BY DENISE MYSHKO

PHARMACEUTICAL MANUFACTURING

Under Scrutiny

The FDA's heightened focus on safety has reached the manufacturing level. Regulators are increasing their presence on the line to ensure GMP is top of mind for companies.

Across the board — from labeling and marketing, to clinical trials, to manufacturing processes — regulators are becoming more active in safeguarding the public and ensuring the safety of pharmaceuticals.

Even before the news broke regarding Genzyme Corp.'s recent virus and contamination problems (bits of steel, rubber, and fiber were found in drugs made by the company and shipped from the same site), the Food and Drug Administration had been increasing its presence in inspecting manufacturing facilities and ensuring companies are GMP compliant and meeting SOPs. In the case of Genzyme, Federal regulators also warned doctors about possible foreign particles in five Genzyme drugs used to treat rare genetic disorders, including two — Cerezyme and Fabrazyme — that have been rationed because of the viral contamination detected in the company's Allston Landing plant last summer. The five drugs represent almost half of Genzyme's $4.6 billion annual sales. (See the digital edition, to read Genzyme's plan for manufacturing improvements.)

"The agency is dedicating more resources to drug inspection programs," says Michael Rogers, deputy director, Office of Regional Operations at the FDA. "This new administration is focused on swift enforcement, the need to be transparent, and the need to hold companies accountable."

In August 2009, Margaret A. Hamburg, M.D., the FDA's Commissioner of Food and Drugs, announced her vision for a stronger agency. One component is to set post-inspection deadlines. The FDA will establish a clear timeline for the industry to respond to significant FDA inspection findings, generally giving no more than 15 days to respond to such findings before issuing a warning letter.

A second component of her plan involves streamlining the warning letter process by limiting their review by the Office of Chief Counsel to those that present significant legal issues.

Pharmaceutical inspections continue to be a top priority for the agency, Mr. Rogers says. The FDA ended fiscal year 2009 with 1,575 consumer safety officers for all of the agency's programs.

Mr. Rogers says there are plans to increase that number to about 1,800 consumer safety officers covering all programs. About 20% of the consumer safety officers are dedicated to the drug program.

"In addition to increasing our total inspections, we want to enhance our investigator training and expertise to stay ahead of manufacturing advances that exist in the pharmaceutical industry," Mr. Rogers says.

In the drug program, he says, the industry can expect a highly skilled staff conducting inspections.

"In many cases, we will be taking a team approach to inspections, and we will be collaborating and sharing information with our regulatory partners," he says.

He points out that the agency is working to focus its assignments based on information referenced in an application or information that was documented as a result of previous inspections.

"This information —as well as our collaboration with our international colleagues — advances our knowledge about firms and in many cases allows us to better target firms to inspect," Mr. Rogers says.

RAHSAAN THOMPSON
Quarles & Brady

"Manufacturers are pushing more of the responsibility for meeting GMP requirements onto their contractors and suppliers."

According to Philip Katz, co-director of the pharmaceutical and biotechnology practice group at Hogan & Hartson, the FDA's inspection guidelines and standards haven't changed; it's the agency's willingness to move forward with enforcement actions and follow-up compliance communications that has evolved.

"I get the sense the agency wants a response to the 483 in a short time and is more willing perhaps to move to a warning letter or to take other actions." (Editor's note: a 483 is the form in which FDA inspectors communicate observations from an inspection.)

DOCUMENTATION, DOCUMENTATION, AND MORE DOCUMENTATION

Because the manufacturing side of the business bears the biggest burden when it comes ensuring quality and safety, says Joe Goodman, head of solutions consultants at Sparta Systems, there is a tremendous amount of pressure to have quality data management systems in place.

"Companies are expected to track a multitude of factors, such as deviations, and what they're going to do about them, corrective and preventive actions (CAPA), the investigations, and change controls."

Ray Bouknight, director of validation and compliance at Interphase Systems, says IT systems that retain documentation, control machinery, touch the production of the drug, or maintain data that may have to be submitted to the FDA have to be validated in some way.

"Companies have to make sure that their networks and servers are properly qualified;

PHILIP KATZ
Hogan & Hartson

"The agency is now more willing to move forward with enforcement actions or follow-up compliance communications that lead to enforcement actions."

About GMP

Current good manufacturing practice regulations (cGMP) are enforced by the U.S. Food and Drug Administration; cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

Adherence to cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.

If a company is not complying with cGMP regulations, any drug it makes is considered "adulterated" under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug.

