BY KIM RIBBINK

GMP A Change

After a quarter century of piecemeal updates to deal with manufacturing inspections, the Food and Drug Administration has launched a major effort to revamp its regulation of good manufacturing practices (GMP).

The goal of the FDA's two-year initiative, Pharmaceutical cGMPS for the 21st Century — A Risk-Based Approach, which the agency launched in August 2002, is to find opportunities for improving pharmaceutical manufacturing, both in terms of efficiency and safety.

"By relying on some new techniques, management techniques, and new medical technologies, new production technologies have been developed in recent years," FDA Commissioner Mark B. McClellan, M.D., Ph.D., said during a recent teleconference. "We have a set of ambitious objectives for this ongoing initiative."

In early September, the FDA released its one-year progress report and implementation plan. Among the agency's objectives are to:

- Encourage the early adoption of new technological advances by the pharmaceutical industry
- Facilitate industry application of modern quality-management techniques, including implementation of quality systems approaches, to all aspects of pharmaceutical production and quality assurance
- Encourage implementation of risk-based approaches that focus both industry and agency attention on critical areas
- Ensure that regulatory review and inspection policies are based on state-of-the-art pharmaceutical science
- Enhance the consistency and coordination of the FDA's drug quality regulatory programs, in part, by integrating enhanced quality systems approaches into the agency's business processes and regulatory policies concerning review and inspection activities

To achieve these objectives, the FDA has established 16 multidisciplinary working groups from many of the FDA's product centers under the direction of a cGMP steering committee coordinated by Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research. The working groups have completed five guidance documents. The first is a new final guidance for industry on the use of electronic records and signatures, which clarifies the scope and application of the Part 11 regulation and provides for enforcement discretion in certain areas.

The second is a draft guidance, entitled Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP, for resolving disputes arising over scientific and technical issues related to GMP to make that resolution process work more effectively.

in FDA thinking

The Food and Drug Administration is embarking on a bold, innovative, and positive initiative to improve the regulation of pharmaceutical manufacturing.

Now, the onus is on the industry to re-engineer its approach to take advantage of this new vision of good manufacturing practices.

Marie McDonald

Companies might be asking if they can take a less thorough approach and yet still satisfy the requirements, or how much is enough, or what they need to do to demonstrate a system or process is compliant.

By Jan. 1, 2004, the agency intends to initiate a 12-month domestic pilot program consistent with the guidance document. The publication of the final guidance is targeted for January 2005.

The third document is a draft guidance on aseptic processes used in the manufacturing of sterile drugs. The draft guidance emphasizes current science and risk-based approaches. The goal is to ensure that operational and raw material inputs are predictable through adequate quality control and quality assurance, as well as reliable and robust product protection through adequate design and control.

The fourth document is a draft on the preparation and use of comparability protocols for accessing chemistry, manufacturing, and control changes to protein drug products and biological products. The guidance describes recommendations for preparing and using predefined change evaluation plans, generally referred to as comparability protocols, to implement postapproval manufacturing changes. Once finalized, the guidance will apply to protein-based human and veterinary drug products and biological products.

The last document is a draft guidance for process analytical technology, or PAT. This is a framework to encourage the voluntary development and implementation of innovative pharmaceutical manufacturing and quality-assurance technologies and to allow for regulatory processes to more readily adapt state-of-the-art technological advances and drug-development production and quality assurance.

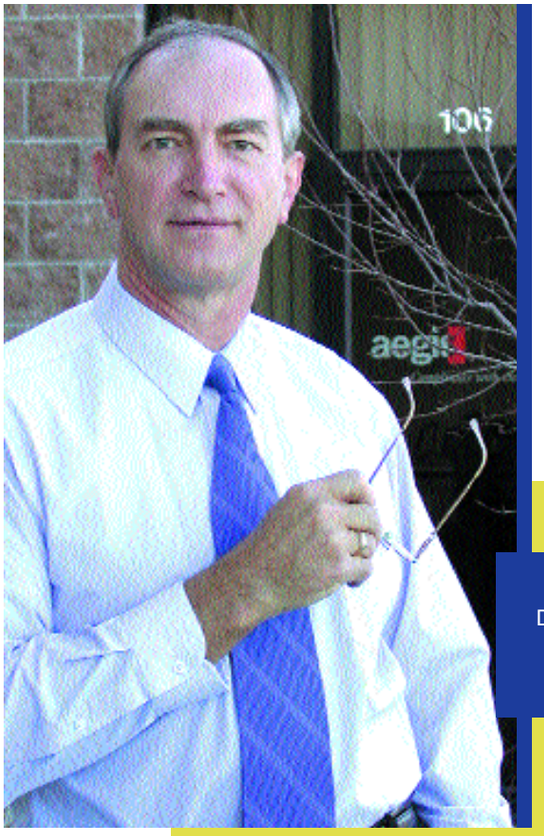
"This is important for the manufacturing concept of continuous quality improvement," Dr. McClellan says. "As many other high-precision manufacturing industries, like the semiconductor industry, have learned over the years there are steps that those involved in manufacturing on the line can take every day to further improve efficiency and reduce errors and defects in product. And our PAT approach is intended to facilitate the best versions of those efforts."

