowledge of the matter. First-round bids were submitted in early April, said the people, who declined to be identified because the talks are private.

Sanofi is selling the operation that chief executive Chris Viehbacher said in 2009 was too small, in order to focus on treatments for diabetes, cancer, and atrial fibrillation, or irregular heartbeat. The company's dermatology products include Sculptra Aesthetic, a wrinkle filler that's used to fill in deep smile lines in healthy patients. "Sanofi-Aventis US is exploring strategic alternatives for the US dermatology business in keeping with its strategy to reallocate resources to high-growth areas including diabetes, oncology, and atrial fibrillation," Sanofi said in an e-mailed statement.

Private-equity firms are the most likely suitors for the dermatology operation, the people said. The valuation of the business has been hurt because competitors introduced generic versions of one of its products, the BenzaClin topical acne treatment, one person said. Viehbacher said in 2009 the drug maker would review the dermatology business. (Source: Bloomberg News, Boston Globe, 14 April 2011)

## FDA OKs First Drug that Helps Melanoma Patients Live Longer

The first drug shown to prolong the lives of people with the skin cancer melanoma got FDA approval in March. The drug, Yervoy, was developed by Bristol-Myers Squibb and is a novel type of cancer drug that works by unleashing the body's own immune system to fight a tumor.

In a randomized clinical trial, patients with metastatic melanoma treated with Yervoy lived a median of about 10 months, compared with 6.4 months for patients in a control group, who received a treatment believed to have had little effect. After two years, more than 20 percent of those who got Yervoy, also known as ipilimumab, were alive, compared with 13.7 percent for the control group.

There were about 68,000 new cases of melanoma in the U.S. last year and 8,700 deaths, according to the American Cancer Society. The number of cases has been rising, probably because of sun exposure without protection at a younger age. Bristol-Myers said it would charge \$120,000 for a complete course of treatment, which consists of four infusions given over a three-month period.

Melanoma detected early as a mole on the skin can be surgically removed. But once it has metastasized, or spread, it is very difficult to treat, and various drugs have failed in clinical trials. The last drug approved was interleukin-2 in 1998, but it is so toxic it is rarely used.

Yervoy is just one sign of progress. Another drug, being developed by Roche and Plexxikon, has also recently been found to prolong lives of patients with metastatic melanoma, according to those companies.

While the trial tested Yervoy in patients who had already tried another treatment, Bristol said that another clinical trial had shown the drug prolonged survival when used as an initial treatment for metastatic melanoma. Details were not divulged, but presumably this finding could broaden the market.

Yervoy is an example of an emerging class of treatments known as immunotherapy that harness the body's own immune system to fight tumors. Last year, the FDA approved what was considered the first of these



treatments, the prostate cancer drug Provenge, developed by Dendreon. Provenge is sometimes called a vaccine because it trains a patient's immune system to attack the cancer. Yervoy, by contrast, works by essentially disabling a brake on the immune system. Because it is not specific for any type of tumor, it might conceivably be effective for many types of cancer, though this has yet to be proved in clinical trials.

"The treatment is of the immune system, it's not of the tumor," said James P. Allison, head of the immunology program at the Memorial Sloan-Kettering Cancer Center in New York, whose work led to the development of the drug. The drawback is that loosening restraints on the immune system can lead to dangerous side effects, the most worrisome being colitis and diarrhea, but also hepatitis, endocrine dysfunction, rashes, and eye problems. In the clinical trial - which involved 676 patients, 540 of whom got Yervoy - seven died of immune-system-related side effects. (Source: Andrew Pollack, New York Times, Boston Globe, 26 March 2011)

#### Repligen Bipolar Drug Fails in Clinical Trial

Repligen has said that a midstage clinical trial showed one of its drug candidates, RG2417, was no more effective than a placebo in treating bipolar depression. The study involved 175 patients who took the drug or the placebo for eight weeks, measuring their symptoms on a 10-item clinical diagnostic survey. Repligen said it will review data from the study and decide if it will continue developing the drug, which is also called uridine.

The company said patients who were enrolled in the study through academic medical centers did significantly better, but in patients who were enrolled through commercial clinical trial sites, there was no difference between RG2417 and placebo. There were 50 patients enrolled through academic sites and 125 through commercial sites. Repligen said it planned to look into those differences.