If the failure to meet cGMPs results in the distribution of a defective drug, the company may subsequently recall that product. While the FDA cannot force a company to recall a drug, companies will usually recall voluntarily or at the FDA's request. If a company refuses to recall a drug, the FDA can warn the public and could seize the drugs that are on the market.

Even if the drugs are not defective, the FDA can bring a seizure or injunction case in court to address cGMP violations. When the FDA brings a seizure case, the agency asks the court for an order that allows federal officials to take possession of adulterated drugs and destroy them. This enables the FDA to immediately prevent a company from distributing those drugs to consumers. When the FDA brings an injunction case, the FDA asks the court to order a company to stop violating cGMPs.

Both seizure and injunction cases often lead to court orders that require companies to take many steps to correct cGMP violations, such as hiring outside experts, writing new procedures, and conducting extensive training of their employees. The FDA can also bring criminal cases because of cGMP violations, seeking fines and jail time.

In August 2009, Margaret A. Hamburg, M.D., the FDA's Commissioner of Food and Drugs, announced her vision for a stronger agency, providing six initial steps designed to hone the effectiveness and timeliness of the FDA's regulatory and enforcement system.

1. Set post-inspection deadlines. The FDA will establish a clear timeline for the industry to respond to significant FDA inspection findings, generally giving no more than 15 days to respond to such findings before the agency issues a warning letter or takes other enforcement action.
2. Take responsible steps to speed the warning letter process. The FDA will streamline the warning letter process by limiting review of warning letters by the Office of Chief Counsel to those that present significant legal issues.
4. Work more closely with the FDA's regulatory partners. In some cases, such as with food safety issues, state, local, and international officials can act more quickly than the FDA.
5. Prioritize follow-up on warning letters and other enforcement actions. The FDA will work quickly to assess and follow up on corrective action taken by industry after a warning letter is issued or major product recall occurs.
6. Be prepared to take immediate action in response to public health risks. To better protect the public health, the agency is prepared to act more quickly and aggressively to deal with significant public health concerns and violations. Such actions may occur before a formal warning letter is issued.
7. Develop and implement a formal warning letter "close-out" process." If the agency can determine that a firm has fully corrected violations raised in a warning letter the agency will issue an official close-out notice and post this information on the FDA Web site.

Source: Food and Drug Administration.
For more information, visit fda.gov.

SHARON JOHNSON
Catalent

"There are increasing expectations that manufacturers have a deep understanding of their manufacturing process, the critical quality parameters, and the consequence of failure."

they maintain proper configuration control procedures; and they have documented physical and logical security, virus protection, back up archives and disaster recovery mechanisms," he says.

Mr. Goodman says a modern enterprise quality management (EQM) system is expected by regulators.

"An EQM system is no longer a luxury for pharmaceutical companies," he says. "Companies need a modern system with good trending capabilities and data transparency. They need a system that is agile and that can be deployed in scale. More and more, global organizations not only have to manage their internal organizations but their vendors and contract manufacturers, so they need a flexible EQM system."

Top Findings from Inspections

Food and Drug Administration officials say the top observations from manufacturing inspections include:

- 21 CFR 211.22, in which responsibilities and procedures applicable to the quality control unit are not followed.
- 21 CFR 211.100b, a failure to follow written production and process control procedures.
- 21 CFR 211.110a, a failure to establish control procedures.

Mr. Katz agrees that companies need to think carefully about their contract terms.

"Companies need to be careful when establishing contractual relationships with vendors, whether they be overseas or in the United States, both in terms of ensuring compliance and identifying who's responsible for compliance, while bearing in mind the company is ultimately responsible to the FDA," Mr. Katz says.

According to Mr. Bouknight companies should all have a quality management system that includes key elements in maintaining records and issue management.

"They should have records retention policies, document management standards, and change control procedures for records management," he says. "A good CAPA (corrective and preventive action) program is also essential for tracking issues, observations, and incidents. The software should be able to properly document issues and their resolution while capturing the proper signatures at the right time during the precess."

Mr. Goodman says the FDA expects manufacturers to have holistic, companywide processes across all manufacturing sites.

