Boston Area Chapter
ENGINEERING PHARMACEUTICAL INNOVATION

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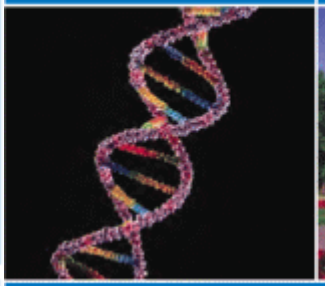


NEWSLETTER

June 2008, Volume XVIII, No 3.

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Why is the ISPE Boston Chapter Growing So Quickly?

Hello ISPE Boston Area Chapter Members,

This week was a milestone of sorts. The ISPE Boston Area Chapter membership reached 1300 dues paying Members. That's around a 12 percent growth rate (11.78 percent for you engineers) over last year and puts us right up there with the largest four of the 12 ISPE Chapters throughout the country - Delaware, we're gaining on you. And this during a time of flat membership numbers at most other Chapters throughout the country. So why are we growing so fast?

To understand the cause and effect, it's first important to understand how the ISPE Boston Area Chapter functions. It's run entirely by volunteers. People like you with a passion to get involved with the leading professional biotech and pharmaceutical organization in the Boston area. The Chapter's Board of Directors is composed of 15 dedicated Members, most of whom also run one of the Committees, providing a vital and mostly fun service to the organization. Some have said we get paid exactly what we deserve (did I tell you we're all volunteers?) and perhaps that's because we certainly have fun while working. Let me tell you about a few of these people and 10 reasons why the Boston Chapter is growing.

1. Dave MacDonald and Mark Sitcoske co-chair the 10-member Educational Program Committee, which is providing 16 high quality educational and networking events this year. That's about two events every month if you consider we give this hard working Committee the summer off (of course their "pay" gets cut). These events have doubled in number over the past couple of years allowing for a big increase in the variety of topics covered. Combined with the continued high quality of the presentations, this has ensured high attendance and has led directly to the Chapter's growth. This Committee can rival Disney Studios in their production capacity - OK, maybe I'm getting carried away here - but they *are* good. You get the message. In addition to organizing a full roster of educational programs throughout the year, this hardworking group, including Board Member Jim Verhulst and others, also coordinates the speakers for the Annual Product Show.

2. Brian Hagopian's energy and diligence has guided the Product Show Committee in organizing and running the largest one-day biotech event in New England for the past two years. This year, the Product Show will be held on

October 8th. By now you'd have to be a hermit not to know it's *the* event to attend at Gillette Stadium (other than a Super Bowl, of course). The last two years, the Show was sold out (269 tables and 6 educational events) and over 1600 people attended. Brian and his dedicated Committee - especially Mark Sitcoske, Doyle Johnson and Mike Denault - work like a high-speed machine and are another one of the many reasons for the Chapter's growth.

3. Janet Tice chairs the Communications Committee with the efficiency of a Spartan general at war while wearing a warm smile that gently says, "Get the article done NOW." She and her Committee somehow consistently publish six detailed, professional quality newsletters (including this one) each year on time and update our Web site too. Janet has an author's eye for editing and an incredible ability to get mere mortals to write polished articles and provide them (including this one) on deadline. Janet and her committee, including Board Member Pietro Perrone and others, is another reason for the Chapter's growth.

4. Sylvia Beaulieu runs the Social Committee with grace, charisma, and a sharp eye for the financials. She and her Committee coordinate the Annual Golf Outing (August 18th this year and already sold out!), Holiday Social, Volunteer Appreciation Outings, Annual Ski Trip and the newly-added Summer Social. When Sylvia is running an event, you want to be there. She is also amazingly creative in finding ways to maximize advertising revenue while minimizing costs to Members. Case in point, the upcoming June 11th Summer Social at Boston Beer Works is free for Members! Sylvia is a big reason for the Chapter's growth.

5. Our Student Activities Committee (full disclosure - I am a member) is going through a transition. Dave Novak is leaving the Committee to join the Chapter's Senior Advisory Board. But new energetic Board Members like Shire's Kevin Lynch are jumping in with both feet. Kevin and a Shire colleague recently gave a fabulous presentation on chromatography and separations to 38 students at UMass Lowell. (Kevin says he also got seven resumes - an added bonus for Shire). Next September, Kevin will hit the speaking circuit and give a similar talk to some of the five other local Student Chapters. Kevin is one of the reasons that our student membership continues to grow along with the Chapter.

6. Jim Berry, our Treasurer and long term Board Member, has the wisdom, experience, and capacity to oversee this nonprofit organization with its substantial cash flow, Product Show revenue and expenses, etc. Known as the "disciplinarian" (or is it the "enforcer?") on the Board, he ensures that every Committee gets their yearly budget in on time and adheres to it throughout the year. No expense is too small for Jim to scrutinize! Let's just say if Jim were running a hedge fund, you'd want to invest your own and your retired mother's savings with him - that's the type of trustworthy guy he is. In sum, Members are well served with Jim keeping an eye on the Chapter's finances.

7. Jim Grunwald and Monique Sprueill co-chair the Member Services Committee. This Committee is responsible for creating ways to attract new Members and thank and retain existing Members. They have held special breakfasts to welcome new Members, initiated an Advocates Program to incentivize individuals at local companies to recruit new Members and routinely make phone calls to gently remind existing Members to renew. Monique is especially adept at describing the likes and dislikes of the younger generation of pharm and biotech professionals to us "older" Board Members while Jim, with years of wisdom acquired in a variety of positions on the Board, has a knack for knowing exactly what works in recruiting Members.

8. Amy Poole is our Chapter Manager (full disclosure - she gets paid for this work) and has become so valuable to this organization that she was sent to the last three ISPE International Conferences to help us understand the ISPE requirements for tax submittals, accounting requirements, legal and insurance issues and numerous other filing requirements which she handles so cheerfully. Amy never forgets anything, which is scary, and she has the patience of a saint. She does the heavy lifting when things have to be done immediately. Thank you, Amy.

9. Thank God for the friendly wisdom surrounding me! Doyle Johnson our Vice President skillfully ran the Social Committee for many years before he turned it over to Sylvia and agreed to be Vice President. He is able to fill in during any emergency, is always ready to advise and help, and knows how to get the work done while having fun. To get a feeling for his sense of humor, read the Ski Trip articles he has written for the last two years. Mike Denault, our Past President, remains on the Board to provide guidance and advice, especially to Doyle and me. His quick advice ("Rick, time to step in and cut off that long-winded questioner before people start leaving") and the wise guidance he has often whispered to us have served the Chapter well. The three of us attend three National ISPE conferences together each year, which we always enjoy. In addition, Marita King, Chapter Secretary and long term Board Member and Past President of CASA, a large ISPE Chapter located in the southeast, is an invaluable addition to our Board. Her sound advice on "Chapter Excellence," as defined by the International ISPE organization, and her many ideas for

improving the Chapter are an outgrowth of her long experience in Chapter leadership. The guidance provided by Doyle, Mike and Marita are another reason the Chapter has grown.

10. Our member companies and vendors continue to support the Chapter and contribute to its growth in so many ways. Our "Top 10" member companies are Wyeth (86), Genzyme (84), Alkermes (31), Shire (29), Abbott (29), AstraZeneca (28), Biogen (27), Lonza (22), Parsons (20) and BMS (20). They have supported the Boston Area Chapter by hosting tours of their facilities, supplying free conference rooms for meetings and providing senior advisors who meet with the Board each year to provide valuable feedback. The vendors overwhelmingly support the Chapter through their participation in the Product Show, sponsorship of Chapter activities, enthusiastic attendance at Chapter events and participation on many committees. The enthusiastic support from both our Member companies and vendors is a big reason for the Chapter's growth.

So there you have it, ten concrete reasons why the ISPE Boston Area Chapter has grown to 1300 Members this year. On behalf of the Board of Directors, I want to sincerely say "thank you" to all of our volunteers (did I mention we're not paid?) and to the 50 or so Committee Members whose names were not listed here. And finally, thank you to all our member companies and vendors for your support. It is your enthusiasm and participation that has made this Chapter so successful. Now on to 1400 Members!

Sincerely,

Rick Pierro
President, ISPE Boston Area Chapter

Upcoming Chapter Events - Mark Your Calendar

June 17, 2008
"You want it when?!? - Insight from corporate quality and facilities on how to plan, organize, and execute the aggressive construction schedule for your GMP facility."
Royal Sonesta, Cambridge, MA

In the highly competitive Life Science market, product research, development, and manufacturing requires lightning fast construction schedules to get products to market. Please join your Bio-Pharm colleagues this evening in understanding the major challenges of merging quality and facility requirements with accelerated construction schedules and what procedures and systems can be implemented to overcome these challenges.

SPEAKERS:

Charles E. Pappalardo
Corporate Vice President Global Facilities Management Services
Charles River Labs

Michael Marino
Senior Quality Engineer - Facilities, Corporate Quality Assurance
Boston Scientific Corp

Click Here to Download a Registration Form and for Full Information

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August 18, 2008
Annual Golf Outing
Ferncroft Country Club, Middleton, Massachusetts

Thank you to our 2008 Golf Tournament Sponsors!

- CRB Consulting Engineers
- DECCO

- GxP Automation, LLC
- Integra Companies
- Invensys Validation Technologies
- Steris Corp
- StructureTone
- Superior Controls

September 16, 2008
Six Sigma Seminar
Genzyme Corporate Center, Cambridge Massachusetts

Wednesday, October 8, 2008
Annual Product Show
Gillette Stadium Clubhouse, Foxborough, Massachusetts

ISPE Boston Area Chapter Student Poster Contest Gets Tougher!

by Rick Pierro with photos by Yatao Liu, Mike Principato and Eric Marchese

Seventeen ISPE graduate students and two ISPE undergraduate students carefully and anxiously placed their research posters on the wall and nervously waited for the five judges to approach. The annual ISPE Boston Area Chapter Student Poster Competition had begun.

On April 2, student members of ISPE Chapters from Northeastern University, Worcester Polytechnic Institute (under formation), Boston University and the UMass Amherst assembled at Northeastern's Dodge Hall to compete for first prize and an all-expense paid trip to Boca Raton, Florida in October to compete in the ISPE International Student Poster Competition and attend the ISPE Annual Meeting. The competition this year was unusually tough. The students were given only five minutes to explain their research and posters and five additional minutes to answer questions fired at them by the five judges.