Repligen is also testing a pancreatic imaging agent and a treatment for Friedreich's ataxia, a genetic disorder that leads to degeneration of the nerves controlling muscle movements in the arms and legs and the nerve tissue in the spinal cord. (Source: Associated Press, Boston Globe, 8 March 2011)

#### Vertex Says Epilepsy Drug Met Goals

Vertex Pharmaceuticals has said that its developing epilepsy treatment met key safety and tolerability goals in a midstage study. The six-week trial included 60 people with treatment-resistant epilepsy, a type of epilepsy where seizures start and occur in a specific part of the brain. The study enrolled and dosed people who had not benefited from the use of at least two available medicines for partial epilepsy. In the study, 48 people received 900 mg of VX-765 three-times-daily and 12 people received a placebo three times a day.

Results showed the drug was similarly safe to a placebo, with dizziness the only side effect that occurred significantly more often in those taking the drug versus placebo.

Key secondary goals of the study focused on how effective the drug was at reducing the frequency of seizures. Vertex said those taking the drug didn't have statistically significant drops in seizure rates or frequency. But the company said greater improvements were observed in the last two weeks of the treatment phase and first two weeks of the follow-up period, which suggests that a longer-duration study may be needed to evaluate the effectiveness of the drug. Vertex expects to begin this study as early as the fourth quarter. (Source: Associated Press, Boston Globe, 11 March 2011)

#### New Lupus Drug Benlysta Approved

The FDA has approved Benlysta, the first new lupus drug since 1955. Benlysta is approved for the treatment of patients with active, autoantibody-positive lupus who are getting standard therapy. Standard therapy includes corticosteroids, antimalarial drugs, immunosuppressive agents, and NSAID anti-inflammatory drugs.

As many as 1.5 million Americans have systemic lupus erythematosus (SLE), commonly called lupus. Lupus is an autoimmune disease in which a particular type of white blood cell, B lymphocytes, turn the body's immune defenses against the body's own cells. Benlysta inhibits the maturation of these B cells. Because B cells are crucial elements of the immune system, Benlysta carries serious risks. There were more deaths and serious infections among patients taking Benlysta than among patients taking placebo.

The drug may work best for patients with moderate disease, says lupus expert Eric L. Greidinger, MD, chief of rheumatology and immunology at the University of Miami Miller School of Medicine. "The hope is that Benlysta may allow some of these patients who have persistently active lupus who are using substantial doses of steroids to bring their disease under better control, so they have less lupus activity and can take less steroids, exposing them to fewer of the many steroid-associated side effects," said Dr. Greidinger.

Lupus is particularly common among African-American women. In clinical trials, African-American patients did not appear to respond to Benlysta as well as other patients. The manufacturer, Human Genome Sciences, has thus agreed to conduct a new study of the drug in this subgroup of patients. (Source: Daniel J. DeNoon, WebMD Health News, 9 March 2011)

#### Amgen Raises Presence In Massachusetts, Buys Biovex, Boosts Hiring

Amgen, the world's largest biotechnology company, has been raising its profile in the Boston area, acquiring a Woburn company with a novel cancer-fighting technology and hiring more scientists at its

research site in Kendall Square.

Its purchase of BioVex Group for as much as \$1 billion, including \$425 million upfront and up to \$575 million in potential milestone payments, closed in early March. The deal gives Amgen ownership of BioVex's promising OncoVex vaccine, which is in late-stage clinical development to treat advanced melanoma and head and neck cancer. If approved for those treatments, the vaccine eventually could be deployed against breast and prostate cancer.

"We clearly have a greater financial underpinning now," said BioVex founder and chief technology officer Robert Coffin, who built the company on research he initially conducted at University College London. "Being owned by Amgen will give us the backing to be able to develop OncoVex more broadly for a range of indications."

Amgen, meantime, is busy filling more than a dozen job openings for biologists, chemists, and researchers at its One Kendall Square drug discovery lab, which opened in 2001. Amgen's research lab now employs about 200 people, while BioVex has about 65 employees in Woburn and another 25 in Oxford, England. Amgen also operates a 1,000-person drug manufacturing plant in West Greenwich, Rhode Island.

