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Advanced Medical Technology Association

U D I ...  
**Getting Ready**

Jeffrey Secunda  
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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

# UDI – Getting Ready



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

# UDI System



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- **UDI Code**
- **UDI Mark**
- **UDI Database**



- **UDI Code**
  - Device
    - Company prefix
    - Product number
    - Package indicator
  - Production
    - Serial Number
    - Lot
    - Expiration, Manufactured Date



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



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

# UDI System



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- **UDI Database - continued**
  - Ownership
  - Governance
  - Validation
  - Access

# Remembering Goals



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- 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



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

# Preparing Users



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

# UDI Implementation



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- Manufacturers
  - Quality Management System Integration
  - Marking
  - Database Entry



***Thank you !***

***Jeffrey Secunda***

**Vice President, Technology & Regulatory Affairs**

**AdvaMed**

**701 Pennsylvania Ave. NW**

**Washington, DC 20004**

**+1-202-434-7224**

**+1-202-783-8750 fax**

**[jsecunda@advamed.org](mailto:jsecunda@advamed.org)**

**[www.advamed.org](http://www.advamed.org)**