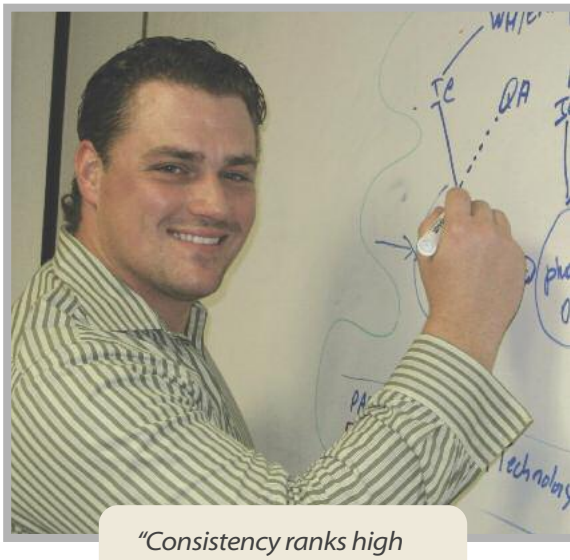
"Consistency ranks high with the FDA," he says. "Regulators want to see that the same processes are in place whether the site is in the United Kingdom or in Minnesota. Companies have to follow the same standards everywhere product is manufactured so they can label it the same way."

Mr. Katz says the FDA's focus also includes systemic issues.

"In addition to reviewing individual areas of compliance, the FDA closely looks to see if there are systemic weaknesses," he says. "If there are broader issues, the agency might devote more attention and resources to these. This approach also allows the FDA to determine whether companies have sufficient quality controls in place across their manufacturing processes."

Quality assurance is critical because it goes to the heart of cGMPs and making sure that a product is safe and meets certain standards, says Rahsaan Thompson, of counsel, at Quarles & Brady.

"The agency has a greater presence and inspectors seem to be more engaged," Mr. Thompson says. "Although they might not request an inspection, they are requesting documentation. When an inspection is warranted, the agency is very clear about what is being inspected and provide their findings in citations and/or warning letters."



JOE GOODMAN
Sparta Systems

"Consistency ranks high with the FDA. Regulators want to see the same processes put in place to create a product with a site, whether it is located in the United Kingdom or in Minnesota."

The agency also is focusing on making sure standard operating procedures are current and up to date and that pharmaceutical companies are adhering to their own policies, Mr. Thompson says.

"The FDA requires companies to have a base level of 'x' but once this has been codified, the agency wants to make sure companies are following their SOPs," he says. "Adhering to SOPs speaks to quality assurance; it speaks to the safety of a product; and it speaks to the efficacy of a product."

Sharon Johnson, senior VP of global quality and regulatory affairs at Catalent Pharma Solutions, says it's not just about following procedures but also understanding why they are important to the quality of the product.

"More than ever, manufacturers are expected to have a real deep understanding of their manufacturing process, the critical quality parameters, and the consequence of failure, as well as being able to detect failure," she says. "There is big drive around the caliber and competency of staff and their ability to really understand processes."

BEST PRACTICES IN MANUFACTURING

Ms. Johnson says companies have to be inspection-ready at all times.

"In the United States, there is a higher tendency for unannounced inspections," she says. "Companies know and recognize that it is entirely possible for the FDA to turn up at their doors without any notice. For example, since September 2009, Catalent has had six FDA inspections in the United States, and all have been either unannounced or with limited notice of inspection."

According to Ms. Johnson, Catalent uses a standard scorecard of metrics, including recalls, field alerts, the number of complaints, corrective and preventive actions, deviations, audit history, the number of regulatory observations, and so on, to measure its quality performance.

"It's important to analyze and understand the trending factors and to make sure improvements, if necessary, are happening," she says. "In the industry, there is definitely a culture of continuous improvement, and regulators actively encourage and require this mindset. There is always some process that can be improved upon to drive consistency. At Catalent, we use metrics to drive that consistency."

Mr. Goodman points to the importance of employee training in GMP and SOPs.

"Employees need to understand the business completely," he says. "They need to know all of the policies that are in place and understand how to interact during inspections. And they need to know how to prepare for inspections, which is very important."

Ms. Johnson says another best practice is to have a real partnership between the quality function and the operations and manufacturing teams.

"In the past, a fairly common observation was that organizations had operations and manufacturing teams," she says. "And then there was the 'police,' or the quality department of the organization. This kind of environment is not conducive to working together to understand and meet cGMP requirements going forward and in a smart way." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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RAHSAAN THOMPSON. Of Counsel, Quarles & Brady, which provides broad-based, national-level legal services through a network of regional practices and local offices. For more information, visit quarles.com.

BY DENISE MYSHKO

Quality
A GLOBAL ISSUE

There continues to be an increasing focus on API manufacturers and oversight of products imported into the United States.

