What Does the Future Hold for Medtech? (Regulators Will Strive for Efficiency)

Posted in Medical Device Business by Jamie Hartford on July 10, 2014

FDA has recently cited increased efficiency and consistency in medical device registration reviews as key long-term operational goals. This sounds like a promising development for medtech companies participating in the U.S. market. But what will added regulatory efficiency and consistency mean in terms of tangible impacts for companies undergoing new registrations or changes to existing registrations with FDA?

Eisenhart

Three current developments at FDA suggest both short- and long-term registration and compliance issues firms will likely face as the agency pursues more efficient pre- and postmarket processes: unique device identification (UDI), the multinational Medical Device Single Audit Program (MDSAP), and electronic medical device reporting (eMDR).

UDI: Significant Compliance Requirements

FDA has begun a years-long implementation process for its UDI system based largely on UDI guidelines issued by the International Medical Device Regulators Forum (IMDRF). Nearly all medical device manufacturers registered for sale in the United States will have to comply with U.S. UDI requirements by 2020.

Developed to improve traceability of registered medical devices, postmarket surveillance, and device recall management, UDI will require manufacturers to affix device and product identification codes to their products' labeling and packaging, and submit device information to a new Global Unique Device Identification Database (GUDID) managed by FDA. Compliance deadlines begin in September 2014 for high-risk devices and extend through September 2020 for the lowest-risk devices.
Compliance will likely require substantial effort for many manufacturers in terms of obtaining UDI information for their devices from FDA-accredited issuing bodies, changing their labeling and packaging processes to incorporate UDI information, and formatting and submitting device information properly to the GUDID.

Some firms will no doubt have to deal with initial challenges as UDI rules are phased-in in the United States, but long-term compliance should prove less resource-intensive. Furthermore, a more automated nationwide device tracking system could help manufacturers respond more efficiently to FDA inquiries, adverse events and recall requirements.

eMDR: Automated Postmarket Reporting Structure

FDA has set August 13, 2015, as the compliance deadline for its electronic medical device reporting (eMDR) rule that will require manufacturers to submit information on adverse events involving their devices only via electronic formats.

Companies will have two submission format options: one for low-volume reporting and another for batch and business-to-business-style reports. (Firms will need to ensure they can interface with FDA's electronic submissions gateway to electronically file their reports ahead of the August 2015 deadline).

Efficiencies gained through electronic submission and processing of medical device reports seem obvious, and a more efficient reporting process may help companies more easily comply with FDA post-market incident reporting rules.

MDSAP: Globalized Quality System Auditing?

Finally, FDA has undertaken a pilot program, the MDSAP, alongside Australian, Brazilian, and Canadian regulators in which the four entities will accept one another's audit and inspection data for some of their respective domestic device registration and quality system requirements. FDA, for example, will accept quality system audit reports from Australian, Brazilian, or Canadian regulators in lieu of its own routine inspections for medical device registrants. This applies to Class I through Class III devices, so it will not be limited to 510(k) holders.

For manufacturers registered in the United States and at least one other country participating in the MDSAP, this potentially means having to undergo only one quality system audit rather than two—at least for the time being.

The MDSAP pilot is expected to end in 2016, but if FDA at that point decides to continue accepting quality system audit reports from its counterparts in Australia, Brazil, and Canada for medical device registrants, such a development would bode well for qualifying manufacturers. FDA Good Manufacturing Practice inspections can take up significant time and resources, so easing those requirements would enable firms to allocate more time to commercial efforts.

A Mixed Bag?

In these three examples of FDA's push for greater regulatory efficiencies, manufacturers potentially face a mixed bag of benefits and challenges. UDI compliance could initially require major overhauls of some firms' processes and procedures, whereas the MDSAP pilot program may already be sparing qualifying manufacturers the burden of FDA inspections. More efficient FDA processes do not necessarily translate into less complicated market pathways for U.S. registrants.

Stewart Eisenhart is senior regulatory analyst at Emergo Group.