Postmarket Surveillance Comes to the Device Industry

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Device manufacturers have to meet new regulations that require them to have a more integrated postmarketing process for their products.

It's a new world for medical device manufacturers. Serialization, product registries, and postmarket surveillance are coming to the medical device industry. And while some companies may experience bumps in the transition to unique identifiers and more vigilant postmarketing monitoring, the overall long-term impact is expected to be positive.

On Sept. 20, 2013, the Food and Drug Administration issued the final rule for the unique device identification system (UDI) that, once implemented, will provide a consistent way to identify medical devices.

The UDI system has the potential to improve the quality of information in medical device adverse events reports, which will help the FDA and manufacturers identify product problems more quickly, better target recalls, and improve patient safety. A UDI consists of a unique code identifier that includes information specific for each device model, as well as production data (lot or batch number, the serial number and/or expiration date), and an FDA-created database that will include a standard set of identifying elements for each UDI. UDI and other product information will be stored in an FDA Global Unique Device Identification (GUDID) database. The GUDID will function in much the same way as the NDC directory does for pharmaceuticals.

Industry experts stress new regulations will be coming in the global arena as well. In fact, the European commission issued its own initial guidance in April 2013 for a common framework for a UDI system.

The FDA is also creating an automated adverse event reporting system for medical devices, and the agency is working with 20 hospitals to develop software capabilities to export real-time adverse event data with identifiers from hospital incident reporting systems.

A new system for identifying devices was needed because the NDC structure that exists today wasn't meant for medical devices; it was meant for pharmaceuticals, says Ken Koldan, business development manager, at FLEXcon.

"The construct that exists today doesn't fit medical devices," he says. "Manufacturers' catalogues have product numbers, but different manufacturers could assign the same number to different products. Hospital records assign numbers based on each product but the number is not necessarily linked to a company. Hospitals don't put in their database the company they sourced it from. We can't get the connectivity between the actual source and actual person who bought it or received beneficial treatment."

Mr. Koldan says there are four steps to establishing the UDI system. The first is to develop standardized UDIs. Then the UDI has to be put onto a human-readable AIDC label. Then the UDI needs to be submitted to GUDID. Finally, companies have to determine implementation timelines for their products.

The rule requires that Class III devices (high-risk devices such as pacemakers and heart valves) be compliant one year after the final rule is published. Class II devices (medium-risk devices) that are implants or that are life supporting) must be compliant the second year after the final rule. The remainder of Class II devices needs to be complaint in the third year. Class I devices (low-risk devices such as bandages) need to be compliant in the fifth year.

Advantages

The move toward the UDI system began in the pharma space with barcoding and with unique identifiers on dosage units a number of years ago, says Brian Bollwage, head of strategic regulatory affairs, at Theorem Clinical Research.

"From a larger viewpoint, this is an extension of that philosophy at the FDA," he says. "This is the movement at the FDA, not just on the device front. There is a similar initiative on the foods front as well. While this is new to the device industry, this theme has existed for some time in other parts of the agency."

Industry experts say regulators used the postmarketing rules on the pharmaceutical side as a guide for developing the device registry.

FAST FACT

THE GLOBAL MEDICAL DEVICE MARKET WAS VALUED AT $331 BILLION IN 2012, 3% HIGHER THAN 2011.

Source: Kalorama Information

Smart Steps for Device Companies

1: Identify new UDI requirements that are likely to apply to your organization, and appoint a UDI champion.
2: Conduct analysis of current company efforts in terms of UDI.
3: Survey customers to determine expectations for UDI.
4: Survey vendors to determine UDI capabilities.
5: Identify gaps in company's capabilities.
6: Identify a pilot project.
7: Correctly estimate costs to reach UDI compliance.
8: Prioritize and start projects to address UDI gaps.