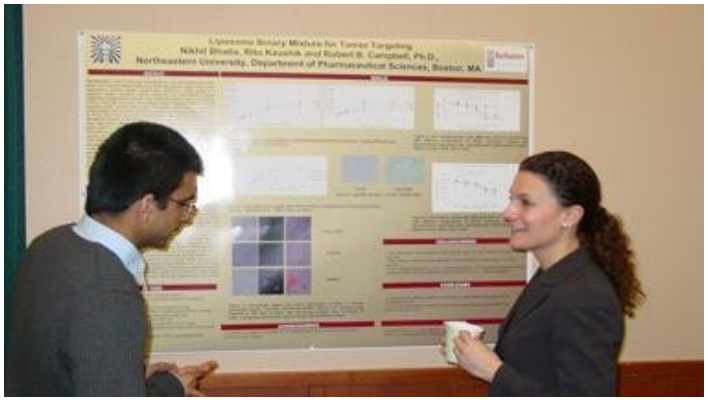
Judges (left to right) Marcia Steger, Rick Pierro and Dave Novak pay close attention as one of the students describes their research.

The judging this year was done by Henry Brush of Alkermes, David Novak of AMEC, Marcia Steger of Massachusetts Biologics, Michael Denault of Denault Associates and Rick Pierro of Superior Controls. Special thanks were given to Professor Rebecca Carrier and the four ISPE Student Chapter Officers of Northeastern University, Lisa Grady, Michael Principato, Kate Forrister and Eric Marchese, who prepared for and hosted the contest. The Student Chapter also provided the pizza and soda which energized the judges throughout the evening.

Judges (left to right) Henry Brush and Mike Denault take meticulous notes as they view the poster presentations.

The presentations went on for several hours and the judges meticulously totaled the points for each one. And finally the winners were announced. Padmaja Magadala, a graduate student attending Northeastern University, won with her poster titled "Epidermal Growth Factor Receptor-Targeted Engineered Gelatin Nanovectors for Gene Delivery and Transfection in Pancreatic Cancer Cells." Sindhura Ganga, also of Northeastern University, was the runner up with her poster titled "Multifunctional Nanoemulsion System for Combination Paclitaxel and Curcumin Delivery to Human Glioblastoma Cells."

Incredibly, the top two undergraduate students tied for first place in the undergraduate category. The judges decided that in this unusual situation it was only proper to send both the winners to Boca Raton. They are Jason Lajoie of UMass Amherst with his poster "Directed Evolution of RhII Protein" and Akshay Navaladi of Boston University with his poster titled "Role of Micro-Environment Stiffness in Directing Mouse Embryonic Stem Cell Differentiation."



Northeastern University Professor and event host Rebecca Carrier provides advice to one of her students prior to the presentations.

Special thanks go to the five judges for their tireless diligence in reviewing each poster and to all the students who participated. I believe I can speak for all the judges in saying we were truly amazed at the advanced and fascinating research being done in our universities and the dedication and expertise brought to each project by the students. Now on to Boca Raton in October for the ISPE Annual Meeting and International Student Poster Competition...stay tuned for the results.

Proud winners (front row, left to right) Akshay Navaladi of Boston University, Jason Lajoie of UMass Amherst and Padmaja Magadala of Northeastern University with judges (back row, left to right) Dave Novak, Rick Pierro, Marcia Steger, Henry Brush and Mike Denault.

Our Experiences at INTERPHEX 2008 and the Northeast Student Leadership Forum

by Jason Lajoie and Jeremy Sauer, with photos by Jason Lajoie

As members of the University of Massachusetts ISPE Executive Board, students often ask us, "Why should I join

ISPE?" We usually tell them that ISPE offers networking opportunities and the chance to learn about the pharmaceutical and biotechnology industries. Recently we experienced these benefits ourselves, first hand.

At the end of March, we were given the amazing opportunity to travel to Philadelphia and take part in INTERPHEX 2008 and the ISPE Northeast Student Leadership Forum (SLF). No sooner had we landed in Philadelphia when we ran into Rick Pierro, President of the Boston Area Chapter of ISPE, in the lobby of our hotel. He was excited to see that we were attending the conference and took us out to dinner to talk about our plans for the weekend. Where else would students be able to sit down and enjoy a meal with such a prominent member of the pharmaceutical industry?

We spent two full days at the Pennsylvania Convention Center viewing the exhibits, speaking with vendors, and learning about the cutting edge technologies and processes in the pharmaceutical industry today. We were amazed at the size and scope of INTERPHEX. Some highlights included a 500-liter wave bag manufactured by GE, the Career Fair and the chance to speak with countless industry professionals who offered career advice.

UMass Amherst Student Chapter Members (left to right)
Jeremy Sauer and Jason LaJoie enjoyed an "amazing learning experience"
at Interphex 2008 where they took part in the
ISPE Northeast Regional Student Leadership Forum.

On our last day in Philadelphia, we attended the ISPE Northeast Student Leadership Forum (SLF) held in the gorgeous Union League of Philadelphia. The SLF was an all-day networking event hosted by the Delaware Valley Chapter of ISPE. This was a great opportunity for us to meet and talk with other students and a group of industry professionals who were interested in helping us along in our careers. We were also able to hear from several professional engineers and hiring managers about what we, as students, can do to make ourselves more attractive applicants for the full-time positions we will be seeking next spring. Both INTERPHEX and the SLF were amazing learning experiences that we could never have had without the assistance of ISPE.

We would like to conclude by sincerely thanking the Boston Area Chapter of ISPE, whose support for our Student Chapter at UMass enabled us to fund our trip to Philadelphia. We truly appreciate ISPE's dedication to fostering student involvement in the organization and we hope that future students are as fortunate as we were to have this amazing experience.

Jeremy Sauer is Vice President and Jason Lajoie is Treasurer of the UMass Amherst ISPE Student Chapter. They can be reached at jsauer@student.umass.edu and jmlajoie@student.umass.edu, respectively.

Preparing for an FDA Audit: Everything You Need to Know but Were Afraid to Ask

by Joyce Chiu with photos by Mike Denault and Rick Pierro

The March 18th educational program sponsored by the ISPE Boston Area Chapter was held at Biogen Idec in Cambridge. Chapter President Rick Pierro opened with a thank you to our generous hosts, commenting that the event was sold out, with about 95 members and nonmembers in attendance. He then turned the floor over to Program Manager Dave Truex who introduced the evening's speakers: Ron Branning, President of Ron Branning & Associates and former Vice President of Quality Operations at Genentech; and Mike Cross, Senior Manager of Quality Engineering at Biogen Idec.

No Boston Area Chapter eductional program would be complete without food, drink and casual conversation before the presentations begin.

FDA Inspections: A Management Perspective by Ron Branning

With 38 years as a Quality professional in biologics, biotech, devices, pharmaceuticals and plasma, Ron was a highly energetic and entertaining speaker. Drawing upon his worldwide experience working with small to large companies on everything from consent decrees to new product approvals, Ron's presentation was accentuated with war stories and interesting anecdotes.

What are senior management concerns when it comes to FDA inspections? Senior management wants to avoid business interruptions and personal liability. Therefore, preparedness is the key, including a professional compliance team, internal and external assessments, and mock inspections. The main areas for focus include the quality system, facilities/utilities/processes, adverse events, laboratory out-of-specifications, CAPA and validation, as well as product release and rejections.

From a management perspective, Ron advised a focus on the top 10 issues - those that FDA inspectors will inevitably look for, based on a company's own documented evidence. During the inspection, backroom documentation staging and expert presenters, trained and rehearsed, need to be in place. In addition, the status of any remediation efforts needs to be updated and preemptive discussion with FDA considered.

During Prior Approval inspections, a company needs prepared responses to FDA's questions, with appropriate backup documentation and internal experts available. Tours of the production area and QC lab, batch records and stability data all need to be ready as well.

Senior management's role is to open the meeting, set the tone, obtain daily updates, preside over the closeout and lead continuous improvement efforts afterwards; but should stay out of the way and let subject matter experts do their job. In closing, Ron emphasized the importance of management's commitment to compliance, creating credibility and transparency, and sticking to "the truth, the whole truth, and nothing but the truth" as the golden rule when it comes to FDA inspections.

Chapter President Rick Pierro (center) with presenters Mike Cross (left) and Ron Branning (Right)

Regulatory Inspections: A Deckplate Perspective by Mike Cross

Biogen Idec is a licensed commercial drug supply facility, with its products distributed worldwide, from five trains of 2,000L scale in two distinct areas. There are more than five products and about 30 lots annually, with a staff of 300 in manufacturing, engineering and support and 35 in QA. With 10 years at the company, Mike has had experience with CMO inspections as well as several major agency inspections. Based on Mike's presentation, Biogen Idec has a well planned and executed inspection process in place, with attention paid to every detail.

In the past six years, Biogen Idec has had inspections by nine agencies; these include FDA, EMEA and Mexican, Japanese and Brazilian agencies. In order to remain ready, weekly inspection preparation meetings are held with senior staff. For actual inspections, there is a well laid out flow with a "war room," document room, inspection room and other closely related areas. Each room has a designated lead, scribes (for note taking), topic leads and inspection consultants; internet access, projection and video conferencing capabilities, etc. are provided where needed.

Mike described the sequence of events comprising the inspection process beginning with the opening day, including organizing presentations and daily wrap-ups. Inspections usually focus on the timeframe between the last inspection and the present, including any citations, utilities, product controls and changeover, supply chain, quality system, stability program and exceptions handling. If caught with a "gotcha," it is OK to ask for a timeout to strategize and respond, according to Mike. The final wrap-up is done with senior management involvement, to solidify response timing and expectations. In summary, a successful FDA inspection takes a year-round commitment, with an eye towards planning, preparation, a strong quality system, and clearly defined roles.

Despite a rather dry topic, Ron and Mike delivered well-thought out presentations, with interesting details and stories that everyone could relate to. They both did a wonderful job!

If the Biogen Idec conference room looks a bit crowded,
its the sign of another sold-out educational program sponsored by the Boston Area Chapter.