Jonathan P. Gertler, senior partner at Back Bay Life Science Advisors, a Boston consulting firm, said biotechnology companies seeking to expand their product pipelines have been working in two ways: buying companies with drugs in late-stage development, and setting up research labs in innovation hubs such as the Boston area, where they can collaborate with start-ups and academic researchers. Gertler said Amgen is pursuing both approaches. "It's not just an isolated strategic move to acquire BioVex," said Gertler. "It's part of their innovation sourcing, accessing the Boston biotech cluster. Amgen has had less of a presence here than others." (Source: Robert Weisman, Boston Globe, 9 March 2011)

Five Life Sciences Firms Loaned \$3.75m

The Massachusetts Life Sciences Center, a quasi-public agency charged with administering Governor Deval L. Patrick's \$1 billion life sciences initiative, said it has awarded \$3.75 million in loans to five early-stage companies. Under the center's Accelerator Program, loans of up to \$750,000 can be provided to early-stage companies that are engaged in life sciences research and development, commercialization, and manufacturing, the center noted in a press release.

Companies getting loans included AesRX, a Newton biopharma developing treatment for sickle cell disease and other orphan drugs; MoMelan Technologies, a Cambridge medical device maker; and Myomo, a Cambridge firm helping people regain movement after neuromuscular impairment. Two Worcester firms are also in line to receive loans: ECI Biotech, a developer and manufacturer of sensors that can be incorporated into any consumer product or medical device, and Grove Instruments, which is developing a painless, noninvasive technology that accurately measures blood sugar. (Source: Boston Globe, 24 March 2011)

Novartis Wins EU Regulatory Approval for Gilenya MS Pill

Novartis AG won European approval to sell its multiple sclerosis medicine Gilenya for patients with active or severe forms of the disease. The European Commission cleared the treatment for use against the relapsing-remitting form of multiple sclerosis. Doctors can prescribe the drug as the second choice of treatment for patients with an active form of the disease who have used beta interferon, or as the first drug for those with a rapidly evolving form of the disease.

The decision excludes some patients, giving the drug a smaller part of the European market than it has in the US. Gilenya won US approval as the first choice for use in all patients with relapsing-remitting MS last year, raising hopes for some of the millions of patients who suffer from the disease and rely on injections for symptom relief.

"Gilenya is the first approved therapy for MS that offers significant efficacy in a capsule, which for many patients will come as a welcome additional option," Hans Peter Hartung, head of the department of neurology at Heinrich-Heine University in Duesseldorf, Germany, said in the statement. The pill costs about \$48,000 annually in the U.S.

The European Medicines Agency's Committee for Medicinal Products for Human Use recommended that Novartis be granted approval to market the drug. Merck KGaA's Rebif and Biogen Idec's Avonex are both beta interferons, as is Novartis's own Extavia.

MS affects about 2.5 million people worldwide, many of whom have trouble sticking with current therapies because they're difficult to use or have side effects, according to the National Multiple Sclerosis Society, a New York-based patient group. (Source: Eva von Schaper, Bloomberg.com, 21 March 2011)

Organogenesis Expanding in Canton

Biotech firm Organogenesis has purchased another office building to accelerate the expansion of its Canton headquarters. The firm said it has acquired a 78,000-square-foot building at 65 Dan Road, which it will use for warehouse space and future growth. Organogenesis is beginning construction of a 95,000-square-foot manufacturing plant, also on Dan Road, scheduled for completion in 2013.

The company, which makes regenerative medicine therapies to speed healing, has grown steadily in recent

years, adding to its office campus with financial help from the state. The campus will ultimately include four buildings with 330,000 square feet of office and manufacturing space.

To support Organogenesis' expansion, the Massachusetts Life Sciences Center has awarded it \$7.4 million in grants and \$458,000 in tax incentives this year in exchange for creating 17 jobs. The firm said it has hired 19 people in the past few months.

The company estimates the expansion of its Canton campus will cost \$63 million. Organogenesis executives said the company intends to continue growing in Massachusetts and bills its new factory as the world's largest living cell manufacturing plant. "This is a huge milestone for Organogenesis, as well as for the state and for the regenerative medicine industry as a whole," said company chief executive Geoff MacKay. "We're growing in Massachusetts in size, in revenue, and capacity; and in order to keep pace with our rapid growth, we're hiring across all departments." (Source: Casey Ross, Boston Globe, 13 April 2011)

#### UMass Stem Cell Bank to Work with UK Partner

Officials at the University of Massachusetts Stem Cell Bank and Registry in Shrewsbury will explore collaborations with the United Kingdom's Stem Cell Bank as part of an agreement recently signed between the two organizations. Both stem cell banks produce human embryonic stem cell lines that are used for research and investigations into treatments for various diseases.

