FDA Oversight of Laboratory Information Systems

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Medical Device

201(h) of the Federal Food Drug & Cosmetic (FD&C) Act

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: …"

Laboratory Information Systems

PART 862 -- CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Subpart C--Clinical Laboratory Instruments Sec. 862.2100

Calculator/data processing module for clinical use.

(a)Identification. A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

(b)Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

Medical Device Data Systems (MDDS)

- Propose Rule FR?
  - The electronic transfer or exchange of medical device data
  - The electronic storage and retrieval of medical device data
  - The electronic display of medical device data
  - The electronic conversion of medical device data from one format to another
- Class I, exempt from pre-market review

MEDICAL DEVICE AMENDMENTS OF 1976

- Regulation Is Risk Based
  - Class I – many exempt (some exceptions)
  - Class II – 510(k) reviews
  - Class III – PMA reviews

Postmarket Controls

- Compliance -- production safety
- Surveillance -- problem identification and correction

General Controls

- Register and list
- Follow good manufacturing practices
- Report device failures
- Inventory of tests on the market
- Tools to require good manufacturing practices
- System for remedying device failures

Quality System Regulations

- GMP regulations revised in 1994
- Based on European ISO model
- Administrative program unchanged
- Administrative program more rigorous

Quality System Regulations

- Independent quality assurance function
- Controlled environment
- Controlled processes
- Trained personnel

Quality System Regulations

- Design Controls
- Design quality in
- Define inputs
- Define outputs

Quality System Regulations

- Verification
- Validation
- Corrective action and prevention programs (CAPA)

Quality System Regulations

- Modern approach toward quality
- Harmonized approach toward quality
- Nidus of new inspectional systems

Requirements for Software Devices

- Software Requirements Specifications (SRS)
- Architecture Design Chart
- Software Design Specification (SDS)
- Traceability Analysis
- Hazard Analysis
- Verification and Validation Documentation
- Revision Level History
- Records of Unresolved Anomalies (Bugs or Defects)

Guidance List

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm)
- Off-The-Shelf Software Use in Medical Devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm)
- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm)

Medical Device Reporting

- Mandatory reporting manufacturers
- Mandatory reporting user facilities
- Voluntary reporting