For the pharmaceutical industry, the initiative offers an opportunity to change its approach to manufacturing, according to Noel Heredia, VP of operations at InfoPro Solutions.

"These new cGMP initiatives provide an opportunity for companies to become leaner and meaner and be better prepared for the 21st century," he says. "Companies need to embark on a major business process re-engineering exercise and take advantage of the new vision of what constitutes good manufacturing practices."

Impetus for change

The cGMP initiative is, say experts in the



Dr. Justin Neway

FDA officials believed their mission for maintaining public safety might be slipping through their fingers because there was an increasing number of recalls, and enforcement actions in general were going up.

field, part of the commissioner's efforts to reorganize the FDA. The agency was forced to rethink its approach to manufacturing inspections, especially in light of budgetary constraints and being without a commissioner for almost two years. Dr. McClellan came on board amid political pressure from Congress to work more efficiently and to help reduce the cost of pharmaceuticals.

"The FDA realized it was going to have to institute a policy where it could do more with less," says Paula Wilkerson, director of regulatory affairs at Applied Genetic Technologies Corp., and a former FDA inspector. "The new cGMPs place far more responsibility on the industry to have all its systems in place. The medical-device industry already has gone this way with the 1997 Quality System Regulation. The regulation included much more stringent internal controls; companies have to state what they plan to do and demonstrate completion. The FDA also instituted a reward system for those companies that did not show up as problematic over a period of time. The new cGMPs will establish a system that rewards pharmaceutical companies that show a clean record, allowing the agency to focus on areas that could be a danger to public health."

The agency has emphasized efficiency as well as safety, which indicates a greater understanding of the pressures facing pharmaceutical companies with regard to the cost of bringing drugs to market.

"Drug prices have become a political issue," says Ludwig Huber, Ph.D., compliance fellow for life sciences and chemical analysis at Agilent Technologies. "The agency's selection of an economist as a commissioner suggests that it is looking at ways to support the pharmaceutical industry to develop and manufacture drugs more cost effectively." (Dr. McClellan is both a physician and an economist.)

Dr. Huber says during discussions with the industry and with other senior FDA officials, it became clear that the reason why drug manufacturing had been relatively old fashioned, and why the industry hadn't been using modern technology, was because the FDA has such high demands for complying with new processes. Companies therefore have hesitated to introduce new technology. That realization spawned the introduction of the draft document on PAT, which is designed to alleviate concerns among manufacturers that introducing new manufacturing technologies would result in a regulatory impasse.

PAT itself is not new; industry observers note that it has been around for about 25 years.

"Using PAT, companies are able to have real-time monitoring over processes," says David Barr, VP of regulatory compliance consulting at AAC Consulting Group. "A number of companies use PAT in certain regulatory processes, but there has been a real problem in filing an entire process using PAT with the FDA. Reasoning suggests that if a company has a pre-existing approval from the FDA, introducing PAT would entail a major supplement that would generate a lot of questions, without any real benefit. With PAT results, monitoring will likely go beyond the ranges of more traditional methods for product manufacturing and quality assurance. Therefore, FDA inspectors might look at those data points and decide to do an investigation, which could result in chaos. The FDA is now working to ensure that companies can upgrade their systems without having a regulatory barrier."

One major obstacle for the industry has been confusion about 21 CFR Part 11 electronic records requirements. The FDA has worked to address these concerns and has included guidance as part of the cGMP initiative.