Talking Shop at Genzyme Science Center

by Arkady Mayblyum with photos by Mike Denault and Doyle Johnson

On Tuesday, April 22nd Genzyme Corporation hosted the ISPE Boston Area Chapter Talking Shop: "The Love Hate Relationship Between Engineering and Quality" at its new Science Center in Framingham, MA. The program format encouraged open dialogue between Talking Shop panelists and the members of the audience on the issues which have been near and dear to everybody involved with the industry.

Attendees at educational programs always have a chance to trade information and
catch up on the latest industry news before presentations begin -
just ask Chapter Member Jay Zaino.

All three panelists, Gael DeAmicis (Principal Validation Engineer at Bristol-Myers Squibb), Linda Graf (QAV

Boston Area Chapter Member Leena Asplund and Vice President Doyle Johnson enjoy the comfortable setting provided for the meeting by Genzyme in Framingham.

Manager at Wyeth Biotech) and Greg Ruklic (Principal Engineer at Wyeth Biotech), have worked in both quality and engineering roles throughout their impressive biotech/pharmaceutical careers and had no trouble engaging the audience in a free-wheeling discussion of the topic. After a short introductory presentation by Greg Ruklic, Linda Graf and Gael DeAmicis each talked about their approach to executing projects with heavy engineering and quality involvement. A few members of the audience, which was slightly tipped towards engineering, went on to share their own "war" stories. Very early in the program it became evident that the quality, validation and engineering groups are acting more and more as partners rather then nemeses as in the past.

Faced with the tremendous pressure, pharmaceutical and biotech companies are looking at the cost of compliance as one of the most significant areas of improvement. The introduction of the ASTM E2500-07 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment started a new trend shifting a lot of quality responsibilities to engineering. This is forcing engineers to be more involved in quality issues and quality professionals to become Subject Matter Experts (SME) in certain engineering disciplines.

Program Manager Arkady Mayblyum launched the Talking Shop by introducing the three industry experts who would help guide the two-hour audience roundtable .

The new ASTM Standard was brought up on numerous occasions throughout the evening, triggering discussions on execution of commissioning and validation activities for projects of different scale; and also led to discussion of the potential effect of other standards like the ANSI/ISA S88 Batch Standard and ANSI/ISA S95 International Standard for the Integration of Enterprise and Control Systems on the industry's future.

Overall, it was very encouraging to see that there is a lot more Love than Hate in the relationship between engineering and quality.

Industry experts (left to right) Greg Ruklic (Wyeth), Gael DeAmicis (Bristol-Myers

Squibb)
and Linda Graf (Wyeth) share their expertise with the audience during the
spirited give-and-take provided by the Talking Shop forum.

Special thanks to Genzyme Corporation for hosting the program, to Stan Rotkievicz from Genzyme and Monique Sprueill of Bristol-Myers Squibb for coordinating the event for ISPE; and to the panelists, Gael DeAmicis, Linda Graf and Greg Ruklic and the Boston Area Chapter Educational Program Committee for an extremely interesting and thought-provoking evening.

ISPE Boston Area Chapter Newsletter Survey

Welcome to the June issue of the Boston Area Chapter eNewsletter. The eNewsletter made its debut in October 2007. It was designed for ease-of-use and quick access to information of interest to members.

Now that you've had ample opportunity to experience the new format, we'd like to know what you think. Simply click on the following link http://survey.constantcontact.com/survey/a07e2b3reitfh23cw6a/start to complete a short survey regarding your likes and dislikes. Your input will help us fine tune the eNewsletter content and functionality in order to serve you better.

As an added incentive, the names of members completing the survey will be entered into a drawing for free attendance at an upcoming educational program plus an ISPE "mystery" gift.

If you have questions, suggestions or comments regarding the eNewsletter, or Chapter communications in general, please contact Chapter Manager Amy Poole at ISPE@camihq.com. We always welcome your feedback.

Technical Article: Value Proposition - I/O Simulation & Testing

[Editor's Note: An earlier version of this article was published in the Great Lakes Chapter Newsletter.]

Value Proposition - I/O Simulation & Testing
by Eric Bird

Innovation in automated systems can often be a challenge in pharmaceutical manufacturing. While other industries have been implementing plant-floor and information-control systems for many years to realize gains in quality, efficiency and productivity, cGMP regulatory requirements have often been perceived to stifle the use of innovative practices or technologies. Consequently, the gains other industries have been realizing through upgrades to process control and information management systems have been to a large extent missed by pharma in relation to:

- new facility initiatives and
- implementation of process improvements on existing validated production systems.

Quite simply, the stringent regulations, while serving a vital quality and safety purpose, have created a situation in which risks associated with change are prohibitively high. So high that once a validated system is in place and product is moving out the door, the overriding question becomes, "Why change a functioning process and open up to unnecessary risk?"

Against this backdrop of high risk associated with change, innovation becomes a secondary issue. And understandably so. Consider that many pharmaceutical companies that have forged ahead with process upgrades have done so only to become painfully aware of the "10 times" rule: It takes 10 times as long to make a system change during each subsequent phase of project delivery - design, engineering, commissioning, and finally qualification.

Typically, pharmaceutical manufacturing environments consist of a wide variety of types of equipment made by multiple vendors. The equipment often runs on proprietary software, with each piece of equipment presenting a

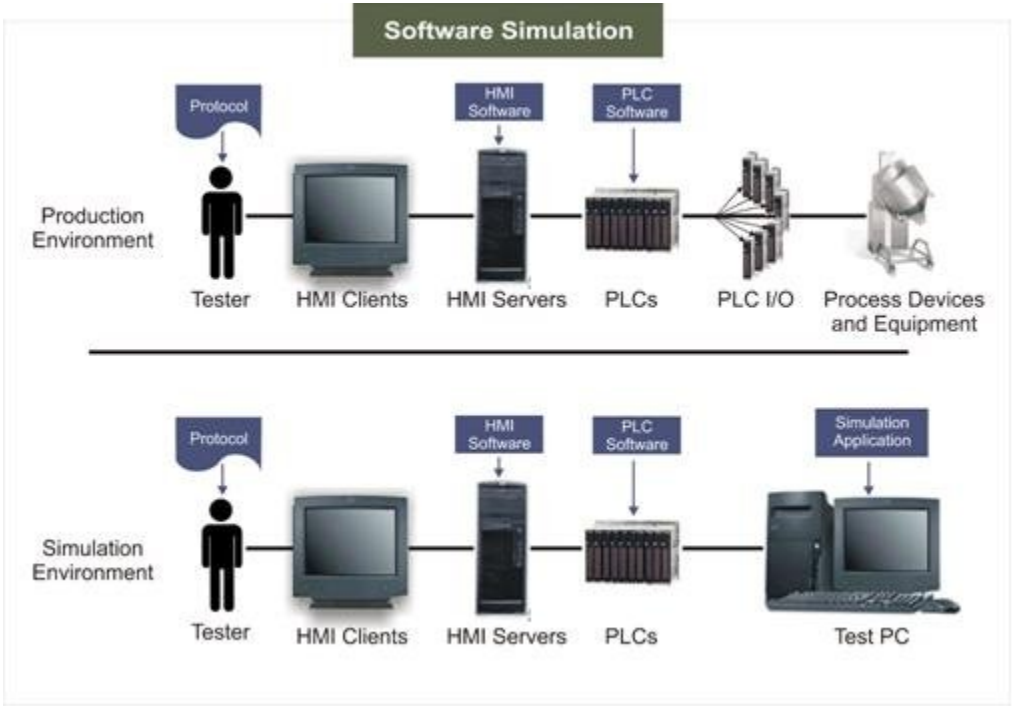
different look and feel. Network communications, controls and data integration can be extremely complex and difficult to troubleshoot. When testing is executed, software issues are often not discovered until late in the project cycle (i.e., during system installation and commissioning or, worse yet, during qualification) and troubleshooting becomes a significant challenge that negatively impacts operations and the bottom line. Companies that have experienced testing and associated troubleshooting under these conditions necessarily hesitate when talks of future upgrade initiatives percolate. The question "Why change?" magnifies, and any persuasion to change has to be nothing short of compelling.

The good news for the pharmaceutical industry is that there has been a shift of thinking within the FDA. The agency now recognizes that:

- innovation is vital for the industry to remain globally competitive and
- regulatory control and innovation must be harmonized.

Accordingly, the FDA is promoting innovation in manufacturing. Pharmaceutical manufacturers are challenged to think more critically about production processes and consider embracing new technologies. Many pharmaceutical companies will be proactive and pursue change. Those that do must still do all they can to help mitigate risk by applying the risk-mitigation tools and practices that are available in the marketplace.

I/O Simulation is a practice used by select controls integrators to manage the implementation of new automated systems. I/O Simulation involves the use of PC-based software to simulate physical field devices such as instruments, sensors, and unit operations for the purpose of testing control system code. A graphic illustration showing a comparison between traditional testing in the production environment and I/O Simulation testing of controls systems is displayed as follows:



The top half of the graphic (entitled Production Environment) represents the traditional approach in which testing of the control system source code is conducted after all equipment and devices are fully installed in the manufacturing

facility. When traditional testing is applied, the root causes of problems are difficult to isolate; installation and commissioning times are prolonged and testing is constrained by equipment availability in addition to physical and time limitations.

The bottom half of the graphic (Simulation Environment) represents the I/O Simulation model in which control system software is tested in an offline environment. The software is programmed to make the system that is being tested believe it is connected to physical field devices - those inputs and outputs that it is programmed to control.

Simulation allows engineers to create a lab model that mimics the real-time, dynamic behavior of the physical field units and provides the controls systems with feedback. To these systems, there is no difference between controlling the simulated I/O and the actual process. In this way, the software can be tested, debugged, and challenged before it goes near the floor. This means that the majority of software issues are identified and eliminated early in the project cycle, essentially taking software off the critical path. Owners are assured that the field commissioning stage is not used for debugging software but, instead, is used for mechanical and system integration and final system testing.

Factor in a risk-based validation approach to the overall effort and the testing performed in a simulated environment can be leveraged to meet validation requirements and thus reduce the overall validation testing in the field using the actual production equipment. The primary focus of the validation effort is then less on retesting every feature and function of the software (as it has already been tested using simulation) and instead is targeted on higher-level system testing to ensure that equipment is fit for use to make product.