Source: Tom Beatty, QPharma

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>
> **KIM MARTIN** / Bradley Arant Cummings

"There are device-specific nuances and different fields but the FDA has used their experience with the NDC Directory for Pharma to create a similar registry for devices," says Tom Beatty, senior principal UDI compliance at QPharma. "There will be required UDI-related and product data elements that a manufacturer will have to submit to the FDA when they are registering and submitting the device's data to GUDID. At that point the UDI should be able to be uploaded into the registry.""

The FDA's plan that has some components that will allow for streamlining of postmarket surveillance, particularly the mobile adverse event reporting system and the registry, says Kim Martin, partner and cochair of the life-sciences practice group at Bradley Arant Cummings.

"Once the new system is in place, it will help to maintain the accuracy of the product information involved," she says. "But there will still be concerns about the accuracy and how those registries tie the adverse event to the device itself, whether there is in fact a causal connection between the adverse event and the device. With the FDA trying to extract safety signals from this information, the signals that are extracted are only as reliable as the underlying information about the cause and effect of the device and the event."

Mr. Koldan says the new UDI and postmarket surveillance system will shorten device recall timelines and puts parameters around recalls.

"Regulators will be able to be more accurate and precise about the manufacturer and the time frame, as well as the specific device," he says.

Being able to manage the long-term observation of products, being able to look at the trends, and conducting recalls will ensure that innovations continue to expand, which are very important to life cycle and product management, says D. Lee Spurgin, Ph.D., senior VP and general manager, medical device and diagnostic development, Theorem Clinical Research.

"This is a positive within the industry," he says. "We are all in this for the same reason: it's about patients. It's about maintaining and helping the long-term management of people's lives. Being able to get this information and being able to manage data long term is a very positive experience."

Ms. Martin says the FDA's stated goal is to improve monitoring so that the agency will have timely information about the benefits and risks of medical devices.

"The hope is that regulators will be able to identify safety concerns or safety signals in real-time as information comes in and allow them to quickly identify these safety signals," she says. "Regulators believe it will reduce the burden and cost of the current medical device postmarket surveillance system because it will be more streamlined. The postmarketing surveillance could also help companies facilitate approval of new devices or new uses for existing devices."

Mr. Beatty says with the UDI, device companies will likely have better control of their inventory as well.

"They will know what product is in the marketplace and what is in the supply chain," Mr. Beatty says. "It will also help with product recalls, especially with products that haven't been implanted yet. They will be able to pull them back in time. In a way, device manufacturers will be closer and more accountable to the patient than ever before because they will know exactly what device was implanted on what date. Of course, it will be anonymized. They won't have direct access to the patient but they will be able to get a sense for how their products are working — and if any safety issues need to be addressed — down to the component level."

Challenges

Industry experts say the UDI system will create some challenges for device manufacturers. Experts from PwC say the implications and the costs of this rule have been understated. They say it is not just a supply chain issue but will affect multiple functions, including product development, operations, quality, and inventory.

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> **KEN KOLDAN** / FLEXcon

"The UDI system will require changes to labeling and packaging, and certain devices will have to have the identifier affixed to it," Ms. Martin says. "This will also create challenges for the manufacturing process as well."

Mr. Bollwage says the device industry in some respects has benefited from the pharmaceutical industry's experience.

"The technology and equipment to add a barcode or add a unique identifier has existed for some time, and the bugs have been worked out," he says. "If anything, I would expect the transition — as long as there isn't an inherent philosophical resistance to it — to be fairly easy."

Industry experts point to the lack of consensus about which coding organization to use and this could create some challenges for manufacturers. Historically, the medical device industry has used UPN codes from the Health Industry for Business Communication Council (HIBCC), and many supply chain and supporting systems have been built using HIBCC codes. But the perception is that this is primarily a U.S.-focused standard.

Mr. Beatty says in the last five to seven years, the code group gaining momentum is Global Standard 1 (GS1), which is an internationally focused standards body. Historically, the pharmaceutical industry has used GS1 codes. Some distributors that have an international focus and international regulators favor this standard.

"Many device companies have dramatically underestimated the expense of getting UDIs on their products in a short time," he says. "And they are just beginning to realize the expense and complex deliverables that they will have to manage in the coming few years." PV