The two stem cell banks have agreed to share best practices around characterization, production and distribution of stem cells. They have also vowed to explore joint research projects that could secure research funds for both organizations.

The UMass Stem Cell Bank and Registry began in 2008 with \$8.9 million in support from the Massachusetts Life Sciences Center and is housed in a 15,000-square-foot facility in Shrewsbury. (Source: Brandon Butler, Worcester Business Journal, 14 March, 2011)

#### ACT Treatment Moves Toward Orphan Status

Marlborough's Advanced Cell Technology has taken a step toward receiving orphan drug designation in Europe for a treatment for Stargardt's disease. The European Medicines Agency gave the human embryonic stem cell-based treatment a positive opinion. The opinion now goes to the European Commission, which will determine whether to grant the orphan drug status. The FDA approved an orphan drug designation for the same product last year. If the European designation receives final approval it would offer the company regulatory and financial benefits as it develops and markets the treatment.

Stargardt's disease, also called Stargardt's Macular Dystrophy, is a genetic disease that causes progressive vision loss. Orphan drug designations provide incentives for companies to develop treatments for serious diseases affecting a small percentage of the population. (Source: Livia Gershon, Worcester Business Journal, 10 March, 2011)

#### RXi Pharmaceuticals Completes Aphera Acquisition

RXi Pharmaceuticals, a biotech focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using RNA-targeted and immunotherapy technologies, has announced the completion of its acquisition of Aphera.

The acquisition provides RXi with a late stage product candidate, NeuVax(TM), a peptide-based immunotherapy for low-to-intermediate HER2+ breast cancer, patients who are not eligible for Herceptin(R). RXi has targeted NeuVax to enter Phase III clinical trials in the first half of 2012. The Company's first self-delivering RNAi product, RXI-109 for anti-scarring in planned surgeries, remains on track for an investigational new drug (IND) application filing this year.

"NeuVax and RXI-109 significantly advance RXi into a product development company with novel therapeutics addressing large unmet medical needs," said Mark J. Ahn, PhD, President and Chief Executive Officer of RXi Pharmaceuticals. "We believe we have the people, pipeline and resources to realize the promise of our innovative products for patients and shareholders." (Source: RXi Website, 14 April, 2011)

#### EarlySense Selects Massachusetts for US Headquarters

Israel-based EarlySense, developer of the EverOn contact-free patient monitoring system, has chosen to locate its U.S. headquarters in Massachusetts. The decision follows the March 2011 visit to Israel by Governor Patrick and a delegation of state leaders from industry, academia and government to promote mutually beneficial collaborations between Massachusetts and Israel. The company intends to hire 10 employees in Massachusetts before the end of the year and has plans to hire an additional 10-20 employees annually thereafter.

Avner Halperin, CEO of EarlySense said, "EarlySense seriously considered several states to locate its U.S. headquarters. We chose Massachusetts for several reasons. For one, we have a favorable history in Massachusetts. EarlySense is engaged in long term research initiatives at various prestigious medical institutions in the state including Partners' Healthcare. However, our final decision was reached following our time together with Governor Patrick in Israel. He convinced us that Massachusetts would be the best



location to run our national operations focused on making the EarlySense system the standard of care in hospitals and nursing homes nationwide."

"EarlySense's decision to grow in Massachusetts highlights the strength of the cluster here in the Commonwealth and the capacity for industry, academia and government to work together to get things done," said Robert K. Coughlin, president & CEO of MassBio, who also accompanied the Governor on the trip. "We're thrilled to have such a cutting-edge, growing, global company join us in telling the story of Massachusetts' strengths." (Source: Massachusetts Life Sciences Center Website, 14 April, 2011)

### **Regulatory & Legislative Highlights**

*by Deepen Joshi, Sunovion Pharmaceuticals*

#### **FDA clears test to help patients with kidney transplants**

The FDA announced that it has cleared a test to help manage potential organ rejection in kidney transplant patients. The test, called QMS Everolimus Immunoassay, monitors the blood level of everolimus, a drug that helps prevent rejection in kidney transplants. The immunoassay is manufactured by Waltham-based Thermo Fisher Scientific.