In addition to debugging software and streamlining validation, the advantages of this testing strategy are numerous and well documented. Consider the following:

- Thoroughly tested emergency and fault-handling procedures assure users that the first true test of sections of PLC logic is not during an actual emergency.
- Code that has been "stressed" in simulation challenges hard-to-test scenarios, verifies security parameters, tests alarms, and uncovers potential for mistakes without endangering production, equipment or personnel. This is especially effective for complex systems or systems with a high risk of endangering operators or equipment.
- Operators can be trained well in advance of the equipment arriving on site. Involving operators early in the process helps them better understand the sequence of "live" operations and the situations they will face on a daily basis.
- Simulation allows for early development of Standard Operating Procedures (SOPs) and operator instructions, which can be applied to the training of new operators or to reviews of the impact of potential upgrades or changes to the system.
- Lastly, simulation is a very effective way to conduct design reviews with the many stakeholders involved in a new system install.

On a recent project involving the delivery of a new powder fill facility, the ROI for applying simulation was very high - over 400 percent before even factoring in the key performance measure of faster time to market. Other highlights of this project included resolving over 500 software discrepancies prior to commissioning, completing automation work under budget and reducing the overall schedule by 36 days.

Understanding how to apply a well-executed simulation and testing program to mitigate the risk inherent in any new systems or upgrades involving technology helps pharmaceutical manufacturers innovate with confidence. Experience has shown that a simulation program can significantly increase the probability of success on capital projects involving automation, process control systems, manufacturing IT and manufacturing execution systems, and essentially takes software off the critical path. And being able to count on the success of a project is vitally important to regulated manufacturers, whose projects are subject to risk factors from many angles - schedule, cost, quality, regulatory compliance, and time to market.

Eric Bird is a practice leader for the Life Sciences Industry Division of Brock Solutions, an engineering solutions company that specializes in projects requiring automation and drives engineering, information

management/manufacturing execution systems (MES), manufacturing IT, and project and installation management. Eric has 10 years experience in the implementation and qualification of plant-floor controls, automation, data management, and manufacturing execution systems. He can be reached at 519 572 0382 or ebird@brocksolutions.com.

Regulatory & Legislative Highlights

By Deepen Joshi

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 Names Director for Center for Drug Evaluation and Research (CDER)

The FDA said former drug-center head Janet Woodcock will return to that post on a permanent basis. Dr. Woodcock's second stint in the job, which she has held on an acting basis since September, is likely to be generally welcomed by the drug industry. Though she is seen as tough, she is a seasoned hand, having begun her previous directorship of the CDER 1994. In 2005, she was appointed a deputy commissioner at the FDA, later adding the title of chief medical officer. Dr. Woodcock will relinquish both positions, an FDA spokeswoman said.

Because she is an architect of the FDA's current approach to drug regulation, industry officials don't view her as likely to attempt wholesale reversals. Still, Dr. Woodcock, an internist and rheumatologist, will take back her former job at a challenging time, overseeing major transitions at the center. Her first and biggest task will be to implement a major law passed last year that will require the hiring of hundreds of new staffers and the drawing up of procedures to implement new authority over drugs already on the market. Under the new law, the FDA is able to take various actions if it believes a drug carries a potential safety concern, including requiring new studies and limiting distribution.

Dr. Woodcock will also take over as Congress has the FDA under particularly close scrutiny. A number of outside groups have said the agency needs more funding and changes in its culture and approach. Some drug-industry officials have ramped up their public venting of concerns that the FDA has become too risk-averse in its approvals, slowing the arrival of new treatments. Among the congressional investigations focused on the agency are probes into its handling of the Sanofi-Aventis SA antibiotic Ketek and the safety of heparin, the blood-thinner that has been linked to hundreds of allergic reactions and some deaths. (Source: Anna Wilde Mathews, The Wall Street Journal, 11 March, 2008)

FDA Makes Recommendations on Drug-eluting Stents

FDA Commissioner Andrew C. von Eschenbach has announced that the agency has issued draft guidelines to aid the development, testing and manufacture of coronary drug-eluting stents. Over the past few years, FDA and the clinical community have been closely monitoring these devices, including concerns over clot formation in some patients several years after implantation. The FDA guidance document outlines the agency's recommendations for pre-market clinical evaluation and post-market studies, which may provide data to better address this and other potential safety concerns.

This draft guidance, announced in the March 26th Federal Register, discusses the development pathway for new drug-eluting stents and provides recommendations on information necessary for a complete marketing submission. It also provides guidance on assessing the toxicity of the drug used to coat the stent, both on its own and as part of the complete product. Because these stents combine device and drug technology, this guidance contains expertise and input from two agency centers, the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research. Also included are draft recommendations for engineering tests, biocompatibility tests, and animal studies to assess the device's overall safety.

A copy of the guidance, "Draft Guidance for Industry on Developing Coronary Drug Eluting Stents," can be found at http://www.fda.gov/cdrh/ode/guidance/6255.html. (Source: FDA Website, 26 March, 2008)

FDA Identifies 25 Drugs and Biologics Requiring Safety Plans

The FDA has identified 25 drugs and biologic products that will be required to submit safety plans called Risk Evaluation and Mitigation Strategy (REMS), the FDA said in a Federal Register notice published March 26th. Under the FDA Act of 2007, the agency can require manufacturers to submit a REMS when a drug first comes on the market, or later if FDA becomes aware of new safety data about the drug. The manufacturers of the 25 drugs and biologic products identified in the notice must submit a proposed REMS by Sept. 21, 2008.

Certain drugs present a dilemma because they can provide an important benefit to patients but can be especially dangerous if not used properly. Rather than deny FDA approval of such drugs, the agency has granted approval and required that the manufacturer develop a safety plan, or REMS, to help ensure that health care professionals prescribe the drug correctly and that patients use it safely. While FDA has previously approved some drugs and biologics with these safety plans, the new law makes explicit FDA's authority to require them and contains specific enforcement authority when violations or noncompliance with the plan's requirements occur. (Source: FDA Website, 26 March, 2008)

FDA Approves New Vaccine for Gastroenteritis Caused by Rotavirus

The FDA announced the approval of Rotarix, the second oral US licensed vaccine for the prevention of rotavirus, an infection that causes gastroenteritis (vomiting and diarrhea) in infants and children. Rotarix is a liquid and given in a two-dose series to infants from 6 to 24 weeks of age.

Although the disease is usually self-limiting, rotavirus causes about 2.7 million cases of gastroenteritis in U.S. children each year-about 55,000 to 70,000 of those require hospitalization; and between 20 and 60 deaths are attributed to it. Without vaccination, nearly every child in the United States would likely be infected at least once with rotavirus by age 5.

There are many different strains of rotavirus. The vaccine protects against rotavirus gastroenteritis caused by the G1, G3, G4, and G9 strains. It is manufactured by GlaxoSmithKline Biologicals of Rixensart, Belgium. (Source: FDA Website, 3 April, 2008)

Orphan Drug Approved for Treatment of Rare Inflammatory Syndromes

The FDA has approved Arcalyst (rilonacept, an Interleukin-1 blocker) for the long term treatment of two chronic inflammatory diseases, Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), both of which are Cryopyrin-Associated Periodic Syndromes (CAPS) disorders affecting about 300 people in the US. The FDA granted the drug a priority review, which speeds the review process for patients who have unmet medical needs. Arcalyst is manufactured by Regeneron Pharmaceuticals of Tarrytown, NY.

Symptoms of both disorders include inflammation such as joint pain, rash or skin lesions, fever and chills, eye redness or pain, and fatigue in both children and adults; however MWS is associated with more severe inflammation and may include hearing loss or deafness. In addition, some MWS patients may also be affected by the buildup of a protein substance that damages organs and tissue (amyloidosis).

Arcalyst blocks interleukin-1 which is a signaling protein secreted by certain immune-related cells. Interleukin-1 acts as a messenger to regulate inflammatory responses, but in excess it can be harmful and has been shown to be key in the inflammation seen in CAPS sufferers with FCAS or MWS. (Source: FDA Website, 27 February, 2008)

AstraZeneca's Nexium Approved for Use in Children

The FDA has approved AstraZeneca's Nexium (esomeprazole magnesium) for short-term use in children ages 1-11 years for the treatment of gastroesophageal reflux disease (GERD). Nexium is part of a class of drugs known as proton pump inhibitors (PPIs). PPIs decrease the amount of acid produced in the stomach and help heal erosions in the lining of the esophagus known as erosive esophagitis.

FDA approved the use of Nexium in patients 1 to 11 years for short-term treatment of GERD based upon the extrapolation of data from previous study results in adults to the pediatric population, as well as safety and pharmacokinetic studies performed in pediatric patients. The safety and efficacy of Nexium has not been established in children less than one year of age. (Source: FDA Website, 27 February, 2008)

FDA Triples Heparin Death Count

The FDA has tripled the number of deaths it attributes to allergic reactions to the blood thinner heparin since January 2007 to 62 from 19. The FDA said these weren't new deaths, and that the tally is based on reports recently received by the agency as well as expanded analysis. The 62 fatality reports appear to match the type of allergic reactions that have been the main focus of safety concerns, the FDA said.

Problems with tainted heparin surfaced in the US in February, raising questions about the safety of the global supply chain for medicines and other products. Baxter International, one of the largest suppliers in the US, and a German company have recalled heparin products that were found to be contaminated. German authorities and Baxter have said the source of contamination appears to be in China, where ingredients for the problematic heparin originated.

The FDA sent a letter to device manufacturers on April 8th, warning them to review the sources of heparin used in their products, such as heart stents. Some vascular stents and grafts, as well as devices used in pulmonary bypass and in-vitro diagnostic procedures, are coated with heparin. (Source: Alicia Mundy, The Wall Street Journal, 9 April, 2008)

China Puts Drug-Safety Onus on Buyers

China's drug-safety agency, responding to questions about oversight of heparin said checks of pharmaceutical ingredients made in China are ultimately the responsibility of the countries that buy them. The agency said it works with foreign counterparts to monitor drug-ingredient production.

The agency also said it is cooperating with the US FDA in its investigation of deaths and illnesses related to heparin sold in the US by Baxter International of Deerfield, IL. Some of the heparin used in Baxter's drugs was made by a Chinese joint venture of Scientific Protein Laboratories, a Wisconsin company that also makes heparin in the US. Scientific Protein owns 55 percent of the joint venture; its Chinese partner, Changzhou SPL, owns the rest.