"There were legacy systems that had existed before the Part 11 regulation that may have been functioning quite well but then all of a sudden were out of compliance," Mr. Barr says. "The regulation didn't give companies any time to come up to speed and I don't think there was anybody who truly understood the regulation outside the FDA."

Ms. Wilkerson concurs. "These were very confusing regulations, and the FDA had the industry cornered over implementation because the agency knew the rules and the industry didn't. One of the first things the new commissioner did was to revisit Part 11 and change the regulation to a far more common-sense approach. It was a good move."

James Vesper

Companies have to have a tracking mechanism to ensure that what was agreed to was not only done and was effective, but that the same measures are being implemented systematically throughout the organization.

A risk-based approach

The agency has stated that its goal with the new GMP initiative is to place the focus on the science of manufacturing. The manufacturing science working group, which was established at the launch of the initiative, has set its sights on finding new ways to use the knowledge acquired during pharmaceutical development — scale-up, optimization, and production — in making regulatory risk-based decisions. Efforts are under way to develop a broad regulatory strategy that ensures that existing application review and cGMP programs are based on sound state-of-the-art scientific and engineering knowledge.

"The FDA's main interest is that the product going out to market is safe, that impurities are within the specified level," Dr. Huber says. "As long as companies can ensure this, the FDA is interested in working with the industry to achieve this at the lowest cost possible."

The agency is developing a quantitative risk-based site-selection model for its inspection criteria. This model will be piloted for human drugs (CDER) in October 2004. The model will help the agency predict where its inspections are most likely to achieve the greatest public health impact. The model will include risk factors relating to the facility, such as compliance history, and to the type of drugs manufactured at the facility. The model also will include risk factors relating to the manufacturing processes and the level of process understanding.

To make it possible for inspectors to focus on areas of greatest risk, the agency has revised and reduced the number of inspection categories that would automatically prompt an inspection when a new drug or supplemental application is reviewed. By reducing the number of mandatory inspection categories, the Office of Regulatory Affairs (ORA) field offices have greater flexibility in determining if a preapproval inspection is warranted.

Maurice Phelan

When everyone gets their arms wrapped around the messages they're hearing from the FDA there will be a vast improvement in the philosophies of manufacturing sciences. In the future, companies will be eager to evaluate technologies that will accelerate development and approval and make their manufacturing processes operationally profitable and efficient.

Dr. Ludwig Huber

The FDA is interested in getting drug-development reports from the industry because it is in a much better position to assess risk to patients if it has information about various development steps.

Under the changes, regular inspections will be carried out in nine specific categories, including new molecular entities, priority new drug applications, and for companies that have not been inspected in the past two years.

"The agency has stated that it didn't make sense to spend resources on areas where there aren't problems; those are the low-risk areas," says Justin Neway, Ph.D., Aegis Analytical Corp.'s executive VP and chief science officer. "The highest risk areas are sites that manufacture sterile products and those that haven't been inspected before."

From an industry perspective, the risk-based approach means companies will be able to place emphasis and resources where they are most needed.

"Putting resources against the points of greatest risk will allow us to address the processes that are less well understood and that we're less able to control," says Norman Winskill, Ph.D., VP and team leader of Global Manufacturing Services at Pfizer.

A cooperative approach

Beyond its guidance documents, the agency also is seeking to uncover and encourage innovative approaches to drug manufacturing and regulation by entering into collaborations with companies and academic institutions.

The goal is to foster a more cooperative relationship with industry as a whole. Over the years, lack of consistency in how regulations were enforced left a bad taste in the mouths of industry executives.

"It wasn't so much the way the regulations were written or the philosophy behind them, but the unevenness of enforcement that caused problems for industry," Dr. Neway says. "Getting an inspector who might not be fully up to speed in a specific area can lead to horrendous consequences for companies, both in terms of cost and lost opportunity to get products to market in a timely fashion."

To address this, the agency is establishing a pharmaceutical inspectorate. This will comprise a staff of highly trained individuals within the ORA, who will devote most of their time to conducting human-drug quality inspections of prescription drug manufacturing and other complex or high-risk pharmaceutical operations. The pharmaceutical inspectorate also will conduct preapproval inspections and may conduct or assist in investigations that require their expertise.

Ms. Wilkerson notes that this step stems from a lack of consistency in the quality of reviewers across the country as well as a massive shift in workload to food and border inspections in the wake of September 11.