Everolimus, marketed under the trade name Zortress, was approved by FDA for use in adult kidney transplant patients who are at low-to-moderate immunologic risk. It is marketed by Novartis.

Transplant patients are routinely given drugs that suppress the immune system, such as a regimen containing everolimus, cyclosporine, basiliximab, and corticosteroids. These drugs help prevent organ rejection, which occurs when the body's immune system attacks and destroys a transplanted organ.

More than 87,000 patients are awaiting a kidney transplant in the United States, according to the Health Resources and Services Administration's Organ Procurement and Transplantation Network. (Source: 11 February, 2011, FDA Website)

#### **FDA Approves First 3-D Mammography Imaging System**

The FDA approved the Selenia Dimensions System, the first X-ray mammography device that provides three-dimensional (3-D) images of the breast for breast cancer screening and diagnosis. The Selenia Dimensions System is marketed by Bedford-based Hologic.

A mammogram is a safe, low-dose X-ray of the breast that is the best tool for early detection of breast cancer. The Selenia Dimensions System, an upgrade to Hologic's existing FDA-approved 2-D system, can provide 2-D and 3-D X-ray images of the breasts. The 3-D images may help physicians more accurately detect and diagnose breast cancer.

The National Cancer Institute recommends women ages 40 and older have a mammogram every one to two years. Nearly 40 million mammograms are performed each year in the United States. (Source: FDA Website, 11 February, 2011)

#### **FDA Approves Product to Prevent Bleeding in People with Rare Genetic Defect**

The FDA approved Corifact, the first product intended to prevent bleeding in people with the rare genetic defect congenital Factor XIII deficiency. Patients with congenital Factor XIII deficiency do not make enough Factor XIII, a substance that circulates in the blood and is important for normal clotting. Without treatment, people with the condition are at risk for life-threatening bleeding.

Congenital Factor XIII deficiency is rare and affects 1 out of every 3 million to 5 million people in the United States. The deficiency may lead to soft tissue bruising, mucosal bleeding and fatal intracranial bleeding. Newborns with Factor XIII deficiency may have umbilical cord bleeding.

Corifact received orphan-drug designation by the FDA because it is intended for use in a rare disease or condition. It was approved for marketing under the FDA's accelerated approval regulations that require an on-going study to demonstrate that patients actually receive the clinical benefit predicted by the data obtained so far.

Corifact is made from the pooled plasma of healthy donors and is manufactured by CSL Behring of Marburg, Germany. (Source: FDA Website, 17 February, 2011)

#### **FDA Approves Edarbi to Treat High Blood Pressure**

The FDA approved Edarbi tablets (azilsartan medoxomil) to treat high blood pressure (hypertension) in adults. Edarbi is an angiotensin II receptor blocker (ARB) that lowers blood pressure by blocking the action of angiotensin II, a vasopressor hormone. It is manufactured by Takeda Pharmaceutical North America of Deerfield, Illinois.

Blood pressure is the force of blood pushing against the walls of the arteries as the heart pumps. If blood pressure rises and stays high over time, it can damage the body in many ways. Nearly 1 in 3 adults in the United States has high blood pressure, which increases the risks of stroke, heart failure, heart attack,

kidney failure, and death. Data from clinical studies showed Edarbi to be more effective in lowering 24-hour blood pressure compared with two other FDA-approved hypertension drugs, Diovan (valsartan) and Benicar (olmesartan).

Edarbi has a boxed warning that says the use of the drug should be avoided in pregnant women because use of the drug during the second or third trimester can cause injury and even death in the developing fetus. If a woman becomes pregnant while using the drug, it should be discontinued as soon as possible. (Source: FDA Website, 25 February, 2011)

FDA Approves New Drug to Treat Chronic Obstructive Pulmonary Disease

The FDA approved roflumilast, a pill taken daily to decrease the frequency of flare-ups or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD), a serious lung disease that makes breathing difficult. Symptoms of COPD can include breathlessness, chronic cough and excessive phlegm. A flare-up can last up to several weeks and result in lung function decline, increased risk of death, and may be associated with severe anxiety.

Cigarette smoking is the leading cause of COPD, according to the National Heart, Lung, and Blood Institute. COPD is the fourth leading cause of death in the United States.

