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International Medical
Device Regulators Forum

U.S. FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPDATE

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CDRH STRATEGIC PRIORITIES

The Center for Devices and Radiological Health (CDRH) issued its 2014 – 2015 Strategic Priorities in February 2014:

- Strengthen the Clinical Trials Enterprise;
- Strike the Right Balance between Premarket and Postmarket Data Collection; and
- Provide Excellent Customer Service.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm384132.htm>



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“REQUESTS FOR FEEDBACK ON MEDICAL DEVICE SUBMISSIONS: THE PRE-SUBMISSION PROGRAM AND MEETINGS WITH THE FOOD AND DRUG ADMINISTRATION STAFF GUIDANCE”

- Guidance issued February 18, 2014.
- Provides overview of mechanisms available to applicants through which they can request feedback from FDA regarding potential or planned IDE applications, PMAs, HDEs, de novo petitions, 510(k)s, CLIA Waiver applications and certain INDs, BLAs.
- Provides information regarding logistics for submission, receipt, tracking, and review of/response to requests for feedback.



“MEDICAL DEVICE DEVELOPMENT TOOLS DRAFT GUIDANCE”

- Draft Guidance issued November 13, 2013.
- Proposes a voluntary process for qualification of medical device development tools (MDDT) for use in device development and evaluation programs in the CDRH.
- Guidance describes the framework and process for voluntary CDRH qualification of MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, considerations for qualification, and the contents of a qualification submission.
- Application of this policy will facilitate the development and timely evaluation of innovative medical devices by providing a more efficient and predictable means for collecting the necessary information to make regulatory assessments.



REPORT TO CONGRESS ON 510(k) MODIFICATIONS

- On February 25, 2014, FDA issued a Report to Congress on its proposed 510(k) device modifications policy.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm269873.htm>

- On March 6, 2014, FDA opened a docket to collect comments. The docket (FDA-2014-N-0237) will be open for 90 days.



REPORT TO CONGRESS ON 510(K) MODIFICATIONS

Following the report's comment period, FDA will develop a new draft guidance document, based on the current guidance from 1997, with targeted revisions to address specific issues, like clarification of key terminology.

- New guidance will include new flowcharts, decision examples, and recommendations for good decision documentation.
- FDA will also look to adding device-specific modifications information to device-specific guidances where appropriate.
- FDA intends to develop a separate guidance on software modifications.



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ELECTRONIC MEDICAL DEVICE REPORTING (eMDR) FINAL RULE

- Final rule published February 13, 2014.
- Requires manufacturers and importers to submit mandatory medical device reports (MDRs) to FDA electronically, rather than in paper form.
- Electronic submission expedites report processing and reduces the burden of data entry on the FDA, manufacturers, and importers.



NATIONAL MEDICAL DEVICE POSTMARKET SURVEILLANCE SYSTEM

- In September 2012, FDA issued a strategy to establish the System.
- In April 2013, after receiving public comment, FDA proposed next steps.
- In March 2014, FDA will stand up a Planning Board for the System and a Medical Device Registry Task Force.



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THANK YOU