"Many investigators who had been assigned to drugs, devices, and so on, were automatically assigned to do two weeks in the office and two weeks in the field to accommodate the border inspections," she says. "Until the agency was able to hire new people, the inspection system just shut down. Eventually the FDA was able to hire new people but only under the Food Safety Act, which assigned them directly to foods and imports. That did release the burden on the experienced investigators and they were allowed to go back to doing inspections."

Even before September 11, uniformity of inspection had been an issue. While there were certification programs in place to make inspectors specialists, these programs weren't consistent across district offices, Ms. Wilkerson explains.

"There have been various programs to try to raise expertise in the field and to focus on the greatest risk areas," she says. "The current commissioner is trying to identify programs that have worked and move these along across the country."

Beyond that, the dispute resolution initiative will, when it is finalized, seek to encourage open, prompt discussion of challenges and lead to their resolution. Industry observers say the efforts to overcome disagreements between companies and inspectors early in the process are noble, but warn that it will take time to find out how well the resolution works.

"There are a lot of broken relationships and broken goodwill between the industry and FDA," Dr. Neway notes.

But the consensus is that this is an unprecedented opportunity for collaboration and discussion.

"Ideally, the agency would like to move from an organization that's able to fine and penalize noncompliance to one that is working in parallel with the brain trust of biopharmaceutical manufacturing to put in place technologies and manufacturing practices that are overdue," says Maurice Phelan, director of pharmaceutical technology at Millipore Corp.

Many of the guidelines are in draft form and the agency is actively seeking industry input before finalizing those documents.

"The FDA is welcoming feedback to finalize the guidelines and industry needs to step up to the plate and play a role, not step back and wait for the final guidelines," Dr. Winskill says.

In addition, the FDA will work to improve international collaboration to bring a standardized approach to GMP through overseas workshops, which are set to begin later this year and into next year.

"This is a truly global market, and these steps to harmonize regulations around the best and latest science are an important way to reduce the cost of worldwide pharmaceutical

David Barr

The FDA initiative has been three or four years in development. The fact that it is risk-based is serendipitous. What the FDA is thinking about in developing these documents is: what is the risk to the patient?

Paul McKim

For decades the pharmaceutical industry hasn't had the incentive to invest dollars in revamping manufacturing facilities. Now there is an unprecedented opportunity for companies to do that.

manufacturing, which in turn can improve access to needed medications while still promoting safety," Dr. McClellan says.

James Vesper, president of LearningPlus Inc., says there is a growing perception that the FDA is becoming more internationally isolated.

"Other regulatory agencies, such as those in Canada and the United Kingdom, have been using risk assessment as part of their inspection process for years, categorizing observations as critical, major, or minor," he says. "In addition, Q7A, the international GMP requirements for Active Pharmaceutical Ingredients, written by the ICH, an international group of regulatory and industry experts, including the FDA, has been very well received. That document was produced using a very different method — collaboration and consensus — from the one the the FDA has ever used."

From theory to practice

The processes and technologies a company puts in place will vary from one facility to another, depending on what is most effective and efficient for manufacturing the product. But the bottom line is to have in place a process that is safe, efficient, controlled, and well-documented. Companies need to have good standard operating procedures, good processes to develop documentation in a compliant way, and good records that are required by regulations and readily available when the inspector comes in. In addition, companies should have corrective and prevention action plans documented.

"Companies need to make sure they have systems in place to monitor parts of the processes that are prone to failure, and that when failures occur, they do a thorough investigation," Mr. Barr says. "They need good documentation, not just of what they found wrong, but what they've looked at to eliminate other potential problems. They need to have documentation that they've considered corrective actions, put in place appropriate corrective actions, and are monitoring the corrective steps."

In her position as director of regulatory affairs at Applied Genetic Technologies, Ms. Wilkerson works with scientists to ensure that all the requirements are in place.

"I give our scientists outlines on what is required for the technical reports," she says. "I request SOPs, I give them the basic training on how to write the technical documents, and then I oversee the entire regulatory process."

Experts in the field note that in the past the majority of deviations have been because SOPs are either not in place or have not been followed. This shortcoming is attributed to a training issue.

"Before the FDA initiative, I put together a report on problems related to SOP compliance," says Marie McDonald, a senior consultant at Clarkston Consulting. "It occurred to me if training was enhanced and staff had the opportunity to understand how procedures originated, why compliance in any particular area was being documented in a particular way, and had a chance to talk through it during their training sessions, then they might be inclined to be more compliant."