Roflumilast, a new drug class for the treatment of COPD, is an inhibitor of an enzyme called phosphodiesterase type 4 (PDE-4). It is indicated for people with severe COPD to treat the symptoms of cough and excess mucus linked to bronchitis. Roflumilast is not intended to treat another form of COPD which involves primary emphysema. The drug marketed by St. Louis-based Forest Pharmaceuticals, a subsidiary of Forest Laboratories. (Source: FDA Website, 1 March, 2011)

Oral Birth Defects in Children Born to Mothers Taking Topamax (Topiramate)

New data suggest that the drug Topamax (topiramate) and its generic versions increase the risk for the birth defects cleft lip and cleft palate in babies born to women who use the medication during pregnancy. Topiramate is approved to treat certain types of seizures in people who have epilepsy; it is also approved to prevent migraine headaches.

Cleft lip and cleft palate, collectively called oral clefts, are birth defects that occur when parts of the lip or palate do not completely fuse together early in the first trimester of pregnancy, a time when many women do not know they are pregnant. The defects range from a small notch in the lip to a groove that runs into the roof of the mouth and nose, possibly leading to problems with eating, talking, and to ear infections. Surgery often is performed to close the lip and palate and most children do well after treatment.

The patient medication guide and prescribing information for Topamax and generic topiramate will be updated with the new information. (Source: FDA Website, 4 March, 2011)

FDA Approves Imaging Agent for Central Nervous System Scans

The FDA approved Gadavist (gadobutrol), a gadolinium-based contrast agent, for use in patients undergoing magnetic resonance imaging (MRI) of the central nervous system. Gadavist provides contrast-enhanced imaging of the central nervous system, helping to detect and visualize lesions that disrupt the cell barrier that normally separates the brain from the blood stream. It also helps to detect and visualize abnormal blood supply and circulation of the central nervous system.

Gadavist is the sixth gadolinium-based contrast agent (GBCA) approved by the FDA for use in patients undergoing magnetic resonance imaging of the central nervous system. It is manufactured by Bayer Pharmaceuticals. (Source: FDA Website, 15 March, 2011)

FDA, EMA Announce Pilot for Parallel Assessment of Quality by Design (QbD)

The FDA and the European Medicines Agency (EMA) have launched a new pilot program that will allow parallel evaluation of relevant development and manufacturing data components, known as Quality by Design (QbD), of new drug marketing applications that are submitted to both agencies.

The parallel evaluation within this voluntary pilot program means that reviewers from both agencies will separately assess the quality/chemistry, manufacturing and control (CMC) section of the new drug applications (NDAs) submitted to the FDA and marketing authorization applications (MAAs) submitted to the EMA. However, there will be regular communication and consultation between European regulators and their US colleagues throughout the review process relevant to QbD aspects of the applications.

QbD in pharmaceuticals involves designing and developing pharmaceutical formulations and manufacturing processes to help ensure product manufacturing quality. Several guidelines have been developed by the International Conference on Harmonisation (ICH) to harmonize and facilitate the implementation of QbD. This pilot program began out of concern that certain ICH guidelines were being interpreted differently in Europe and the United States.

This pilot program applies to NDAs and MAAs, some supplements, and CMC meeting requests that include QbD elements submitted to both agencies at about the same time. The pilot will only include chemical entities and not biologically-derived products. Review of QbD applications does not change statutory deadlines. (Source: FDA Website, 16 March, 2011)

### FDA Approves Zostavax Vaccine to Prevent Shingles in Younger Individuals

The FDA approved the use of Zostavax, a live attenuated virus vaccine manufactured by Merck & Co of Whitehouse Station, New Jersey for the prevention of shingles in individuals 50 to 59 years of age. Zostavax is already approved for use in individuals 60 years of age and older.

In the United States, shingles affects approximately 200,000 healthy people between the ages of 50 and 59 each year. It is a disease caused by the varicella-zoster virus, which is a virus in the herpes family and the same virus that causes chickenpox. After an attack of chickenpox, the virus lies dormant in certain nerves in the body. For reasons that are not fully understood, the virus can reappear in the form of shingles, more commonly in people with weakened immune systems and with aging. (Source: FDA Website, 24 March, 2011)

### FDA Approves New Treatment for Rare Form of Thyroid Cancer

The FDA has approved vandetanib to treat adult patients with late-stage (metastatic) medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms. The drug is marketed by AstraZeneca Pharmaceuticals LP of Wilmington, Delaware.

