UDI – Getting Ready

- UDI System
- Remembering the Goals
- Preparing Healthcare Users
- UDI System Implementation
UDI System

- UDI Code
- UDI Mark
- UDI Database
UDI System

• UDI Code
  – Device
    • Company prefix
    • Product number
    • Package indicator
  – Production
    • Serial Number
    • Lot
    • Expiration, Manufactured Date
UDI System

- **UDI Mark**
  - Placement
    - Package or Devices
    - Package Level
    - Limited Real Estate
  - Machine Readable
    - Symbology
  - Human Readable
UDI System

- **UDI Database**
  - Data Elements Library
    - Core Elements
    - Device Variable Elements
    - Relational Elements
    - Regional Elements
UDI System

• **UDI Database** - continued
  – Ownership
  – Governance
  – Validation
  – Access
Remembering Goals

- FDA Amendments Act of 2007
- Patient Safety
  - Adverse Event Reporting
  - Recall Tracking
- Global Harmonization
  - One UDI used worldwide
  - Core Database Elements
  - Regional Flexibility
Preparing Users

- FDA
  - OSB, ODE, OC, OAA (FURLS)
- Other US Agencies
- Other Regional Regulatory Agencies
- Healthcare Providers
- Manufacturers
- Purchasing Organizations
Preparing Users

- Healthcare Providers
  - Hardware
  - System Integration
  - Adverse Event Reporting
  - Recall Tracking
  - Inventory Management
UDI Implementation

- Manufacturers
  - Quality Management System Integration
  - Marking
  - Database Entry
Thank you!

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