Perspectives: FDA and Innovation, Part I

Some might point to FDA as an obstacle to achieving true device innovation to provide enhanced healthcare. Others view the agency as a necessary element to help ensure patient safety and provide regulated oversight. In this month's Perspectives feature, industry leaders shared their viewpoint explaining which side of the debate they fell and why.

Are current FDA regulations inhibiting medical device innovation or requiring companies to work more effectively within the established parameters? Would FDA/regulation reform aid the situation?

Brian Stein
CEO, SYSPRO USA

Every manufacturer in the United States is subject to a multitude of governmental rules and regulations. No industries, however, are as fully regulated as those dealing with food, pharmaceuticals, and medical devices. The U.S. FDA requires companies in these segments to comply with standards for quality, safety, effectiveness, identity, and strength. The FDA regulations inhibit medical device innovation only to the extent that most medical device manufacturers today employ costly, stringent procedures; maintain in-depth documentation; and generate a myriad of substantiating reports to show FDA compliance. By employing the appropriate computer software, medical device manufacturers can satisfy FDA requirements and free up more resources to the design and manufacture of medical devices.

Medical device manufacturers are similar to other manufacturers that have long embraced ERP (Enterprise Resource Planning) and CRM (Customer Relationship

Management) software systems. However, they have primarily employed them to achieve operational efficiencies as well as further sales and marketing objectives. Indeed, today's sophisticated ERP and CRM systems support a broad set of activities that help manage and coordinate business functions, including production planning, purchasing, inventory control, supplier interaction, order tracking, and customer service. However, many medical device manufacturers have also discovered that their choice of ERP and CRM software can play a significant role in their abilities to comply with strict FDA regulations at minimal costs.

However, there's a cautionary note. While most ERP solutions facilitate controls through the real-time integration of accounting, manufacturing, and distribution functionalities, the challenge is to find a software solution that also integrates CRM in real-time. The integration of ERP and CRM enables medical device manufacturers to have single-point of contact for visibility into the most current customer-related data, providing quick and easy access to the information needed to make decisions that impact quality and security.

In addition to enhanced operational efficiencies and insight, a well thought-out software choice can facilitate adherence to FDA regulations, producing the necessary backup reports and freeing resources to apply to product development.

Kevin Quinley
CPCU, Vice President, Council on Litigation Management

Despite the frictional cost of time and money needed to run the FDA gauntlet, FDA regulation fosters *responsible* medical device innovation. The existing regulatory scheme matches the level of regulation to the type of device under consideration. For example, devices with enhancements that are nonetheless substantially equivalent to products already on the market can take the streamlined 510(k) path.

Without FDA regulation or with less FDA regulation, there would likely be a drop in responsible device innovation. FDA regulation is one safeguard of public health to

balance the aim of innovation with patient safety. Without such a tempering force, sales and marketing imperatives might drive the innovation needle into the "red zone" of shortcutting patient safety factors, pushing the proverbial envelope into perilous turf.

In light of the recent Supreme Court decision in Riegel v. Medtronic, upholding Federal preemption as a legal defense in certain types of medical device product liability claims, there is a perception in some quarters that mere FDA approval is an inadequate safeguard of responsible, safety-focused innovation. Much is made of strapped budgets and staff at the FDA compromising its ability to discharge its mission. This adds fuel to those who will seek legislation to reverse the Riegel decision and boost consumer and trial lawyer groups who claim that lawsuits are the only effective way to safeguard public safety in light of a toothless FDA.

Thus, strengthened FDA regulation in the form of added staff, increased budget, heightened rigor, inspection of foreign manufacturing facilities, etc. may blunt such legislative and lawsuit-driven "reforms," thus encouraging responsible product innovation in medical devices. Creativity balanced with patient safety factors is the aim and FDA regulation helps provide a healthy medium between those twin goals.

Luis J. Maseda
Senior Director of Product Development, NP Medical

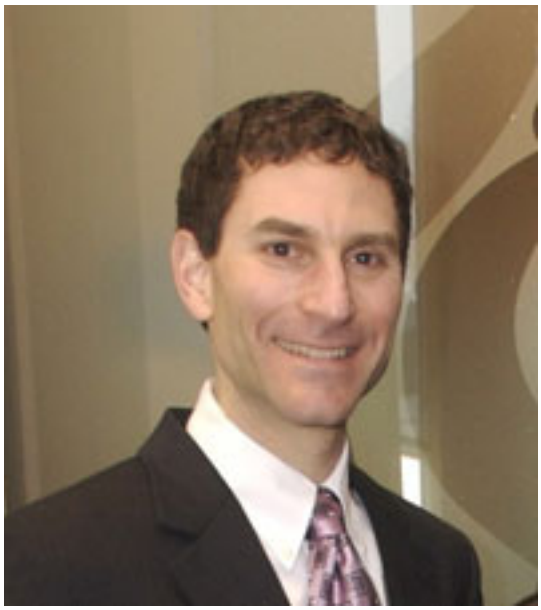
Companies pointing to FDA regulations as the source of their innovation troubles need look no further than the mirror to understand where their problems start and stop. If we define innovation as the process by which an invention is developed into a commercial product, then FDA regulations encourage innovation since they facilitate this process and level the playing field for companies of all sizes. The Quality System Regulations (QSR) codifies a generic product development process (PDP) and management oversight structure that is sufficient to ensure medical device developers are going through all the right steps and worrying about all the right things. The QSR also gives our industry a common language that facilitates collaboration and information exchange-cornerstones of innovation.