Thyroid cancer is a cancerous growth of the thyroid gland, which is located in the neck. Medullary thyroid cancer involves specific types of cells that are found in the thyroid gland and can occur spontaneously, or be part of a genetic syndrome.

About 44,600 new thyroid cancer cases were diagnosed in the United States during 2010, and about 1,690 people died from the disease, according to the National Cancer Institute. Medullary thyroid cancer is estimated to represent 3 to 5 percent of all thyroid cancer; its estimated incidence in the United States for 2010 is about 1,300 to 2,200 patients, making it one of the rarer forms of thyroid cancer.

Vandetanib targets medullary thyroid cancer's ability to grow and expand. There are currently no FDA-approved treatments for this type of cancer. Vandetanib is administered orally on a daily basis.

Vandetanib was shown to affect the electrical activity of the heart, which in some cases can cause irregular heart beats that could lead to death. Vandetanib is being approved with a Risk Evaluation and Mitigation Strategy (REMS) to inform health care professionals about these serious heart-related risks. (Source: FDA Website, 16 April, 2011)

### FDA Approves Horizant to Treat Restless Legs Syndrome

The FDA approved Horizant Extended Release Tablets (gabapentin enacarbil), a once-daily treatment for moderate-to-severe restless legs syndrome (RLS). Horizant was developed by GlaxoSmithKline of Research Triangle Park, North Carolina and Xenoport of Santa Clara, California.

RLS is a disorder that causes a strong urge to move the legs. This urge often occurs with unpleasant feelings in the legs. People who have RLS describe feeling pulling, itching, tingling, burning, or aching in their legs, and moving the legs temporarily relieves these feelings. The urge to move often happens when a person is inactive, and the symptoms typically are worse in the evening and early morning.

Horizant will be dispensed with an FDA-approved Medication Guide that explains the drug's uses and risks. Horizant may cause drowsiness and dizziness and can impair a person's ability to drive or operate complex machinery.

Horizant contains gabapentin enacarbil that becomes gabapentin, a drug used to treat seizures in people with epilepsy, when absorbed into the body. All drugs used to treat epilepsy carry warnings that they may cause suicidal thoughts and actions in a small number of people. Horizant will have the same warning. (Source: FDA Website, 7 April, 2011)

### FDA Permits Marketing of First Test to Help Diagnose Dengue Fever

The FDA allowed marketing of the first test to help diagnose people with signs and symptoms of dengue fever or dengue hemorrhagic fever, a leading cause of illness and death in the tropics and subtropics. The dengue virus is transmitted to humans by the bite of an infected Aedes mosquito. As many as 100 million people worldwide are infected by the virus each year, according to the Centers for Disease Control and Prevention (CDC).

The DENV Detect IgM Capture ELISA test detects antibodies to dengue virus in blood samples from patients who have signs and symptoms of dengue. The test will be available for use in clinical laboratories and will assist in the diagnosis of dengue, which can improve patient care and management.

There are currently no FDA-cleared or approved tests for direct detection of dengue virus. The DENV Detect IgM Capture ELISA test is based on technology patented by the CDC and manufactured by Seattle-based Inbios Inc.

This new test shows cross-reaction with other closely related viruses such as those that cause West Nile disease. However, in most patient testing situations found in the United States, a positive test result in a patient with signs or symptoms consistent with dengue should be considered presumptive evidence of dengue. (Source: FDA Website, 8 April, 2011)



FDA Approves Actemra to Treat Rare Form of Juvenile Arthritis

The FDA has approved Genentech's Actemra (tocilizumab), given alone or in combination with methotrexate, for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in children ages 2 years and older.

SJIA, or Still's disease, is a rare, potentially life-threatening disorder in children that causes severe inflammation throughout the body. Actemra is an interleukin-6 receptor blocker approved by the FDA for treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to other approved therapies.

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

FDA Approves New Medical Device for Form of Brain Cancer

The FDA approved the NovoTTF-100A System, a new device to treat adults with glioblastoma multiforme (GBM) that recurs or progresses after receiving chemotherapy and radiation therapy. The NovoTTF-100A System is made by Novocure of Portsmouth, New Hampshire.

