FDA'S EYE ON MDR

Inadequate Medical Device Reporting (MDR) procedures are in the top five for violations identified by FDA investigators when inspecting Medical Device facilities. Poorly written procedures, insufficient information, late transmission of complete reports to FDA, incomplete documentation, poor training – all these failures show up in 483s, Warning Letters and even product recalls.

Medical Device companies have good reason to pay attention to the frequency of MDR violations throughout the industry. MDR is just one part of the Food and Drug Administration's Center for Devices and Radiological Health's (CDRH) expanding scrutiny of Medical Device post-market surveillance. Every year, the FDA receives several hundred thousand medical device reports of confirmed or possible device-related serious injuries, deaths and malfunctions. Still, FDA notes, "While MDRs are a valuable source of information, this passive surveillance system has notable limitations, including the potential submission of incomplete or inaccurate data, underreporting of events, lack of denominator (exposure) data and the lack of report timeliness."

The FDA's September 2012 report, *Strengthening Our National System for Medical Device postmarket Surveillance* left no doubt about the FDA's focus moving forward. The report proposed a strategy for improving the current system for monitoring the safety and effectiveness of medical devices in the marketplace. FDA's strategy envisions an integrated national medical device postmarket surveillance system that communicates timely and accurate information on the benefits and risks of medical devices; identifies potential safety issues in real-time; reduces the burdens and costs of medical device postmarket surveillance; and facilitates the approval of new devices.

Few Medical Device companies would argue with FDA's vision. The value of the strategy, unsurprisingly, lies in the details. In April 2013, FDA attempted to provide some of those details when it issued an update to the September 2012 report. That update describes several initiatives the FDA plans in order to advance its vision of a national postmarket surveillance system. Among the initiatives is the modernization of adverse event reporting and analysis through:

- Implementation of a mobile application for voluntary adverse event reporting;
- Piloting an initial functional release of the FDA Adverse Event Reporting System;
- Implementation of prospective "data mining" tools in at least three major device areas to enhance identification of high-quality adverse event reports and report trends and clusters;
- Identification of gaps in current methodological efforts to promote data standardization, interoperability, and linkage between registries and disparate data sources.

Those initiatives are still in the planning stage. While it's worthwhile for Medical Device companies to understand what the FDA plans for the future, it is even more important for companies to recognize the scrutiny the FDA is applying to MDR procedures in today's facilities. Inadequate MDR systems are likely to remain in the top ten of FDA's inspectional observations. Staying off the FDA's hit list depends on understanding and complying with MDR requirements consistently and thoroughly.

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UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.