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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 UPDATE

**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>



**EXPEDITED ACCESS FOR PREMARKET APPROVAL MEDICAL DEVICES  
INTENDED FOR UNMET MEDICAL NEED FOR LIFE THREATENING OR  
IRREVERSIBLE DEBILITATING DISEASES OR CONDITIONS –  
FINAL GUIDANCE**

**BALANCING PREMARKET AND POSTMARKET DATA COLLECTION FOR  
DEVICES SUBJECT TO PREMARKET APPROVAL – FINAL GUIDANCE**

- FDA will finalize an expedited access program for high-risk medical devices to promote the development of innovative products that treat or diagnose U.S. patients who have serious conditions and medical needs that are unmet by current technology.
- By engaging with manufacturers earlier in the product development process and developing a plan for collecting data to support approval, the proposed program should provide patients with earlier access to innovative, safe and effective medical devices for serious conditions for which there are few or no treatments or diagnostics.
- The FDA will also issue a final guidance document on achieving the right balance between pre-market and post-market data collection – a critical step in providing timely patient access to safe and effective breakthrough devices.



## CUSTOMER SERVICE SURVEY

- On June 16, 2014 CDRH launched the CDRH Customer Service Survey:  
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm384176.htm>
- Our survey measures how we interact with our stakeholders and provides feedback on how to improve our processes.
- Between June and December 2014 we received 2,657 surveys.
- As of December, 2014 we achieved an 83% customer satisfaction rating.
- Industry gave us an 88% satisfaction rating while internally we rate ourselves at 82%.
- 64% of the surveys coming from FDA and industry equally. The other 36% comes from Healthcare Providers, Patient/Consumers, Academia and others.
- On August 5, 2014 we provided our stakeholders with a live link to our Customer Satisfaction rating which is located on our Customer Service Webpage.
- Our goal is to reach a 90% Customer Satisfaction Rating by December 2015.



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## **FDASIA HEALTH IT REPORT FDASIA SECTION 618**

Charged FDA, in consultation with ONC and FCC, to develop and post on their respective websites:

*“a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”*

Permitted the convening of external stakeholders and experts to provide input.



## **FDASIA HEALTH IT REPORT**

### **FDASIA SECTION 618**

On April 21, 2014, FDA, FCC, and ONC published the FDASIA Health IT Report on each agency's respective website after extensive stakeholder input. The strategy:

- Proposes a framework that is current yet flexible to accommodate future technology;
- Fosters the development of a culture of safety and quality;
- Leverages standards and best practices;
- Is based on the idea that for health IT functionalities, regulation should not be the first approach used.
- Since the publication of the proposed strategy, the three agencies have continued to work collaboratively and interactively on health IT-related activities to ensure an efficient, coordinated, and transparent federal approach.



## **FDASIA HEALTH IT REPORT**

### **FDASIA SECTION 618**

- In addition, FDA has fulfilled commitments made in the FDASIA Health IT Report by finalizing our guidance on *Medical Device Data Systems (MDDS)*, and we recently issued two draft guidance documents that outline our thinking about low-risk devices intended to promote general wellness, “*General Wellness: Policy for Low Risk Devices*” and our risk classification approach to medical device accessories, “*Medical Device Accessories and Classification Pathway for New Accessory Types.*”



## UNIQUE DEVICE IDENTIFICATION (UDI)

UDI Final Rule – September 24, 2013

- Establishes a system to adequately identify devices throughout distribution and use.
- Implementation phased in over 7 years, based on device risk/class.
- Actively working with class III device companies to address challenges and efficiently achieve compliance.

Guidance documents:

- Global Unique Device Identification (GUDID) – June 2014
- UDI Small Entity Compliance Guide – August 2014
- UDI Frequently Asked Questions (FAQs) – August 2014



## UNIQUE DEVICE IDENTIFICATION (UDI)

- Effective September 24, 2014, UDI labeling and GUDID data submission was required for all class III devices. Also, as of that date, the GUDID collected over 33,000 records of specific models/versions of class III medical devices from over 200 labelers. On, January 26, 2015, the FDA opened the GUDID for submission of UDI information for implantable, life-supporting, and life-sustaining devices. The FDA will enable public access to the GUDID data in Spring 2015 through a partnership with the National Library of Medicine. Future UDI labeling requirements are:
  - September 24, 2016, UDI labeling and GUDID data submission will be required of Class II devices
  - September 24, 2018, UDI labeling and GUDID data submission will be required of Class I devices



# **NATIONAL MEDICAL DEVICE POSTMARKET SURVEILLANCE SYSTEM**

- CDRH continues to take steps to establish a National Medical Device Postmarket Surveillance System that can quickly identify new safety concerns, better characterize real-world performance of medical devices, and be leveraged to reduce premarket data burdens.
- In September 2012, the FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," which proposed a strategy for improving and addressing the limitations of our current system for monitoring medical device safety and effectiveness.
- In February 2015, the multi-stakeholder Planning Board issued a report with recommendations for how to establish the surveillance system.
- In the coming months, we will also receive a report from the Medical Device Registry Task Force. It will address issues such as defining effective registry governance and data quality practices.



## LABORATORY DEVELOPED TESTS (LDTs)

- The evolution of laboratory-developed test (LDT) use, technology, marketing and business models has increased the risks associated with LDTs and has created the need for increased oversight to address risks and other concerns including: significant adverse public health consequences; a non-level playing field that stifles innovation, and stalling progress in personalized medicine, which relies on having accurate diagnostic tests to deliver the right treatment to the right patient.
- CDRH issued draft guidances that proposes a risk-based, phased-in approach for regulatory oversight of LDTs. The guidances describe the agency's enforcement policy for LDTs to address public health concerns while enabling innovation.
- CDRH is currently reviewing comments received on the draft guidances as well as information received from a recent workshop on LDTs.



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**21<sup>ST</sup> CENTURY CURES**

**HEADS UP**



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**THANK YOU**