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FDA announces new staff training for medical device reviewers

Training a key step to improving device review program, strategic priorities

The U.S. Food and Drug Administration today announced two new training programs designed to improve the consistency of medical device reviews by enhancing the skills of those reviewing premarket applications at the Center for Devices and Radiological Health (CDRH).

The Reviewer Certification Program, which began as a pilot in April 2010 with participants from CDRH's Division of Anesthesia, General Hospital, and Infection Control and Dental Devices, will launch this month and is intended to include all new device reviewers.

The program includes up to 18 months of training, aimed at complementing the skills and knowledge that new reviewers bring to CDRH from fields such as biomedical engineering and health care. Reviewers in the program will complete online training modules, instructor-led courses, and obtain practical experience in the medical device review process. Courses include medical devices, food and drug law and regulatory requirements, the CDRH review process, device design, and the impact of human factors.

"We are investing resources so that new device reviewers at CDRH are equipped to handle the range of issues that arise during the premarket device reviews," said CDRH director Jeffrey Shuren, M.D. "This investment will improve the quality of submission review and make the process more consistent and predictable."

CDRH is also developing a pilot Experiential Learning Program for premarket reviewers. The program will include visits to academic institutions, manufacturers, research organizations, and health care facilities and is intended to give reviewers a better understanding of how medical devices are designed, manufactured and used. The program will also help new medical device reviewers understand the challenges of technology development and the impact of medical devices on patient care.

"Providing our review staff with opportunities to experience medical device development and use from outside the agency will provide new reviewers with a broader view of the regulatory process for medical devices," Shuren said.

The Experiential Learning Program is in the design stage and scheduled to begin as a pilot program in 2012.

Enhancing staff training is one of the 25 action items listed in the FDA's Plan of Action for Implementation of 510(k) and Science Recommendations announced earlier this year to increase the

predictability and transparency of regulatory pathways and to strengthen the 510(k) process. The 510(k) is the most common pathway to market for medical devices.

For more information:

CDRH Plan of Action for 510(k) and Science
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm

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