Taken this way, the QSR should be viewed as a valuable set of instructions and guidance documents that are freely provided by FDA to ensure the success of any would-be developer. With this resource in hand, developers can dedicate their bandwidth to being creative rather than trying to figure out the perfunctory steps necessary to develop a device. The regulations unfairly get a bad rap when people prematurely push inventions into a PDP which leads to a tremendous amount of wasted resources, time delays, and team frustration. This pain is quickly attributed to the regulations when "insisting on inventing when it is time to develop" is clearly an industry issue.

Another reason FDA gets a bad rap is due to the market clearance/approval process that exists because we, the industry, make mistakes and don't always do as we should. The value of economic rents available to companies post approval/clearance far outweighs the required investment; if this is not the case for a product, it is difficult to blame FDA for that too. We medical device developers would do best to focus on challenging each other to do better within the rules of our game than to continue blaming those entrusted to make sure we don't lose sight of what we are all supposed to be doing in one way or another-improving patient lives.

David Rubin
Director, Vertical Market Strategy, Medical Devices, PTC
I do not feel that FDA regulations are inhibiting medical device innovation. Our products were developed with all verticals in mind-automotive, aerospace and defense, high tech and electronics, and industrial, as well as life science and medical device. Interestingly, our highest revenue generating PLM product-the standard Windchill platform-facilitates compliance with 21 CFR Part 11, not to address the needs of medical device manufactures, but to promote best practices. Features such as audit tracking, dual authentication, noting the name of the signer, the date the signature was executed, and the meaning associated with the

signature are desirable regardless of the industry.



Similarly, many aspects of Design Controls required by 21 CFR Part 820 are followed in other verticals. For example, Design Inputs are universally referred to as Requirements Capture & Management. The aerospace industry practices FRACAS (Failure Reporting and Corrective Action System) and the automotive industry requires APQP (Advanced Product Quality Planning).

We have direct experience working with the world's leading device manufacturers. These companies are highly innovative while adhering to FDA regulations. Companies that find it challenging to innovate should review their business processes and seek means of optimizing performance through changes in people, processes, or technology.

Jerry Palecki
Director, Regulatory and Quality, Summa Design

The premise that FDA regulations inhibit medical device innovation does not hold up in the real world. FDA regulations are enacted and enforced to provide a framework for pre-market review and approval of medical devices to ensure that they are safe and effective for their intended use and, ultimately, to protect the public health.

The challenge is for medical device companies to understand how to work within the FDA regulatory framework and create an environment that best fits its business model and accomplishes its goals. This is achieved by effective collaboration between the various company departmentsmanagement, engineering, manufacturing, sales/marketing, quality, regulatory, and clinicalto guide an output that can demonstrate to FDA final fitness for approval and use.

There is always room for improvement in any process. However, medical device companies can work within the FDA's existing regulations to develop new and innovative technologies. New medical devices may be validated as extensions of existing technologies, by comparison to similar devices, or by conducting tests and clinical trials to demonstrate device safety and effectiveness.

FDA also provides for direct communication via formal meetings and informal discussions during the early stages of device development in order to provide the company with information about how to best satisfy requirements along the regulatory pathway.

Additionally, there is opportunity for companies to participate in FDA's regulatory processes through awareness of pending medical device legislation and submission of comments during review periods.

In summary, a company that operates from a position of strength by understanding the underlying purpose of FDA regulations and organizing to ensure compliance during the device design and manufacturing processes will have no difficulty employing new technologies to make innovative medical devices that will benefit patients and provide the company with deserved rewards.

Bob Dickson
CFO, CardiacAssist Inc.

Although the overall product innovation objectives may be relatively the same, medical device companies and the FDA look at the objectives from different perspectives. The FDA's focus is biased toward the regulatory objectives of safety and efficacy, while a company also considers innovation and speed-to-market because that is their measure of success. Both parties could probably do a better job of understanding the other's perspective and work together to develop superior products. The FDA is frequently viewed as a nitpicking regulator, searching for issues to claim "gotcha" while offering little in the way of constructive comments. Companies are viewed as being too aggressive in searching for ways to beat the system for earlier approval. These views may lead to distrust and an "us vs. them" mentality.