Lembit Rago, head of drug safety for the World Health Organization, says many Chinese manufacturers don't "have an understanding of international regulations or the training" to comply with them. Consumers in the US and European nations are protected in part by their own regulatory agencies, Dr. Rago says. For other countries without the capacity to check drug quality, "it's a much bigger problem."

Makers of crude heparin -- who extract the chemical from pig intestines, often in small workshops, and supply this raw material to companies such as Changzhou SPL and other producers of refined heparin -- say that they face little oversight from Chinese health authorities. (Source: Gordon Fairclough, The Wall Street Journal, 28 February, 2008)

FDA Takes Step Toward Establishing Overseas Presence

The FDA has received approval from the State Department to establish eight full time permanent FDA positions at US diplomatic posts in the People's Republic of China, pending authorization from the Chinese government. This is an important step forward in the FDA's plans to hire and place FDA staff in China over the next 18 months. In addition, the FDA will be hiring a total of five local Chinese nationals to work with the new FDA staff at the US Embassy in Beijing and the US Consulates General in Shanghai and Guangzhou.

Building the FDA's capacity outside of the United States supports the agency's "Beyond our Borders" initiative. The initiative facilitates the building of stronger cooperative relationships with the FDA's counterpart agencies around the world and enhanced technical cooperation with foreign regulators. The permanent overseas offices in China will also allow greater access for inspections and greater interactions with manufacturers to help assure that products that are shipped to the United States meet US standards for safety and manufacturing quality.(Source: FDA Website, 14 March, 2008)

FDA Panel Backs Curbs on Anemia Drugs

An FDA advisory committee called for new limits on cancer patients' use of blockbuster anemia drugs made by Johnson & Johnson and Amgen, a move that could significantly trim a major market for the medications known as erythropoiesis-stimulating agents, or ESAs. The panel said that because of safety concerns, cancer patients who are getting treatments that could cure their disease shouldn't take the drugs, which are sold as Procrit by J&J and

Epogen and Aranesp by Amgen.

The decision by the FDA's advisers are a mixed result for the companies, which had proposed far more limited steps aimed at addressing growing evidence of potential risks for cancer patients taking the drugs. The medications are approved by the FDA to boost red blood cell production in cancer patients whose anemia stems from chemotherapy. Even if the FDA limits the population of cancer patients for whom the drugs are recommended, doctors would still be able to prescribe them to others "off label," although such uses aren't always covered by insurers. It wasn't immediately clear how much of the drugs' revenue would be affected by the panel's recommendations, if they are adopted by the FDA. (Source: Anna Wilde Mathews and Marilyn Chase, The Wall Street Journal, 14 March, 2008)

J & J Antibiotic Hits FDA Roadblock

The FDA requested additional information from Johnson & Johnson and its Swiss partner Basilea Pharmaceutica AG before it will consider approving ceftobiprole, their jointly developed drug that has the ability to kill antibiotic-resistant bacteria. The holdup was surprising to some analysts and will likely delay the antibiotic's potential market entry by at least three to six months, according to Bruce Cranna of Leerink Swann.

At least four other antibiotics are expected to be reviewed by the FDA this year, according to a Credit Suisse report. The "approvable letter" for ceftobiprole and one issued in October to Theravance Inc. for televancin, as well as the FDA's cancellation of advisory-committee meetings for both drugs in February, suggest heightened caution about approving anti-infection drugs.

Infectious-disease experts have been frustrated by the rate of novel antibiotic development, which has slowed in recent years even as bacteria have become increasingly antibiotic resistant. (Source: Shirley S. Wang, The Wall Street Journal, 19 March, 2008)

Study Reports Deadlines May Affect FDA Decisions

Congress set strict deadlines for the FDA to speed the arrival of new medications, but critics have long complained that the ticking clock has spurred a dangerous rush to judgment. An analysis of decades of drug approvals, published in the New England Journal of Medicine in March, provides the first scientific evidence supporting some of those complaints.

Deadlines were first imposed on the FDA by a 1992 law that allowed drug makers to pay millions of dollars in fees directly to the cash-strapped agency so it could hire more reviewers and clear a backlog of pending drug applications. In return, the FDA had to make a decision - either approve or reject - on 90 percent of all drug candidates within 12 months of their application, or lose money. The deadline was 6 months for drugs so novel or potentially lifesaving to be classified high-priority. Congress tightened the deadline for most drugs to 10 months in 1997.

In the published study, Harvard professor Daniel Carpenter found approval is 3.4 times as likely in the two months leading up to the user-fee deadline as at any other time. Drugs approved in that just-before-deadline period had a four- to fivefold higher rate of being withdrawn or requiring serious safety warnings, compared with drugs approved faster - presumably slam-dunks - or those that miss the deadline, Carpenter concluded.

The FDA argued the findings weren't accurate, rushing out its own statistics that showed somewhat more withdrawals among drugs approved just before the deadline but not enough to be statistically significant. But the Harvard researchers in turn rechecked their statistics, which had passed review by the medical journal, and said they were standing by the findings. (Source: Associated Press, The Boston Globe, 27 March, 2008)

Possible Suicide Link Prompts FDA to Probe Merck Asthma Drug

The FDA said it is investigating a possible association between Merck's widely used asthma medication Singulair and behavioral changes, including suicide. Singulair is approved to treat asthma and allergy symptoms such as sneezing and stuffy noses, as well as to prevent exercise-induced asthma. The FDA said in a so-called "early communication" that it is reviewing postmarketing reports of behavior and mood changes, suicidal thoughts and actions, and actual suicides by patients who took Singulair. The regulator also asked Merck to look at its own database for signs of trouble.

Early communications are a recently developed tool the FDA uses to tell consumers and health-care professionals

that the agency is looking into a particular safety concern but that it hasn't reached any conclusions. It is expected to take about nine months for the FDA to review whether Singulair is linked to suicidal thoughts and behavior.

The agency said "posting this information does not mean that FDA has concluded there is a causal relationship between the drug product and the emerging safety issue." The FDA said Singulair is effective and that patients shouldn't stop taking it without talking to their doctors. (Source: Jennifer Corbett Dooren, The Wall Street Journal, 28 March, 2008)

Abbott Gets FDA Nod for Glucose Monitor

Abbott Laboratories has received FDA approval for a continuous glucose-monitoring system that allows constant tracking of blood-sugar levels to help diabetes patients manage the disease. The FreeStyle Navigator system works through a sensor placed in the back of the upper arm or abdomen, and a transmitter that sends wireless information to a receiver device that is the size of a pager. It will be available by prescription starting in the second quarter. The system was approved in Europe in June 2007 and has been available outside the US since September. (Source: The Wall Street Journal, 14 March, 2008)

FDA Rejects Merck's Cholesterol Drug

The FDA has rejected Merck's treatment to raise levels of "good" HDL cholesterol with issuance of a "not-approvable" letter. Merck for years has touted the drug, which it had planned to call Cordaptive, as one of its most important experimental medicines and a major new weapon to prevent heart attacks and stroke. It is an extended release form of niacin that is combined with a chemical meant to reduce flushing - uncomfortable redness and burning of the face and neck that is a side effect of niacin. Merck did not explain why the FDA spurned Cordaptive, other than to say the agency wants additional information on the drug.

Investment analysts speculated that the FDA, seen as increasingly cautious after the 2004 withdrawal of Vioxx and controversy over the failed Vytorin study, won't clear Cordaptive until long-term trials establish it can prevent heart attacks and improve other health-related outcomes. The FDA, in a recent draft of recommendations for the drug industry, calls for such outcomes studies where side effects are an issue. Furthermore, the rejection raises doubts about whether the FDA would be willing to approve another potentially lucrative Merck drug, now in development, that combines Cordaptive with Merck's older Zocor cholesterol fighter. It also spells good news for Merck rival Abbott Laboratories, whose Niaspan drug is the leading niacin HDL-booster on the market. (Source: Ransdell Pierson, Reuters, 29 April, 2008)

FDA to Require Additional Studies on Cholesterol Drug Licensed by Genzyme

The FDA has dealt a blow to Genzyme and Isis Pharmaceuticals, saying the companies must conduct additional studies of their cholesterol drug, mipomersen. Isis licensed mipomersen to Genzyme in January. In the deal, Genzyme agreed to buy $150 million of Isis shares at $30 each and pay a $175 million upfront for the right to develop and commercialize the drug.

Genzyme and Isis said the FDA would not grant their drug broad approval based solely on lower cholesterol levels. Instead, the companies said they will have to conduct a large-scale study tracking whether patients actually live longer or have fewer heart problems while taking their drug. The agency's "guidance" comes on the heels of its rejection of Cordaptive, Merck's cholesterol-lowering drug. Investment analysts saw the dual actions as a potential signal of a more worrisome trend: tougher approval standards for cholesterol drugs. WBB Securities analyst Steve Brozak said the FDA has increasingly rejected drugs that don't offer a clear advantage over older medications.

The FDA's actions come amid a debate over the benefits of newer cholesterol drugs, triggered by a failed study of Merck and Schering Plough's blockbuster Vytorin. The drug, which had 2007 sales of $5 billion, combines Merck's older cholesterol-lowering drug Zocor with Schering's Zetia. Results released by the companies in January showed that while the combination did lower cholesterol levels, it was no better at reducing fatty plaque than Zocor alone, which is now available as a low-cost generic. Experts called on doctors to return to the older, more established class of cholesterol-lowering drugs known as statins, which includes Zocor and Pfizer's Lipitor.

Lawmakers have also questioned whether the FDA's "lower is better" criterion for approving cholesterol drugs should be reexamined. The FDA has long approved drugs based on their ability to lower bad cholesterol, which is believed to reduce risk of heart attack and death. But the Vytorin results suggest the connection between higher cholesterol

and negative outcomes may not be as concrete as initially thought. While FDA staffers have said they are not changing the standards for approving cholesterol drugs, analysts say their actions suggest a shift. (Source: Associated Press, 30 April, 2008)

FDA Orders Merck to Correct Vaccine Plant Faults

The FDA has ordered Merck to correct numerous manufacturing deficiencies at its main vaccine plant, the latest in a string of setbacks for the drug maker. A warning letter sent to Merck's chief executive, Richard T. Clark, states FDA inspectors determined manufacturing rules are not being followed at the company's West Point, Pennsylvania plant, which makes a number of children's vaccines and four for adults, and recalled two vaccines in December over sterility problems. The nine-page letter states FDA found "significant objectionable conditions" in the manufacture of vaccines and drug ingredients during repeated inspections between November 2007 and January 2008.