Paul McKim, senior director of business development at KMI, points out that taking advantage of the FDA's encouragement to implement new technologies to improve the manufacturing process will help companies reduce their costs and, in the long run, enable them to invest those savings in development and discovery to bolster pipelines.

"According to published reports, companies spend upward of 35% of the cost of sales in manufacturing, and, because of inherent inefficiencies in the process, between 5% and 10% of manufactured products have to be reworked or discarded," Mr. McKim says. "If the industry could trim its spending, millions of dollars could be shifted into discovery. The FDA is looking at how it interacts with industry to remove some of the roadblocks that have prevented companies from implementing new technologies so that they can improve their manufacturing processes and also expedite the review and cycle times for new market applications that are filed."

Most advantageous for companies will be changes in their approaches to business processes.

"The most cost-effective way of improving compliance is for companies to re-engineer their business processes around IT solutions," Mr. Heredia says. "This provides companies with an opportunity to invest in upgrading their manufacturing facilities and processes to bring those up to more contemporary levels."

A cost- and time-cutting opportunity for industry would be the introduction of a real-time release in the production process. For example, if a company has been making a drug, such as an uncomplicated tablet or a capsule with a small molecule and some excipient, for a long time it knows the parameters and has evidence and can demonstrate which parameters singly and in combination drive the outcome. It has a track record of success with a very high probability of when those parameters are met.

"Therefore the company has a releasable batch that it can put into the supply chain without having to wait for all the results of the assays of the final product," Dr. Neway says. "This is an economic incentive. If a company can put product straight into the supply chain without having it hang around in a warehouse for two weeks while the labs work on it, that would enable a company to reduce costs."

The area of disposable manufacturing is an area of great interest for companies involved in the production of biopharmaceuticals. Millipore offers its customers single-use bioprocessing solutions instead of traditional stainless steel, which is extremely labor, validation, and capital-intensive to transfer and store products.

"These are made of high-tech plastic polymers," Mr. Phelan says. "That's a huge leap forward for users and manufacturers. Getting into a routine of using these one-time containers allows ease-of-use convenience and lets customers do what they're supposed to be doing,

Dr. Norman Winskill

The update by the FDA on the new GMPs is going in the right direction toward better application of science and a better assessment of risk, rather than just a checkbox approach to see whether someone follows procedure.

PFIZER AND THE FDA — A COOPERATIVE EFFORT

THE FDA AND PFIZER HAVE ENTERED INTO A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA) TO RESEARCH CHEMICAL IMAGING APPLICATIONS IN PHARMACEUTICAL MANUFACTURING AND QUALITY ASSURANCE. Chemical imaging can now be applied to process monitoring and control. Such modern chemical-imaging tools can offer novel, efficient approaches to ensuring pharmaceutical quality.

"Our chemical-imaging research is based on a relatively new technique that we think is potentially superior to traditional methods of testing solid oral-dosage forms, such as tablets and capsules," says Norman Winskill, Ph.D., VP and team leader of Global Manufacturing Services at Pfizer. "Solid oral-dosage form performance is usually influenced by the interaction of different components in the solid — the active ingredient, the excipient, and the lubricant. Traditional testing methods, such as HPLC, would destroy that interaction by dissolving the tablet or the blend in a solution.

"Chemical imaging will enable manufacturers to evaluate the various interactions of the different components in the solid and potentially use that to be a better predictor of bioavailability and therefore true performance."

Dr. Winskill says the agreement with the FDA will last two years, after which the goal is to have the research published and provide guidelines that others can then implement. The company will continue to work on the project beyond the two-year period.

"Pfizer and the FDA will jointly publish the results of this work, which will be made available freely to the rest of the industry to use or not as it sees fit," he says. "This collaboration is just one part of the broader FDA initiative. The goal is to help raise the level of science and help raise the level of process understanding to be applied toward the broader initiative."

which is making products, developing and producing therapeutics for the marketplace versus having to figure out how to validate and sterilize stainless-steel tanks for reuse."

As a leader in GMP standards, Pfizer has implemented a number of strategies to improve its manufacturing process.

