IMDRF 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

FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and FDA Staff

- This guidance was developed to promote the initiation of clinical investigations to evaluate medical devices under FDA's IDE regulations.
- This guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasons for those decisions.

Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversible Debilitating Diseases or Conditions – Draft Guidance

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval – Draft Guidance

- FDA proposed 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.

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.
- Our customer satisfaction target for December 2014 is 70%.
- As of August 20, 2014 we have received 1,281 surveys and have achieved an 84% customer satisfaction rating.
- 40% of our Surveys are submitted by industry and 45% from FDA.
- 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.
- As of August 18, 2014 we have trained 50% of our staff.

DRAFT GUIDANCE
DE NOVO CLASSIFICATION PROCESS (EVALUATION OF AUTOMATIC CLASS III DESIGNATION)

- The de novo guidance covers the process for the submission and review of a de novo request.
- Provides updated recommendations (from the previous draft de novo guidance) for interactions with FDA related to the de novo process, including what information should be submitted in a de novo.
- Describes two mechanisms for FDA/sponsors interactions:
  - Pre-Sub: FDA can provide feedback on whether de novo is the appropriate regulatory pathway; provide recommendations regarding the data necessary to support the submission; and likely regulatory controls.
  - De Novo: A de novo may be submitted with or without a preceding 510(k). Sponsor should research potential predicates, identify risks and special controls, and define and collect adequate data to provide reasonable assurance of safety and effectiveness.
- Includes recommended content and questions relevant for a de novo pre-sub as well as the suggested content of a de novo.
- Includes a detailed flow chart outlining the de novo process.

RECENT PERFORMANCE AS A RESULT OF DE NOVO MODIFICATIONS

De Novo Petitions Received		
timeframe	*type*	#
FY 2010	Post-NSE	24
FY 2011	Post-NSE	20
July 9, 2012 – June 26, 2014	Direct	58
	Post-NSE	25
	Total	83

Average Review Time*			
timeframe	*type*	*average # of days to decision^*	#
FY 2010	Post-NSE	673	22
FY 2011	Post-NSE	486	20
July 9, 2012 – June 26, 2014	Direct	166	34
	Post-NSE	190	20
*total time (FDA time + industry/hold time) ^statute requires decision in 120 days			

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.

Categories of Health IT Functionality

Administrative Functionality*	Health Management Functionality*	Medical Device Functionality*
• Admissions • Billing and claims processing • Practice and inventory management • Scheduling • General purpose communications • Analysis of historical claims data • Determination of health benefit eligibility • Reporting communicable diseases • Reporting on quality	• Health information and data management • Data capture and encounter documentation • Electronic access to clinical results • Most clinical decision support • Medication management • Electronic communication (e.g. provider-patient, provider-provider, etc.) • Provider order entry • Knowledge management • Patient ID and matching	• Computer aided detection software • Remote display or notification of real-time alarms from bedside monitors • Radiation treatment therapy planning software • Arrhythmia detection * Examples provided. Not intended to be an exhaustive list of functionalities.
No Additional Oversight	Primary Focus of Proposed Health IT Framework	Primarily FDA Oversight

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Strategy and Recommendations for Health Management Health IT Framework

Promote the Use of Quality Management Principles

Identify, Develop, and Adopt Standards and Best Practices

Leverage Conformity Assessment Tools

Create an Environment of Learning and Continual Improvement

Health IT Safety Center

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

THANK YOU