According to the heavily redacted warning letter, Merck officials didn't thoroughly investigate when vaccine batches inexplicably failed to meet specifications, even if batches had been distributed, and some combination measles-mumps-rubella shots that failed "visual inspection for critical defects" were distributed anyway. The letter also said the plant didn't have written procedures, tests, or other laboratory controls to ensure "identity, strength, quality, and purity" of products. However, the FDA said it "does not believe that the issues identified will affect the safety of the vaccines" made at West Point, or their availability.

"We're committed to working with the FDA to ensure that all these issues are addressed to their full satisfaction," said Merck spokeswoman Amy Rose, who added that the company does not distribute contaminated products. "We are confident in the quality, effectiveness, and safety of our medicines and vaccines," she said.

The warning letter gives Merck 15 days to tell the FDA how it will correct the violations. If Merck does not comply, the letter states the FDA can take actions including suspending or revoking the plant's manufacturing license, and seizing products. (Source: Associated Press, 1 May, 2008)

Industry News In Brief

by Patti Charek

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.

Shire ADHD Drug Approved for Adult Use

Shire PLC said its hyperactivity treatment Vyvanse has won U.S. approval to treat adults, widening the market for the drug. Around a third of current Vyvanse prescriptions are written for off-label use in adults already, although Shire hasn't been able to promote the drug to these patients until now.

Attention deficit hyperactivity disorder becomes apparent in some children in the preschool and early school years but often can continue into adulthood. Treatment for adults has become a fast-growing market for drug makers. The main symptoms of ADHD are inattention, hyperactivity and impulsivity.

Taken once daily, Vyvanse doesn't become active until the pill is digested, offering fewer chances of abuse and overdose compared with competing products, including Adderall XR, Shire's main hyperactivity drug now. Switching patients from Adderall XR to Vyvanse is crucial for the company because the older product is set to lose patent protection in April 2009. "We are confident that this approval for adult patients will help continue to increase prescription share and volume of Vyvanse," said Shire CEO Matthew Emmens. (Source: Elena Barton, The Wall Street Journal, 24 April, 2008)

GlaxoSmithKline to buy Sirtris for $720m

Sirtris Pharmaceuticals, the Cambridge biotech that has attracted national attention for trying to use drugs based on an extract in red wine to fight diabetes and other age-related diseases, is being sold to British pharma giant GlaxoSmithKline for $720 million. The sale is the latest in a series of Bay State biotechs getting scooped up by large drug companies looking to fill their pipelines with new drug prospects as patents on their old, established drugs

expire. Recently, Japan's Takeda Pharmaceutical bought Millennium, the state's third largest biotech, for $8.8 billion, making it the biggest deal in the history of the state's biotech industry. Last fall, Pfizer bought Wellesley-based Coley Pharmaceutical $164 million; and Bristol-Myers Squibb bought Adnexus Therapeutics for $430 million.

The sale marks the latest success for Sirtris chief executive Christoph Westphal, a former venture capitalist who previously cofounded Alnylam Pharmaceuticals and Momenta Pharmaceuticals in Cambridge. GlaxoSmithKline says it plans to continue to operate Sirtris as an autonomous drug discovery unit, with Westphal and the rest of the management team at the helm. And Westphal said he plans to stick with the company for the long term because of its potential to attack aging-related diseases.

Though Sirtris is at least four years away from bringing any drugs to market, Westphal has dazzled investors and the media with tantalizing research that resveratrol, a compound found in red wine, might be able to stimulate enzymes called sirtuins that appear to play a key role in aging. Sirtris, founded in 2004, is in the early stages of testing a reformulation of resveratrol to treat Type 2 diabetes. But Sirtris eventually hopes to develop drugs to treat a number of aging-related diseases, such as cancer. As part of GlaxoSmithKline, Westphal said Sirtris, which has close to 60 employees, will have deep pockets to step up its resources without needing to do additional fund-raising. (Source: Todd Wallack, The Boston Globe, 23 April, 2008)

FDA Rejects Genzyme's Myozyme Made at Allston Plant

In a decision that shows how difficult it is to copy complex, biologic drugs, federal regulators rejected Genzyme's request for permission to sell a version of its Pompe disease drug, Myozyme, produced at its Allston manufacturing plant. Though Genzyme already has permission to sell batches of Myozyme manufactured at its smaller Framingham plant, the FDA ruled that Myozyme made at the Allston plant should be considered a different product because of small differences in its chemical structure.

In order to sell the Allston version of the drug in the US, Genzyme will have to file another application with new data showing the drug is safe and effective in large numbers of patients. Genzyme chief executive Henri Termeer said he believes the FDA decision will be only a temporary financial setback. The company said it had been preparing to give the FDA positive data collected from 900 patients who are already taking the Allston-made drug. In addition, more than 40 countries have approved Myozyme made at the plant.

The FDA decision suggests that regulators may be reluctant to approve any generic versions of biologic drugs, called biogenerics or biosimilars, without clinical data proving the drugs are at least as safe and effective as the original if there are even slight differences in the compounds. "It sends a very loud message and sets a very high bar," said Alison Lawton, Genzyme's senior vice president for regulatory affairs. Lawton noted that Genzyme had the advantage of having full access to all the original information about the drug and still had trouble replicating the manufacturing process exactly.

While traditional "small molecule" drugs are usually mixed from chemicals, biologic drugs are made from living organisms and considered much harder to replicate. Congress is currently considering at least two bills to create a process to let drug makers market generic versions of biologic drugs. But there is disagreement about how long brand-name drug makers should be entitled to exclusive rights to their drugs before facing generic competition, as well as how difficult the approval process should be. Most specialists believe some version of the legislation will likely be adopted by the end of 2009. (Source: Todd Wallack, The Boston Globe, 22 April, 2008)

EMD Serono Plans $50m Expansion in Billerica

Add EMD Serono to the growing list of drug companies expanding in Massachusetts. The biotech company plans to spend $50 million on a 125,000 sf addition to a building in Billerica, allowing it to consolidate local research operations and have space to grow. EMD Serono said it also hopes to hire 100 more researchers in Billerica by 2012.

EMD Serono is just the latest in a parade of biopharm companies that have unveiled plans to increase their footprints here. Genzyme is expanding its Allston manufacturing plant and building a facility in Framingham. Shire PLC is building a campus in Lexington as part of plans to add 680 jobs in the state. Sepracor is constructing another building next to its Marlborough headquarters and Organogenesis recently leased a third building for its Canton campus.

In the case of EMD Serono, the firm already has a long history in the state. Switzerland's Serono established its US headquarters in Massachusetts more than a quarter-century ago and has gradually added employees since then. It

now has 500 employees in Rockland and 150 in Billerica. Still, the future of the company's local operations was in question after Serono went on the auction block two years ago. Merck KGaA, a German pharmaceutical and chemical company, eventually bought Serono for $13 billion last year. To avoid confusion with NJ-based Merck & Co., Merck Serono operates in the US as EMD Serono.

After the sale, Merck Serono told employees it was committed to US operations. Executives said the company is delivering on its promise with the Billerica expansion. In addition to the 100 scientists it plans to hire over the next four years, EMD Serono said it will transfer 100 researchers from Rockland to Billerica. The company wants to combine its research operations in one location and hopes to break ground on the building addition early next year and finish construction by 2010. (Source: Todd Wallack, The Boston Globe, 16 April, 2008)

Rituxan Joins List of Treatments that Fail for Severe Form of MS

Rituxan, a top-selling drug from Genentech and Biogen Idec, failed to slow the course of the most severe form of multiple sclerosis in a large study, the companies said. The findings make Rituxan at least the sixth unsuccessful attempt to treat so-called primary-progressive MS, or PPMS. In the US, about 35,000 to 40,000 people have primary-progressive MS, out of roughly 350,000 to 400,000 total MS patients. There are no approved treatments for PPMS. Genentech and Biogen Idec had hoped that Rituxan, which is approved for blood cancer and rheumatoid arthritis, might become the first such treatment.

But in the companies' study, which followed 439 patients for 96 weeks, Rituxan didn't significantly slow the course of the disease, which gradually robs patients of motor function and causes tremors, tingling and fatigue. "We are disappointed in the outcome of the primary endpoint, but not surprised given the significant clinical challenges presented by PPMS," said Hal Barron, chief medical officer at Genentech.

In a smaller study last year, Rituxan slowed down the less-severe form of MS, which has several approved drugs, including Biogen Idec's Avonex and Tysabri. The companies have disagreed over what to do next. The matter is subject to an arbitration hearing this summer. Rituxan is also being studied in lupus, another immune-system disease with few treatment options. (Source: Keith Winstein, The Wall Street Journal, 15 April, 2008)

Takeda to Pay Billions to Get Into Biotech with Purchase of Millenium

Japan's Takeda Pharmaceutical Co. agreed to buy US biotech company Millennium Pharmaceuticals for $8.8 billion, giving Takeda a major presence in the lucrative cancer-drug market while also adding a number of promising drug candidates to its pipeline. Takeda, Japan's biggest drug maker by revenue, will buy Millennium for $25 a share, representing a 53 percent premium at the time for Millennium shares. The deal, the largest acquisition by Takeda, is structured as a tender offer, conditional upon a majority of shareholders accepting the terms.

The purchase comes as many of the world's largest pharmaceutical concerns are exploring deals for companies and drugs that will boost their own flagging pipelines. By acquiring Millennium, Takeda will help address a revenue problem it will likely face soon as the patents on two of its biggest-selling products expire in 2009 and 2011. Revenue from Millennium's best-selling product, blood-cancer treatment Velcade, is growing quickly and is expected to reach as much as $345 million this year.

Millennium also has seven compounds in clinical trials, the most promising of which is a treatment for Crohn's disease. The medicine, an antibody that works by binding to cells believed to play a role in the genesis of inflammatory-bowel diseases such as Crohn's, is slated to begin final-stage testing later this year. Other drugs in development include treatments for cancer and multiple sclerosis.

