



Which Of The European Regulations For Medical Devices Are Going To Be Adapted By The FDA?

The FDA is currently reviewing the 510(k) regulations. The current regulations are designed to assure the safety and effectiveness of medical devices. These regulations govern various aspects of the design, clinical evaluation (where required), manufacturing, packaging, labeling (including promotional information), commercial distribution, and post-market surveillance of medical devices. In a memo from 2009, the former (as of March 26, 2010) Director of the Office of Device Evaluation at FDA, Donna-Bea Tillman, stated there is an indication that the FDA is already clamping down on the current 510(k) process by which the majority of medical devices are approved. The Institute of Medicine (IOM) has initiated a study that will address questions including:

"Does the current 510(k) process optimally protect patients and promote innovation in support of public health?"

In 2007, the 501(k) process was used to review 3,052 devices and approved 2,640 of them. Using the more comprehensive PMA approval process which includes IDE clinical trials, only 27 applications were accepted out of the 41 novel devices submitted. However on the other side of the coin most of the products approved under the 510k process were for improvements in predicate medical device products that were already being used by the medical community.

In The European Community (EC) there is no 510(k) approval process. The regulation and approval of medical devices in the EC are covered under an umbrella of regulations called the Medical Device Directives (MDD). A new medical device directive — 2007/47/EC — was approved, clarifying and updating the current regulations. On account of these regulations, some of the key changes that the FDA will be looking at carefully are:

- Clinical data (in the form of a Clinical Evaluation Report) will be required for ALL devices, regardless of classification.
- The entire regulatory data package will need to be collated into a central database and include information on registration, vigilance reports and certificates as well as data relating to clinical investigations.
- All medical devices will be classified by their primary mode of action and not by intended use.
- Companies will be required to conduct sustained and coordinated clinical post-market surveillance of their products. Under the new directive, the surveillance rules are further tightened. The vigilance system will need to proactively monitor

how their devices are being used and are performing in the field. There will be significantly more emphasis placed on post-market clinical follow-up as part of the post-market surveillance plan. As part of the process, companies will need to have a vigilance tracking, monitoring and reporting system in place to assess and react to any unexpected changes once their products are released into the marketplace.

- The MDD continues to place substantial emphasis on quality and the need to have proactive risk management systems in place from concept to post marketing.

At the FDA there have already been recent substantial changes in the safety monitoring of drugs with the implementation of Risk Evaluation and Management Systems programs, and in food science with the new process for Reportable Food Safety and the 2009 revision of reporting adverse events for dietary supplements. In February 2010 the FDA director Margaret Hamburg told **MassDevice (8 Feb 2010 <http://www.massdevice.com>)** “The 510(k) process was developed in a different era. Devices have grown very much in terms of the complexity and in advancement, where we have an obligation to make sure we have a regulatory oversight program that really addresses the needs of the evolving technology and assure we are adequately assessing between safety and effectiveness, and what possible steps could or should be taken.”

“Striking a balance between effective regulation and promoting innovation is as important to the manufacturers as it is to consumers,” she added. “The 510(k) process needs to evolve along with the biomedical science that drives the medical device industry for both the safety of the consumer and the success of the industry.”

“I’m very, very supportive of innovation. I see that as fundamental to progress,” Hamburg said. “And an effective regulation system can help us do a better job of assuring the medical products we have are safe.”

It is likely that some of the aspects of the EC MDD, particularly those that require clinical evaluations and Postmarketing Surveillance will be harmonized. The quality management systems for manufacturing are already closely harmonized with some subtle differences.

By anticipating upcoming regulations such as these and creating effective monitoring systems during every step of the manufacturing process, device manufacturers can create a real competitive advantage.

Many medical device manufacturers would be smart to critically evaluate their quality systems as a result of the FDA’s reviews of medical device approval systems and the recent 2011 budget request for additional funds to address product safety.

The well-designed Medical Device Risk Management Plans (RMP) are intended to be used as feedback loops, with the ability to collect from consumers and users the complaints and untoward medical occurrences and use that information to improve quality management and the overall safety of the device. Improper handling of medical

device complaints is the largest source of 483's and warning letters for manufacturers. A well designed medical information collection and distribution process is critical to comply with this part of the RMP.

Medical device manufacturers would do well to assure that their medical device reporting (MDR) systems for reporting to the FDA are fully compliant and robust enough to include more vigilance requirements for post-market approvals and to be able to analyze trends to initiate the proper corrective and preventive actions.

A few medical device manufacturers have automated the process of adverse event report submission to the FDA in response to the electronic MDR mandate, a requirement that will likely become mandatory later in 2010 or 2011.

John McLane
COO & VP Clinical and Regulatory Affairs
Clinquest, Inc.