There have been a number of safety issues in the last few years associated with manufacturing in China, says Sharon Johnson, senior VP of global quality and regulatory affairs at Catalent Pharma Solutions.

"In response, the FDA is more heavily scrutinizing product importation."

Because of the many scares, too many, in the manufacturing space, says Rahsaan Thompson, of counsel at Quarles & Brady, regulators are going a step further to assure quality and are asking companies to inspect and evaluate source material from subcontractors.

"Companies have to go further into the supply chain to evaluate and analyze any and all of the participants involved in the process of making a pharmaceutical product," he says.

Industry experts point to heparin, which was being manufactured in China. In February 2008, Baxter Healthcare temporarily stopped manufacturing multiple-dose vials of the injectable blood thinner because of reports of serious allergic reactions and hypotension. Although the FDA states that the relationship to the drug is unclear, four people died after receiving heparin.

The FDA inspected the plant in China where the drug was being manufactured and tested samples of the crude materials and finished heparin drug products. The sampled heparin API contained a contaminant — oversulfated chondroitin sulfate — that mimicked heparin activity so closely that it was not recognized by routine testing.

In October 2009, the agency began requiring a new testing method to determine the potency of certain types of heparin and to detect impurities.

In addition, the U.S. Pharmacopeia (USP), a nonprofit standards-setting organization, adopted new manufacturing controls for heparin. These changes include a modification of the reference standard for the drug's unit dose. Four companies market heparin in the United States. APP, the largest manufacturer, markets heparin in vials; Hospira markets heparin in intravenous bags, vials, and syringes; Baxter markets heparin in intravenous bags; and B. Braun markets heparin in intravenous bags.

In addition to China, U.S. regulators are looking more closely and inspecting more sites. In October 2008, the FDA announced it would send staff to India, Europe, and Latin America. FDA officials say an expanded overseas presence allows for greater access and greater engagement with foreign industry and regulators.

In November 2008, the FDA officially opened its China Office, with locations in Beijing, Shanghai, and Guangzhou. FDA specialists at the China posts include senior technical experts in foods, medicines, and medical devices, along with inspectors. The goals of this office include working in concert with the regulatory authorities in China to strengthen the capacity of the regulatory bodies, increase FDA inspections, and help the Chinese pharmaceutical industry understand FDA standards and expectations.

The FDA's staff members in India are located in offices in New Delhi and Mumbai. The first FDA employee to the India Office arrived in December 2008. The India Office includes senior technical experts covering medicines, foods, and medical devices. When fully staffed, the FDA will have 12 staff members in India — seven in New Delhi, and five in Mumbai.

RAHSAAN THOMPSON
Quarles & Brady

"Regulators are going a step further to assure quality and are asking companies to inspect and evaluate source material from subcontractors."

In Latin America, the first FDA staff members arrived at the U.S. Embassy in San Jose, Costa Rica, in April 2009. There is also an FDA office in Santiago, Chile. Another office in Mexico City was scheduled to open by year-end 2009. The Latin American Office is responsible for the FDA's interactions with Mexico and the countries of Central America, South America, and the Caribbean.

And in Europe, the FDA first arrived at its office in Brussels, in May 2009. Other FDA staff members are located at the European Medicines Agency (EMEA) in London, with plans for an FDA employee to join the European Food Safety Agency (EFSA) in Parma, Italy, in 2010. A staff person from EMEA is expected to join the FDA in Rockville, Md. The counterpart liaison official from EFSA has already joined the FDA. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

The top observations from manufacturing inspections from 2000 through Nov. 29, 2009.

NUMBER OF TIMES CITED	FED. CODE REFERENCE	INSPECTION DESCRIPTION
1020	21 CFR 211.22(d)	The responsibilities and procedures applicable to the quality control unit are not [in writing].
777	21 CFR 211.100(b)	Written production and process control procedures are not [followed in the execution of production and process control functions] [documented at the time of performance].
688	21 CFR 211.110(a)	Control procedures are not established which [monitor the output] [validate the performance] of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.
632	21 CFR 211.160(b)	Laboratory controls do not include the establishment of scientifically sound and appropriate [specifications] [standards] [sampling plans] [test procedures] designed to assure that [components] [drug product containers] [closures] [in-process materials] [labeling] [drug products] conform to appropriate standards of identity, strength, quality, and purity.
588	21 CFR 211.100(a)	There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.
579	21 CFR 211.192	There is a failure to thoroughly review [any unexplained discrepancy] [the failure of a batch or any of its components to meet any of its specifications] whether or not the batch has been already distributed.
520	21 CFR 211.165(a)	Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the [final specifications] [identity and strength of each active ingredient] prior to release.
512	21 CFR 211.188	Batch production and control records [are not prepared for each batch of drug product produced] [do not include complete information relating to the production and control of each batch].
504	21 CFR 211.25(a)	Employees are not given training in [the particular operations they perform as part of their function] [current good manufacturing practices] [written procedures required by current good manufacturing practice regulations].
454	21 CFR 211.67(b)	Written procedures are not [established] [followed] for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product.