The acquisition is part of an aggressive campaign by Takeda President Yasuchika Hasegawa to spend a good chunk of the roughly $20 billion the company has in cash on acquisitions or licensing agreements. Last year, the company set aside $10 billion as part of a strategic fund to help it expand into overseas markets. In February, Takeda struck a deal to buy biotech giant Amgen's Japan unit, as well as gain marketing rights to 13 Amgen drugs for Japan and elsewhere in Asia. Last month, it bought out partner Abbott Laboratories' share of a US joint venture. Takeda specializes in diabetes, cardiovascular and anti-infective drugs. (Source: David Armstrong and Andrew Morse, The Wall Street Journal, 11 April, 2008)

Genzyme Recalls Transplant Drug In Further Setback

Genzyme voluntarily recalled more than 100,000 vials of Thymoglobulin, a drug used during kidney transplants. The FDA said the batches of Thymoglobulin, when liquefied, appeared to be cloudier than the form approved by the agency. The drug should only be slightly cloudy when liquid is added. Bo Piela, a spokesman for Genzyme, said there were no safety threats or efficacy issues involving the recalled vials. The product was manufactured in the first half of 2007, he added.

Thymoglobulin is a freeze-dried product made from rabbit proteins administered by injection to patients undergoing kidney transplants. The drug is intended to prevent a patient from rejecting the transplanted organ. In September, the FDA issued a warning letter saying the company had violated the agency's manufacturing rules at a Lyon, France plant making Thymoglobulin. The warning letter listed violations that had occurred on several occasions and noted that the company's investigations into adverse events were "inadequate." The recalled drug was made at the same factory in France, said Mr. Piela. He said the company has been working with the FDA to address the manufacturing issues and Genzyme had uncovered the latest problem.

The FDA directed customers to immediately discontinue use of the drugs from the recalled lots and to return the vials to Genzyme. The company said most of the product has been consumed. (Source: Suzanne Sataline, The Wall Street Journal, 11 April, 2008)

Cubist Finds its Cubicin Antibiotic is Tainted

Cubist Pharmaceuticals said it has warned the FDA that one of its antibiotic drugs, Cubicin, used to treat skin and blood infections, has been tainted with a potentially harmful industrial chemical. The impurity, 2-mercaptobenzothiazole (MBT), is known to cause skin irritation and is linked in laboratory testing to an increased risk of tumors in rodents. The Lexington-based drug manufacturer told the FDA that the contamination was discovered recently during routine testing performed as part of Cubist's quality-control program.

Eileen McIntyre, a Cubist spokeswoman, said the company believes the contamination came from ReadyMED drug pumps made by Cardinal Health of Dublin, Ohio, that are used to administer the antibiotic. She said MBT wasn't found in test samples of Cubicin stored in pumps made by I-Flow Corp.

Cubist said MBT is used in the manufacture of rubber and is said to have leaked from rubber stoppers and syringe components into medical devices in the past. A spokesman for Cardinal Health said the company is "conducting our own investigation to figure out what the issue is, and we don't know the results yet." The spokesman said the pump is "a disposable single-use infusion device" and the antibiotic is typically "self-administered" by patients recovering at home. It isn't known how many patients may have used the tainted drug. (Source: Joseph Pereira, The Wall Street Journal, 10 April, 2008)

Disease Foundations Provide Millions to Boost Research

In addition to raising venture capital and launching stock offerings, Massachusetts biotech companies are increasingly turning to another source of funding to support early drug research: nonprofit foundations dedicated to fighting serious diseases. For instance, the Cystic Fibrosis Foundation said it has awarded more than $300m to for-profit companies over the past decade to help develop cutting-edge therapies for the disease, including $192m in the Boston area. Epix Pharmaceuticals plans to announce that the foundation will give it as much as $37.7m, in addition to about $12m it has already received, to help them discover new cystic fibrosis drugs.

The Juvenile Diabetes Research Foundation said it has given about $25m to 22 companies, including local companies Biogen Idec, Genzyme and Tolerx; and since 2006, the Multiple Myeloma Research Foundation has given $6m to for-profits, including $1m to Cambridge-based Acceleron Pharma.

Overall, disease foundations invested roughly $75m in the biotech industry in 2007, up from $7m in 2000, according to CenterWatch Monthly, an industry publication. "It's becoming a significant method of funding," said Robert Coughlin, president of the Massachusetts Biotechnology Council, which is brainstorming ways to help bring more foundations and biotech companies together.

Like most other disease foundations, the Cystic Fibrosis Foundation originally steered its research awards to academic and nonprofit researchers to conduct basic research. But it needed drug companies to start developing actual therapies to treat the disease. That wasn't happening, though, partly because cystic fibrosis affects relatively

few people. Even companies that might be interested in treating rare diseases weren't pursuing cystic fibrosis drugs because it is so difficult to raise money for early drug discovery work, according to Robert Beall, President of the Cystic Fibrosis Foundation. Most investors prefer to wait until a company can offer some preliminary evidence that it's on the right track before pouring in tens of millions of dollars into a fledgling research program.

Beall decided to give companies money to do that early, basic research - jump-starting their research programs. He said the investment has already shown results. The Cystic Fibrosis Foundation estimates it has helped to produce more than 30 potential drugs. And in March, Vertex_Pharmaceuticals reported promising, though early, results for a cystic fibrosis drug it has helped to develop with foundation funding, called VX-770.

Once companies start showing results, disease-research advocates say, firms can usually raise the rest of the money on their own to bring a drug to market. The Cystic Fibrosis Foundation, for example, gave Vertex $79 million to help find drugs to treat cystic fibrosis. But Beall said Vertex is willing to spend a significant amount of its own money to conduct further trials to prove VX-770 is safe and effective. While the foundation didn't receive any stock for its investment, it did gain the right to some royalties if the drug becomes successful.

In the case of Epix, the biotech has already used money from the Cystic Fibrosis Foundation to create and analyze three-dimensional models of the defective protein that is believed to cause the disease in more than 80 percent of patients. Epix now plans to use the additional foundation money to start identifying possible drugs to thwart the illness. (Source: Todd Wallack, The Boston Globe, 7 April, 2008)

Clinical Results for Hepatitis C Therapy Boost Vertex

Investors are becoming upbeat once again about Vertex Pharmaceuticals. The company's stock surged 28 percent after the company reported positive clinical data for its experimental hepatitis C drug, called telaprevir, in a small clinical trial, while rival Schering-Plough Corp. released lackluster data for its competing drug in development, boceprevir.

The stock gain was good news for Vertex, which had been hammered over the prior six months on concerns that its drug could take longer than expected to be approved by regulators and face fierce competition from rival medications in development. If Vertex is successful in broader, Phase 3 trials, the drug is expected to reach the US market around 2011. The grim outlook began to change when Vertex reported early, promising data about an experimental drug designed to help treat cystic fibrosis, a disease that affects 70,000 people worldwide.

Still, Vertex's stock remains far below its recent high of more than $40 per share last September, underscoring the risk of investing in biotech companies that are years away from bringing a drug to market. Many emerging biotechs tend to swing sharply on each significant bubble of clinical data as investors bounce between optimism and skepticism over the drugs' long-term potential. Vertex faces potential competition from at least a dozen other hepatitis therapies in development. (Source: Todd Wallack, The Boston Globe, 1 April, 2008)

Swiss Pharma Santhera Plants Roots in Hub

A Swiss pharmaceutical firm has revealed plans to put its North American headquarters in Boston as it readies to begin sales of its lead drug, the first to tackle a rare and deadly genetic disease. While many foreign companies keep offices in Boston, Santhera Pharmaceuticals has chosen the Hub to be its main commercial outpost for the US and Canada. It has tapped MJ Roach, a former marketing director at Biogen Idec to be general manager of the operation, and plans to open an office at 40 Warren Street in Charlestown to serve as temporary space as it staffs up over the next two years and weighs a move to larger confines in Cambridge.

Santhera has staked its growth on marketing drugs for rare diseases - similar to the strategy that propelled Genzyme Corp. from a startup to a multibillion-dollar company; in Santhera's case, the focus is on drugs for neuromuscular disorders. In January, the firm began Phase 3 clinical trials in the US for its lead drug, idebenone, to treat Friedreich's ataxia. This rare genetic disease, which affects fewer than 10,000 Americans, is caused by the lack of a protein believed to be important in powering nerve and muscle cells and typically kills its victims before they turn 50.

Santhera's idebenone is pending approval in Europe. Though not a cure for the disease, idebenone is intended to transport electrons into mitochondria - the power plants of cells - to prevent damage to nerve and muscle cells. Santhera hopes to gain approval for idebenone, which is also in development for other neuromuscular diseases, in Canada in the second half of 2008 and in the US by the end of 2009 or early 2010. The firm has licensed the drug to

a Japanese drug firm for sales in Europe but plans to sell the drug on its own in North America.

To handle the expected US launch of idebenone, Santhera wants to build a staff of 25 workers in Boston by the end of 2009, said Barbara Heller, the company's CFO. Santhera estimates that about half of the worldwide market for the drug is in the US, yet annual revenue from the drug would depend on reimbursement rates.

The FDA has granted idebenone an "orphan" designation for Friedreich's ataxia. The designation, awarded for drugs and devices for rare diseases, provides Santhera with seven years of market exclusivity and other benefits. Santhera officials compare the firm's focus on treatments for rare diseases to the business model successfully executed by Genzyme, which markets drugs to tiny pools of patients with sicknesses such as Pompe disease, a neurological disorder. The company, which will remain based in Switzerland, is also developing drugs for neuromuscular disorders such as Duchenne muscular dystrophy and dyskinesia, which describes the involuntary movements made by patients with Parkinson's disease. (Source: Ryan_McBride, Mass High Tech 21-27 March, 2008)

Tysabri's Liver Warning Expanded to MS Patients

Biogen Idec and Elan Corp. have warned doctors of the possibility of serious liver injury in patients being treated with the multiple-sclerosis drug Tysabri. The new warning was included in prescribing information for Tysabri's use in patients with Crohn's disease, a chronic, progressive disease marked by inflammation of the bowel. Now the same liver warning is being included in information aimed at neurologists who treat multiple sclerosis.