Brain tumors are the growth of abnormal cells in the brain tissue. According to the National Cancer Institute, each year about 19,000 people in the United States are diagnosed with primary brain cancers. In 2010, there were 13,140 deaths from brain and other nervous system cancers in the United States. GBM is the most common primary brain cancer. The brain tumor is highly resistant to standard treatments such as surgery, radiation and chemotherapy.

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

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

**New Members**

- Ms. Rebecca C. Boduch, *Controls Engineer*, Organogenesis Inc
- Mr. Chris Brady, *Manufacturing Manager*, BIOVEX
- Anthony Casassa, *Head of Sales and Marketing*, Mettler-Toledo Process Analytics
- Mr. David Chen
- Ms. Emma J. Chory, *Student*, Northeastern University
- Mr. John Cumper, *Engineer*, Genzyme
- Mr. Prabhat Dhar, *Sales Manager*, Bioengineering, Inc.
- Mr. Michael D. DiModica, *Sr.Automation Engineer*, Genzyme Corp.
- Mr. Dana Etherington, *Mechanical Engineer*, CRB Engineers
- Brian Feeney, *Process Engineer*, Genzyme
- Dalia L. Ficut, *Systems Engineer*, New England Controls
- Mr. Steven J. Gattuso, *Facilities Supervisor*, Shire HGT
- Mr. Chuck Gillingham, *Process Sales Leader*, Rockwell Automation
- Mr. William E. Gittler, *VP Life Science*, Airgas East, Inc.
- Mr. Hector Guzman, *Principal Engineer*, Alkermes
- Lindsay Gwyther, *Manager, Engineering Documentation*, Genzyme
- Mr. Blake W. Hughlock, *Validation Eng.*, Stryker Biotech
- Mr. Michael Keech, *Executive Director*, Ernst & Young
- Niranjan S. Kulkarni, *Operations Specialist*, CRB Engineers

Mr. Douglas J. Lantigua, *Principal*, MUSA Technology Partners LLC  
Ms. Jody Leggett, *Client Relations Manager*, Worcester Polytechnic Institute  
Mr. Dennis P. Lockhead, *Electrical Engineer*, CRB Consulting Engineers  
Kevin W. Lockwood, *Instrument & Controls Engineer*, Genzyme Corp  
Mr. James Love, *Principal*, JSL SYSTEMS  
Mr. Robert M. Lucas, *Student*, Boston University  
Mr. Jason A. Manchester, *Process Engineer Associate*, Genzyme Corporation  
Mr. Trevor P. Merrill, *Student*, University of New Hampshire  
Kathleen Moxham, Waters Corporation  
Ms. Stephanie E. Polgar, *Student/co-op*, University of Massachusetts Amherst  
Mr. John M. Polidoro  
Mr. Ben M. Potenza, *Vice President of Marketing*, EquipNet Inc  
Ms. Alyssa M. Rocco, *Lead QA Specialist*, Vertex Pharmaceuticals Inc  
Mr. James B. Stewart, *Student*, University of New Hampshire  
Mr. Francesco Ventre, *Assoc. Dir. EVM- Asset Manager*, Pfizer  
Mr. Christopher Welch, *Process Engineer*, Genzyme Corp

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Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation  
Mr. Cesar B. Daou, PE, Daou Engineers Inc  
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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  
Mr. Jerome Justin, Shire HGT  
Dr. Richard V. Levy, PDA  
Mr. Frank J. Manning, VNE Corp  
Mr. Hank Moes  
Mr. Thomas W. Moss, Applied Process Solutions, Inc  
Mr. Armen J. Nahabedian, Pfizer  
Mr. Richard D. Priestester, Strategic Facility Planning LLC  
Mr. Thomas Ramundo, New England Controls, Inc.  
Mr. Thomas Ransohoff, BioProcess Technical Consultants Inc.  
Mr. Pasquale M. Sacco, Shire HGT  
Mr. Alexander E. Smith, Jr., Parsons  
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

**15 Year Anniversary**

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Ms. Lucy Lavallee, Genzyme Corp  
Mr. Albert G. Prescott

**10 Year Anniversary**

John Hurst, A/Z Corporation  
Jonathan Whitney, Johnson Controls

**5 Year Anniversary**

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Mr. Joseph F. Devlin, Skanska USA Building Inc.  
Ms. Amy Foley, The Richmond Group Inc  
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Mr. Timothy M. Zetts, Topline Process Equipment Co

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