Source: Food and Drug Administration. For more information, visit fda.gov.

BY DENISE MYSHKO

Genzyme Corp. RESPONDS

In an open letter to Genzyme shareholders, Henri A. Termeer, CEO, and Robert J. Carpenter, Lead Independent Director, issued a letter in mid-December to address the company's manufacturing issues in 2009. *(Editor's note: Excerpts taken directly from Genzyme's Website.)*

As 2009 comes to a close and we look ahead to 2010, we want to provide you with an update on the current status and future direction of the company. This year has been the most challenging one in our 28-year history due to setbacks in our manufacturing operations. From these challenges came opportunities to learn and to engage with our key constituencies — our patients and physicians, our shareholders, and employees. We have learned some important lessons and are acting decisively to improve our manufacturing, quality, and regulatory operations. Importantly, we are aggressively taking a proactive approach to risk management.

Genzyme has made meaningful progress this year in making organizational changes and operational improvements and significantly reducing risk in our manufacturing operations. We expect to emerge a stronger company that is better prepared to deliver on our commitment to sustainable growth.

ADDRESSING MANUFACTURING OPERATIONS

We faced two challenges at our Allston Landing manufacturing facility; the first related to compliance issues and the second related to a temporary facility shutdown due to a rare virus. While these two items are independent, we realize there was increased stress placed on the plant due to the introduction of Myozyme production. We based our decision to place Myozyme in Allston on the need to immediately supply patients with this lifesaving new therapy. We intended Allston to serve as a temporary solution until completion of a new facility in Belgium, which could sufficiently supply global demand.

By placing Myozyme production in Allston, we operated with lower-than-normal Cerezyme and Fabrazyme inventory levels. Because we had a 20-year track record of successfully manufacturing biologics, we did not anticipate being affected by the rare virus. The low inventory levels were insufficient to bridge the time necessary to shutdown and sanitize the facility. This temporary interruption ultimately affected our ability to supply the market. We have now moved all Myozyme production to our Belgium facility. Allston is focusing on Cerezyme and Fabrazyme production, thereby decreasing the risk of this situation happening again.

This fall we made significant progress in resuming operations at the Allston plant and have successfully produced both Cerezyme and Fabrazyme. We resumed Cerezyme shipments in November and anticipate our first Fabrazyme shipments in late December. These are crucial developments in restoring the supply of our products and ensuring that patients have full access to treatments as soon as possible.

Our goal is to restore Allston to world-class standards and establish best practices throughout Genzyme's global manufacturing organization. This effort has the highest level of management attention. Working with a leading quality assurance advisory firm, we developed a comprehensive strategy and two-year plan that will significantly lower the probability of another setback. We are implementing the plan with a sense of urgency and are making progress every day.

COMPREHENSIVE MANUFACTURING OPERATIONS PLAN

1. **RISK MITIGATION:** After we identified the rare virus, which was previously undetectable, we developed an assay to detect it and began using this test throughout the production process. We put additional safeguards in place before re-starting the plant. We continue to evaluate other ways to further lower our manufacturing risk including treating raw materials through irradiation or UV light and developing new manufacturing processes that would avoid the need for certain raw materials. Some of these steps require FDA and other health authority approvals, and are expected to come on line beginning in 2010.
2. **CAPACITY EXPANSION:** Our plan is to have sufficient inventory on-hand to absorb any future unanticipated facility shutdowns. Genzyme began to invest in a number of new facilities during the past decade. We are completing a new cell-culture facility in Framingham that will begin to provide additional capacity for Fabrazyme and Cerezyme in 2011. We expect to begin engineering runs in early 2010 followed by process validation runs that are required for approval during the second half of the year. In our Belgium facility, we are adding another 4000L reactor for Myozyme that is expected to be on line in mid-2011. We are actively evaluating additional sources of existing capacity for Myozyme to support its future potential. Beyond bulk production, we are removing our fill/finish capabilities from the Allston facility and expanding our capabilities in our Waterford facility. We are on track to install equipment next year and expect approval in 2011. These expansion efforts collectively will increase our capacity four-fold. Importantly, there will be redundancy that supports operational

flexibility and the future growth of our products.

