FDA CDRH Informatics Update

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About CDHR Informatics Staff

• Small Team; Formally Initiated 5/2010
  – Latousha Leslie, Nurse Informaticist

• Identify *Informatics* role as part of “Information” team
  – Agency Information Management and Data Standards Council
  – CDRH Information Technology Group
  – CDRH Information Analysts
  – Data Sharing Partners/Regulated Entities
Health Informatics

- For CDRH
  - Data Standards
    - Data Exchange
    - Data Format
    - Terminology
- Vision of Health Informatics
  - Facilitate sharing and aggregating of data across device total product life cycle and with other stakeholders. Result is improved data quality – foundation for effective analysis.
CDRH Activities to Meet Goals

- Coordinate with Agency and Center Initiatives
- Collaborate with Data Sharing Partners - Regulated Industry, Healthcare facilities, AHRQ, CDC, and other Federal Health Architecture Members
- Standards Development – HL7, ISO, IEEE, AAMI, GMDN, SNOMED
- Apply Standards to CDRH Initiatives (e.g. UDI, eMDR)
Examples of CDRH Informatics Projects

Standard Vocabularies

• Event Problem Codes – Fully Live 4/2/2010
• Evaluation Codes
• Product Dictionary – Unique Device Identifier (UDI) + Global Medical Device Nomenclature (GMDN) + Procode + Other Attributes
Examples of CDRH Informatics Projects

Data Standards

- Supported by FDA Data Standards Council
  - HL7
    - **Study Data**
    - Clinical Trial meta-data: Clinical Trials Registration and Results (CTR&R)
    - Structured Documentation: CDA (Clinical Document Architecture)
    - Adverse Event Reporting: Individual Case Safety Report (ICSR)
    - UDI - Product Information + Content of Labeling Structure Product Labeling (SPL)
UDI: Important for Informatics Efforts

Using **UDI** as source of Product Information:
- Improves ability to link internal CDRH databases
  - Greater level of specificity in postmarket oversight
    - Facilitates analysis of AE Reports
    - Improves effectiveness of device recalls

EHR and Supply chain adoption of UDI:
- Allows CDRH to use EHR as a rich data source for device-specific safety surveillance/observational study
  - **Level of detail - device data to pull from EHR?**
  - **Best method**
UDI Update

- Finalizing Proposed Rule
- Working on requirements for development of a UDI Database
  - Pilots
  - Collaboration with CDRH IT
- Establishing Internal Team to include IT and Business
GHTF Attributes

• Device Identifier – base + higher levels
• Manufacturer Name (on label)
• Manufacturer Address
• Contact Information
• Nomenclature code and term (GMDN)
• Trade Name (Brand Name)
• Device Model Number
• Controlled by – serial, lot, exp date, mfr date
• Size
• Short Product Description
• Storage and Handling Conditions
• Labeled as Single Use
• Sterility
• Labeled as containing latex
GHTF Attributes (cont’d)

- Authorised Representatives (OOUS)
- Licensing Number (OOUS)
- URL for Additional Information
- Critical Warnings or Contraindications
• **Objective:**
  – Determine the risks and benefits that result when the reporting requirements change from a reliance on manual data entry after an event to real-time, automated data capture, storage, and transmission using standard vocabularies and open data transmission methods.
Member of ASTER-D Project on IHE PCD group
– Created a Scenario Use Case for capturing AE
Questions?