The letter to doctors said that the companies have received "clinically significant" reports of liver injury in patients being treated with Tysabri, and that signs of liver injury occurred as early as six days after the first dose of Tysabri. Liver injuries also occurred after multiple doses of the drug. The letter instructed doctors to tell their patients that Tysabri may cause liver injury and said they should stop drug treatment if patients show signs of liver injury including jaundice. Shannon Altimari, a Biogen spokeswoman, said the rate of liver injuries is less than one in 1,000 patients. As of the end of December, about 21,000 patients had been treated with Tysabri. None of the injuries required a liver transplant, she said.

Biogen Idec and Elan reported that about 26,000 patients are using their Tysabri multiple-sclerosis treatment, as of the end of March. Notably, since the drug's relaunch in July 2006, there have been no cases of a rare, often deadly, brain infection called progressive multifocal leukoencephalopathy, or PML, that caused the drug to be pulled from the market in early 2005. The drug is now sold under a restricted-distribution program, and patients are routinely monitored for signs of the brain infection and for other side effects. (Source: Jennifer Corbett, The Wall Street Journal, 28 February 2008)

AstraZeneca's Recentin Fails Lung Cancer Trial

AstraZeneca is stopping a clinical trial of Recentin as a treatment for lung cancer after a mid-stage study failed to meet its main goal, although trials in colorectal cancer will move ahead. The mixed news adds to the company's patchy record on drug research, analysts said. AstraZeneca, which is facing the threat of generic competition to its two biggest sellers, Nexium and Seroquel.

Recentin, which is given as a pill, was being tested against non-small-cell lung cancer, the most common form of the disease. AstraZeneca said Recentin had shown some evidence of clinical activity in lung cancer but a Phase II/III trial would not progress into Phase III because among patients given the drug "there appeared to be an imbalance in toxicity."

John Patterson, the company's executive director for development, said AstraZeneca remained committed to investigating the potential of Recentin in lung cancer, despite the setback. AstraZeneca, meanwhile, is progressing with a final stage Phase III clinical trial comparing Recentin plus chemotherapy with Avastin plus chemotherapy in colorectal cancer. AstraZeneca also has another similar experimental drug in development for lung cancer, called Zactima. Clinical trial results for this product are expected to be announced in the coming months.

On another front, AstraZeneca has said it signed a deal with United Kingdom biotechnology company Silence Therapeutics PLC to develop improved delivery systems to treat diseases using gene silencing, a cutting-edge technology in which several major drug makers are seeking to gain a foothold. (Source: Ben Hirschler, Reuters, 27 February, 2008)

Alnylam Says RNAi Drug Study Meets Goal

Alnylam Pharmaceuticals has reported that its midstage study for experimental drug ALN-RSV01 met its main goal and reduced levels of the respiratory syncytial virus, a highly contagious virus that causes infections in the respiratory tract. The company's stock fell, however, as some analysts questioned the drug's true potential effectiveness in a real-world scenario, because patients in the trial took the drug before becoming sick.

ALN-RSV01 is an RNA-interference (RNAi) drug, a class of drugs designed to treat illnesses by shutting off the genes that cause them. The company claimed ALN-RSV01 is the first RNAi drug to show effectiveness in humans. The Phase II clinical trial of ALN-RSV01 showed "statistically significant" effectiveness, with about a 40 percent reduction in RSV infection rate. Alnylam also said the drug showed an increase in the number of subjects who remained free of infection. In addition, the drug was safe and well-tolerated, the company said.

In an interview with AP, Needham & Co. analyst Alan Carr highlighted potential challenges for the drug in light of the study's design. He said that while the results were positive, people in the trial were given the drug before they were infected with the virus, meaning the results fail to show a "real-world" scenario. The numbers were slightly disappointing with respect to viral load and symptom reduction, said Carr, and left him wondering how the drug would work in patients who don't take the drug before infection. (Source: Associated Press, 29 February, 2008)

Novartis Buys Control of Eye-Care Company Alcon for $39 Billion

Novartis AG, the Swiss drug maker facing product delays and generic competition, agreed to buy 77 percent of eye-care company Alcon in a two-step transaction totaling $39 billion. Novartis will buy an initial 25 percent stake in Alcon from Nestle SA, also based in Switzerland, for $11 billion; Nestle has an option to sell a further 52 percent of Alcon to the drug company for $28 billion.

Acquiring all of Nestle's shares in Alcon would make Novartis the world's biggest maker of eye-care products, including contact lenses and treatments for glaucoma. Novartis would also lessen its reliance on pharmaceuticals as new drugs face delays and sales of the hypertension drug Lotrel and the Lamisil antifungal medication are hurt by cheaper versions.

The acquisition "furthers our strategy to strengthen in areas of the market which grow dynamically and which allow us to diversify risk," Novartis chief executive Daniel Vasella said. The purchase, the biggest in healthcare this year, comes on top of the $13 billion Novartis spent on generic-drug makers Hexal AG and Eon Labs Inc. in 2005 and the $5.7 billion acquisition of vaccine maker Chiron Corp. in 2006. (Source: Bloomberg News, The Boston Globe, 8 April 2008).

Bristol-Myers Job Plans Ahead of Schedule in Devens

Bristol-Myers Squibb isn't expected to produce drugs at its plant under construction at Fort Devens until 2011, but that hasn't stopped the New York pharmaceutical company from hiring a bevy of new employees there. The company has already brought on nearly a third of the 350 workers it plans to employ in Devens by 2011, with 105 employees in management and support roles housed at temporary and leased facilities there, said spokeswoman Linda Jordan. What's more, Bristol-Myers plans to employ 214 people in Devens by the end of 2008.

Finding enough workers for the new plant has been a primary objective of Bristol-Myers and the company has worked with local community colleges, technical schools and industry officials to ensure it has an ample work force ready when production begins. The company is ahead of its initial hiring plan, which called for 115 workers in Devens by the end of this year, according to state records, rather than the 214 it now expects.

"It takes a lot of people working in advance to get a facility like that up and running," said Peter Abair, director of economic development for the Massachusetts Biotechnology Council, which has worked with Bristol-Myers to ensure it has enough workers for the Devens plant.

Jordan said that the drug company has nearly finished hiring its management team for the Devens site and is now recruiting for the lab tech and process operator positions that will be two-thirds of the work force there once hired. About half the employees there work in prefabricated, temporary offices in Devens and the others in leased offices in a building owned by the pharma services division of British chemical firm Johnson Matthey.

Last spring, Bristol-Myers began construction on the first phase of the Devens plant. With a projected cost of $750 million and finish date in 2009, the first phase is expected to include two production facilities, a warehouse and an office building. Plans are to ask the FDA to approve the operation in 2010.

The facilities under construction have a modular design to enable later expansion that could bring the total investment in the operation to $1.1 billion and the number of workers there to 550, according to the company, which likely could afford it. Bristol-Myers, which employs 42,000 workers worldwide, reported a 2007 profit of $2.2 billion on revenue of $19.3 billion.

Plans are to use the plant to produce Orencia, a protein drug approved to treat rheumatoid arthritis, in addition to producing other biological medicines. (Source: Ryan McBride, Mass High Tech, 4 April, 2008)

New Members

Jennifer A. Acker, Eisai Research Institute

Mr. Ronald G. Belling, Burt Process Equipment

Mr. Nikhil A. Bhatia, Northeastern University

Mr. Michael C. Chagnon, Lonza Biologics

Mr. David R. Cotter, Davis Brothers Inc

Ms. Jen Couture, University of Massachusetts Lowell

James K. Cramer, Fluid Line Technology Corporation

Mr. Jason S. Crater, Northeastern University

Stephanie L. Cruise, Momenta Pharmaceuticals

Thomas Dee, TBS Technologies

Dr. G Thomas Fortune Jr, Vertex Pharmaceuticals

Mr. Prateek Gadhoke, Bristol-Myers Squibb Co.

Ms. Sindhura Ganga, Northeastern University

Ms. Sheba Goklany, Northeastern University

Mr. John W. Graham, Plastic-Concepts, Inc.

Anthony Grieco, Jr., Airgas-East, Inc.

Mr. Francis X. Herlihy, Belimed, Inc

Joshua Hodgdon, Genzyme Biosurgery

Mr. Ross W. Israel, University of Massachusetts Lowell

Ms. Aditi M. Jhaveri, Northeastern University

Mr. Ramesh V. Kapur, Medical-Technical Gases, Inc.

Dr. Jeffrey A. Kaster, Altus Pharmaceuticals

Mr. David P. Kublbeck, Charles River Lab

Mr. Roop Kumar, Aztec Technologies

Christina Lach, Maxiom Group

Mr. Allen E. LeBoeuf, Oliver M. Dean, Inc.

Mrs. Myra J. Leets, Genzyme Corp

Mr. David T. Lewis, Organogenesis Inc

Ms. Padmaja Magadala, Northeastern University

Ms. Amrita M. Mehta, Northeastern University

Erin Meister, University of Massachusetts Dartmouth

Mr. Eftim Milkani, Worcester Polytechnic Institute

Mr. Jeffrey C. Moses, University of Massachusetts Boston

Mr. John Najim, Dyax Corp

Mr. Joseph Naughton, Linbeck

Mr. Akshay Navaladi, Boston University

Ms. Anu Nigam, Northeastern University

Claribel M. Oliveras, AstraZeneca, LP

Mr. Christopher Osmena, Process Design Corp.

Ms. Sunaina R. Pai, Northeastern University

Mr. Nicholas Pashos, Drexel University

Mr. Chris Patterson, Stryker Biotech

Ms. Dana C. Pentia, ImmunoGen Inc

Ms. Courtney Pfluger, Northeastern University

Ms. Shweta A. Raina, Northeastern University

Jon Russell

Mr. Paul Sabin, Sabin Design

Ms. Jenny G. Soucier, Excellerex

Norman F. Strate, TBS Technologies

Shifalika Tangutoori, Northeastern University

Ms. Jay P. Tilley, Banner Industries

Mr. Paul T. Tsang, Parsons Corporation

Mr. Aldo Villanueva, Spherics, Inc.

Ms. Rozanna Yaing, MIEE Solutions, LLC

Dr. Alexander B. Zhivich, Cubist Pharmaceuticals

Dr. Andrei A. Zlota, Mass.Coll. Pharm/Zolta Company

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