3. **ORGANIZATIONAL RENEWAL:** We are enhancing our quality programs through organizational changes and employee training. Last May we added senior leadership by placing direct oversight of Corporate Operations under David Meeker, M.D., Executive Vice President. We moved Sandra Poole, Senior Vice President, to lead the Allston plant as part of the large reorganization of the management team at the facility. Ms. Poole recently led Genzyme's state-of-the-art Belgium facility from construction to European approval. We also plan to make significant investments throughout 2010 within the organization.

We are actively recruiting new leaders of Corporate Operations, Quality Assurance, and Supply Chain Management who we expect will be in place in early 2010. Finally, we are systematically reviewing all Genzyme facilities to identify and implement process improvements, and are enhancing our employee training programs. Our employees at every level are motivated and focused on getting this right.

STRENGTHENING OPERATIONAL LEADERSHIP

To create the organizational capacity to deliver future growth, we are strengthening our internal structure and expertise to match our increasing size, complexity, and global reach. Early in 2009, we launched the Business Excellence Initiative (BEI) to ensure the corporation has the world-class processes and capabilities we need to be successful. We appointed Ann Merrifield, a senior executive who previously ran two of our business units, to lead BEI. Ms. Merrifield and her team have completed an in-depth organizational assessment working with a leading advisory firm. Based on this evaluation, BEI and senior management are developing and implementing actions to continuously improve the way we do business.

To provide enhanced focus on the management of day-to-day operations, we have consolidated oversight for most of Genzyme's commercial and manufacturing operations under three executives who report to the CEO:

- David Meeker, M.D., Executive Vice President, is overseeing the Genetic Diseases and Biosurgery business units, as well as Corporate Manufacturing Operations.
- John Butler, Senior Vice President, is overseeing the Cardiometabolic & Renal business unit.
- Mark Enyedy, Senior Vice President, is overseeing the Transplant, Hematologic Oncology, and Genetic Testing business units along with the alemtuzumab development program.

We have brought in new senior managers to the Biomedical & Regulatory Affairs organization to strengthen support for our marketed products and the development of new products within the pipeline.

- Pamela Williamson has assumed the role of Senior Vice President and Global Head of Regulatory Affairs and Corporate Quality Compliance. Prior to joining Genzyme, Ms. Williamson was Vice President of Regulatory Affairs and Quality Assurance for Serono Inc. where she was responsible for development of U.S. regulatory strategy, registration of drugs and biologics and post-marketing support for the therapeutic areas of Reproductive Health, Metabolic Endocrinology, Neurology, and Oncology.
- Ulrich Goldmann, M.D., joined Genzyme as Senior Vice President of Global Medical Affairs, responsible for leading the Medical Affairs function across all businesses and affiliates. Dr. Goldmann was previously Vice President and Global Head of Medical Affairs with Novartis Pharmaceuticals where his responsibilities covered Global Health Economics/Outcomes Research, Global Scientific Operations, Strategic Medical Planning and Global Medical Information & Communications.
- Andrew Lee joined Genzyme as Senior Vice President for Clinical Research, responsible for Global Clinical Operations. Mr. Lee was previously Vice President with Pfizer where he held a variety of leadership positions, including Global Head of Clinical Study and Data Management, Global Head of Clinical Study Operations, and Global Clinical Project Management and Clinical Quality Management.
- Michael Panzara, M.D., M.P.H., joined Genzyme as Therapeutic Area Head and Group Vice President for Multiple Sclerosis and Immune Diseases, responsible for the clinical development of alemtuzumab. Dr. Panzara was previously Chief Medical Officer for Neurology with Biogen Idec where he was responsible for development of late-stage neurology products, including pegylated interferon, Tysabri, and BG-12.

Finally, the Board of Directors recently appointed a new member, Robert Bertolini, who was Executive Vice President and Chief Financial Officer at Schering-Plough Corp. until its recent merger with Merck & Co. Mr. Bertolini joined Schering-Plough during a time when it was facing challenges across several areas. He was part of the team that turned the company around and drove strategic decisions that more than doubled its adjusted net sales from $8.6 billion in 2004 to $20.8 billion in 2008.

Editor's Note: To read the entire Genzyme communication, please go to: http://www.genzyme.com/corp/investors/GENZ_Shareholder_Letter_121009.pdf. ✦

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