"Probably the most important initiative we have in the manufacturing division of Pfizer is something called Right First Time," Dr. Winskill says. "This initiative focuses on making sure that our production, testing, documentation, and investigation procedures are conducted right the first time; and at the moment they're not. We have a goal of 100% for all these processes. This is a comprehensive, global program that incorporates quality, manufacturing, process development, and engineering. The objectives are very much aligned with what the FDA has come out with in its GMP for the 21st century initiative — a focus on science, route-cause analysis, and good formulation design."

As part of the Right First Time initiative, Pfizer has been making use of PAT.

"We've had a PAT group for about 20 years, but in the past three or four years we've more than quadrupled the size of the group because of the success these individuals are having in influencing the industry," Dr. Winskill says. "In this year's budget we increased resources another 30%. We're spending tens of millions of dollars a year to apply PAT, and as a result we have noticed a tremendous benefit in alignment of objectives, prioritizations, and acceptance of applications. Pfizer has more than 100 applications around the world already and most of those have been installed in the past two or three years."

Additionally, in the wake of several acquisitions, Pfizer has taken steps to update and globalize its internal quality systems.

"Because we've gone through that exercise, we think we have a pretty good set of updated internal quality systems in place, or are writing them as we speak, and rolling them out," Dr. Winskill says. "We need to train people in those new systems as we implement them."

Elsewhere, several companies are using a quality-system approach that includes 8 to 25 different quality-system elements, such as documentation of records or validation, Mr. Vesper says.

"These system elements are defined in policies that describe minimum requirements," he explains. "Local sites and business units can then develop detailed, specific procedures that are consistent with policies. The beauty of this approach is that people see how the system is connected, for example how change control connects to validation, which connects to documents and records.

"Some companies also are starting to formally use tools such as corrective and preventive actions (CAPA) in their deviation investigation program," Mr. Vesper adds. "In terms of change control, companies are doing a better job in formally evaluating the potential impact that a change could have and then putting controls and monitoring systems in place to manage the change."

Push and pull

Some in the industry say companies are taking a cautious approach to the GMP initiative, waiting to assess what develops.

"Manufacturers are conducting process optimization surveys, and they're looking at how they can update manufacturing facilities," Mr. McKim says. "Generally when a company brings a new product to market it looks at what new technologies it can use, so it can build them in from the beginning. Existing manufacturing facilities are easing into the process of using new technologies, often running processes in parallel with older quality control and testing procedures for fear of interrupting production or creating delays."

Mr. Phelan says there seems to be a definite momentum swing, with far greater industry interest and enthusiasm.

"Five years ago, if a representative from the FDA was speaking at a public meeting, typically no one would ask questions," he says. "Now these meetings routinely run over and there's a line of people at the podium after the question-and-answer session to talk with FDA representatives. This is a response to the FDA's invitation to become more involved in a process of change."

Opinions differ as to which companies will

Paula Wilkerson

The technical complexity of the market has expanded, and therefore the demand on investigator expertise has extended. The FDA commissioner is trying to focus on higher risk facilities and those that have a bad track record, rather than routine investigations.

lead the drive for change. Some argue it will come from small, innovative companies that are just bringing products to market because they will be under close FDA scrutiny. Others believe big pharma is most likely to be involved in initiatives with the FDA.

Regardless, the industry will need a new outlook for its manufacturing practices and how it interacts with the agency. Mr. Vesper points out that the FDA initiative is not just focused on the GMP side of the business, but the drug approval aspect as well.

"The implication for the industry is that it will need to consistently conduct formalized risk assessment on new products and changes to existing products," he says. "Once companies and the FDA understand the risks, companies will need to take actions to manage those risks with a variety of technological and procedural controls."

Adapting to the guidelines also will require a culture change to operate successfully and get the maximum benefit that the new guidelines offer, Dr. Winskill says.

"Companies need to recognize that product quality is not tested at the end of the batch or in a laboratory; quality has to be built into the process during the formulation design," he says.

Additional pressure could come from other legislative arenas, such as the Sarbanes-Oxley Act of 2002, which seeks to improve accuracy and reliability of corporate reporting.

"If companies are confronted with manufacturing problems that could impact their bottom line and they're not reporting to the public market, then the directors and officers could be accountable," Mr. McKim says. "More importantly, directors have a fiduciary duty to make sure if there are manufacturing problems they know about them and the company is taking appropriate corrective action."◆

Noel Heredia

The emphasis has shifted from the philosophy of GMP to the reality of practice that revolves around risks.

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

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