External forces impact both parties. Companies experience pressure from management, shareholders (venture capital and angel investors), and stock analysts if the company is publicly traded. The FDA faces pressure from legislators and consumers. This environment discourages risk taking by both parties and innovation suffers. This risk can be reduced by communicating early and often for mutual understanding rather than each party playing their role of regulator and company. The FDA should be willing to hold informal discussions with company representatives early in the development process and the company should become thoroughly familiar with FDA requirements.

The time required and cost of obtaining FDA approval for a new product can be significant, which discourages innovation. Significant inflows of venture or IPO money make it easier to throw money at development to get to market quickly before competition develops. Companies should recognize that their "hurry-up offense" sometimes contributes to their problems through increased budgets and missed objectives. As a financial officer, I have seen the inflow of VC money and the heavy outflow for regulatory and development expenses. At the same time, the FDA is probably underfunded and consequently understaffed, making it difficult for the FDA to react in the approval process as quickly as companies would like. Most

seasoned industry people know the perceived game of waiting until the FDA clock is running out, the FDA then asks questions or requests data, and the clock starts over. Perhaps companies should lobby for increased funding for the FDA to enable them to become more effective rather than changing regulations.

Although the process has not been perfect, we fortunately live in a capitalistic society and rewards for innovation exist. Angel and venture capital investors continue to invest in medical device companies with the hopes of realizing significant return on their investments. Innovation responds to high financial returns since the risks are rewarded when innovative products are developed. Although the IPO market has been weak in recent months and uncertainties about healthcare reform after the presidential election has subdued the markets somewhat, the baby boomers continue to age and will need increasing medical care. Innovation is the solution to many of the ills and net/net should reduce the long term cost of healthcare, driving the need for companies and the FDA to work closer together.

Mary McNamara-Cullinane
RAC, Senior Regulatory Consultant, Medical Device Consultants Inc.

The primary objective of the FDA over the past century has been to provide safe food, drugs, cosmetics, and medical devices. Current FDA regulations are in place to provide controls against unsafe imported and U.S.-made products. The recent scare on imports from China regarding pet food, toothpaste, and toys demonstrates the need for FDA oversight on both prescription use and consumer products. However, FDA does work outside of the original intention of the medical device regulations. This can contribute to the inhibition of medical device innovation.

In the last decade, when demand at the FDA for approval of new drugs and devices increased, both the Prescription Drug User Fee Act (PDUFA) of 1992 and the FDA Modernization Act of 1997 provided the FDA with increasing levels of resources for the review of human drug and device applications. With each passing year, there is an expectation for innovation in drugs, devices, and clinical procedures. Public and FDA policies are intertwined with the innovative process at every stage which impedes progress in the FDA application process and approval. The challenge is to

determine how to address and alleviate the burden of approval for manufacturers that are the leaders in innovative and novel products in the medical device industry.

The best strategy to minimize the impact of FDA's occasional overly burdensome regulations during the premarket review process is to develop a well-crafted regulatory strategy that generates the appropriate safety and effectiveness information. In order to provide FDA with the most effective pre-market submissions, the sponsor must communicate with the reviewing branch as effectively as possible within the established parameters to identify potential roadblocks to clearance/approval for their medical device. The current pre-IDE process provides a useful tool to discuss a pre-clinical or clinical testing strategy for a novel or innovative device with FDA in advance of the submission of a premarket application.

Furthermore, the FDA acts as the sole protector of the U.S. public health standards and gatekeeper for regulated products. In addition to that role, the FDA is also increasingly involved in advancing innovation, including initiating and promoting new thinking, means, and strategies for protecting and promoting the health of the public.

The emphasis on innovation has become much more intensive and comprehensive since the exploration of new technologies and scientific findings increases exponentially each year. FDA has undergone reforms to modernize regulations more so in the last two decades then in the history of the FDA.

Advances in medical technology can save hundreds of thousands of lives and also billions of dollars in healthcare costs each year. Industry must get facts such as these to the public, to purchasers, and to the regulators. It must be pointed out to the legislators that the abrupt rise in technological advances and innovation has lead to lifesaving medical devices and cost savings to the general public. Congress should be informed that regulators need to act as partners and not roadblocks to the medical device industry in order to reap the benefits of high technology companies.

Medical device manufacturers hold some responsibility in that their scientific and self-regulatory activities during the development of their products should be well-conducted and well-controlled. Self-regulation is efficient and demonstrates good science. The medical device industry must actively participate in the legislative process to ensure that innovation and high technology are appropriately utilized as tools to help physicians and consumers make responsible choices about their treatment options. Industry initiative is required for the success of such programs.

In order for regulators and industry to provide a critical component to the public, the FDA must maintain some regulatory flexibility. FDA regulation must be flexible and not obstructive to high technology and innovation. In order to achieve the goals of ensuring the safety and efficacy of those products under its jurisdiction, legislation must not change FDA's authority nor negate the agency's ability to evaluate each innovative products unique safety and efficacy profile. There must be close communication between the FDA and industry during all stages of innovative

product development. The process works most efficiently when industry and the FDA work together from the early stages of research and development.