Unique Device Identification Update – FDA and GHTF

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UDI Can Improve… Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

Medical Device Identification

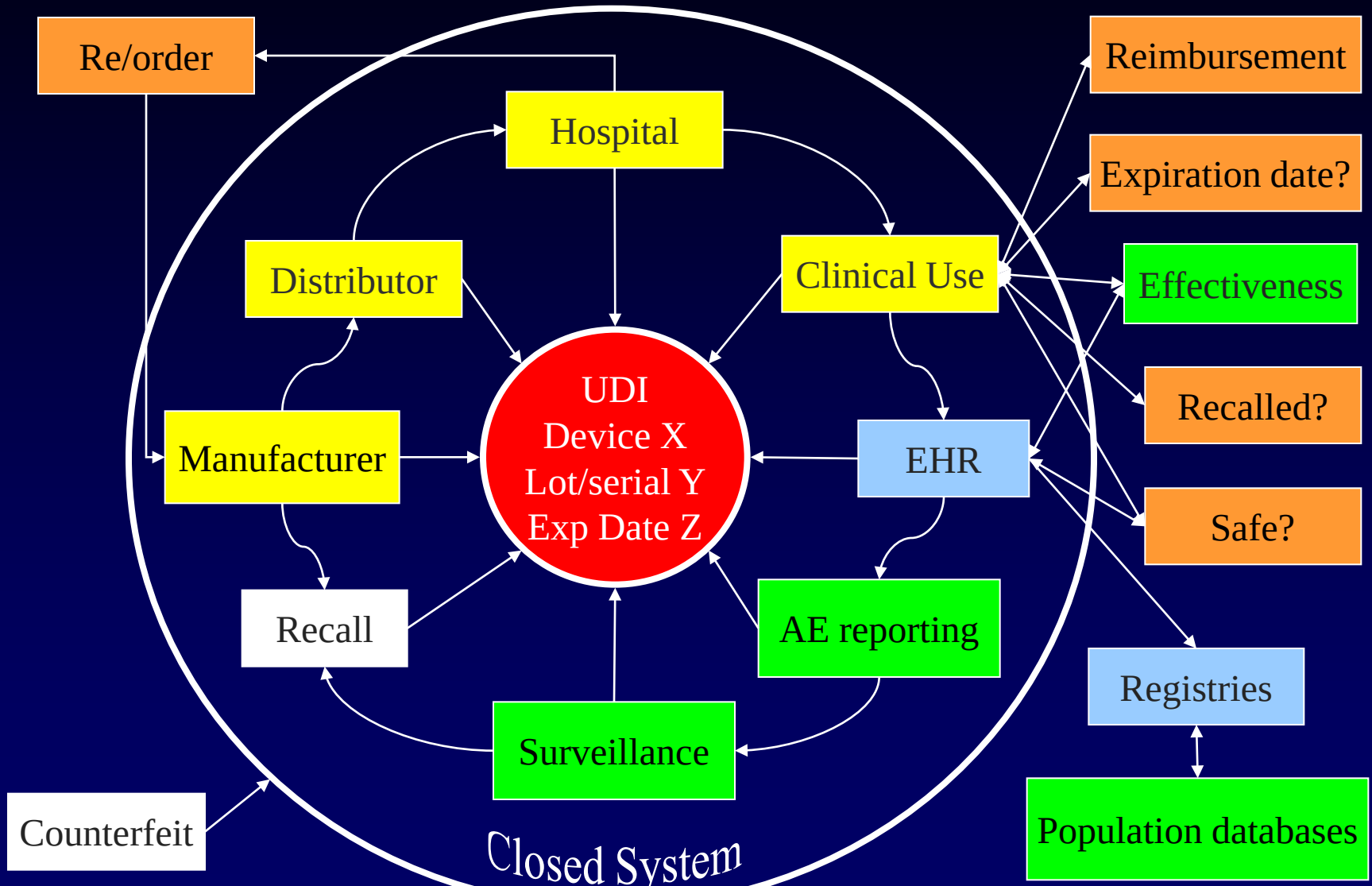
Develop a system to identify medical devices, which is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

And facilitates the:

- **Storage,**
- **Exchange, and**
- **Integration of data and systems**

Future Information Lifecycle



Balanced Approach

Specific

- Tell me how and when
- Select a UDI standard
- Select an auto-ID standard
- Describe application for every device
- Implementation
- Require participation

Flexible

- Allow SSOs/stakeholders to develop best approach
- Based on UDI Standards
- UDI Placement
- Various AIDC standards
- Use on different devices
- Application/integration
- Data attributes

Medical Devices Include…

A very wide range of medical products – such as:

- Traditional hospital based devices (beds, ventilator)
- Implants
- In vitro diagnostic devices (IVDs) – both clinical lab and Point of Care (POC).
- Health Information Technology (HIT) – e.g., EHRs
- Stand-alone software
- Convenience kits
- Combination products
- Used in alternative sites – e.g., homecare, dental

GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada
- AHWP recently joined (China)
- Public Document – available at: www.ghtf.org/documents/AHWG-PD1-N2R1.doc
- Washington April 2010; Brussels June 2010; Ottawa September 2010
- Final guidance submitted to Nov 2010 SC meeting
- 6 month comment period

FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

> The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation

1st – Developing the UDI

- Develop UDI code according to ISO 15459 [GS1, HIBCC]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date

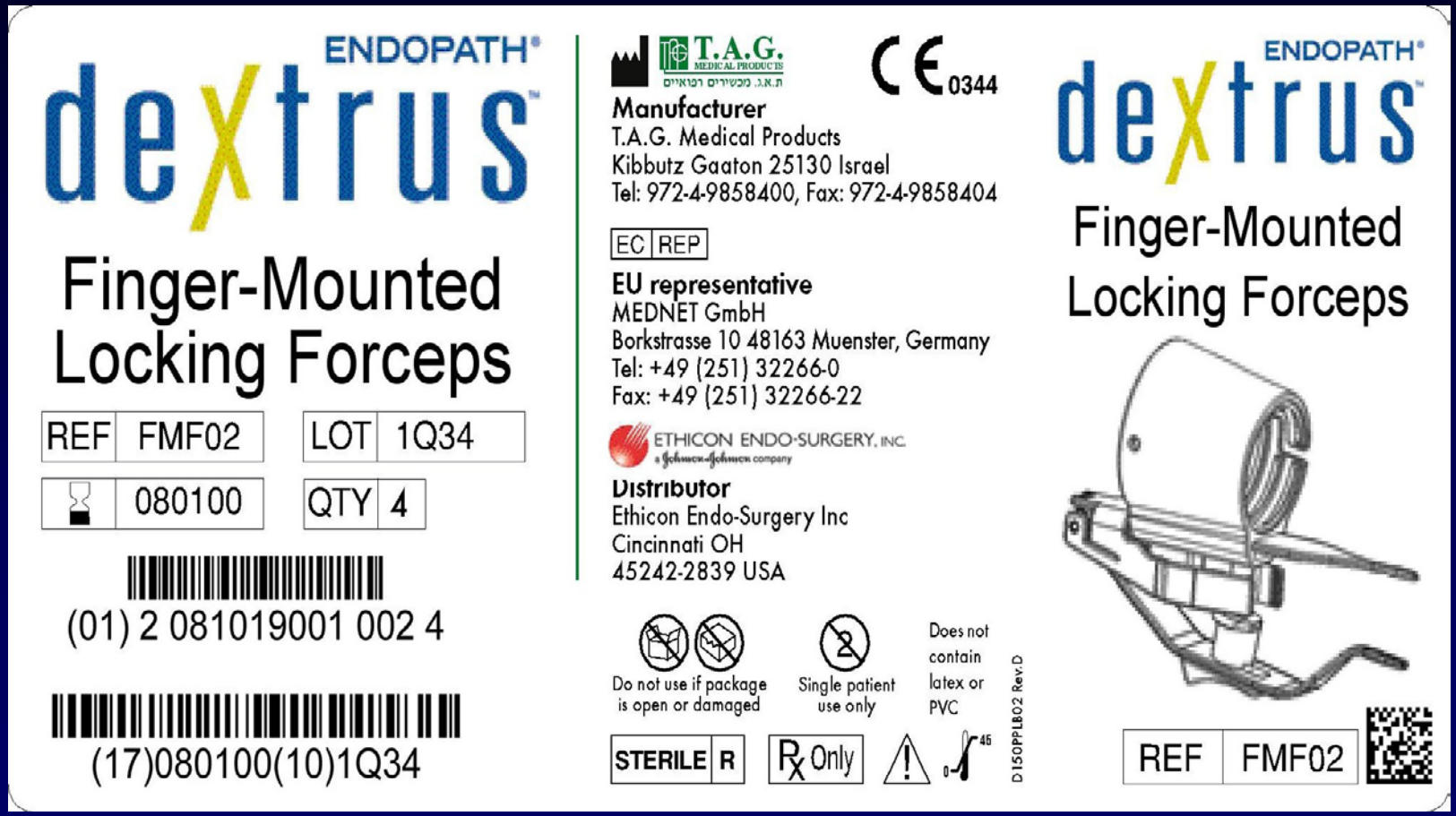
Risk-based Approach

- Production identifier reflects current control (label) – not requiring serialization.
- Granularity of marking based on risk of device - UDI for some devices on multi-packs or higher levels of packaging
- Not all devices require production identifiers
- Take into account realities of retail environment

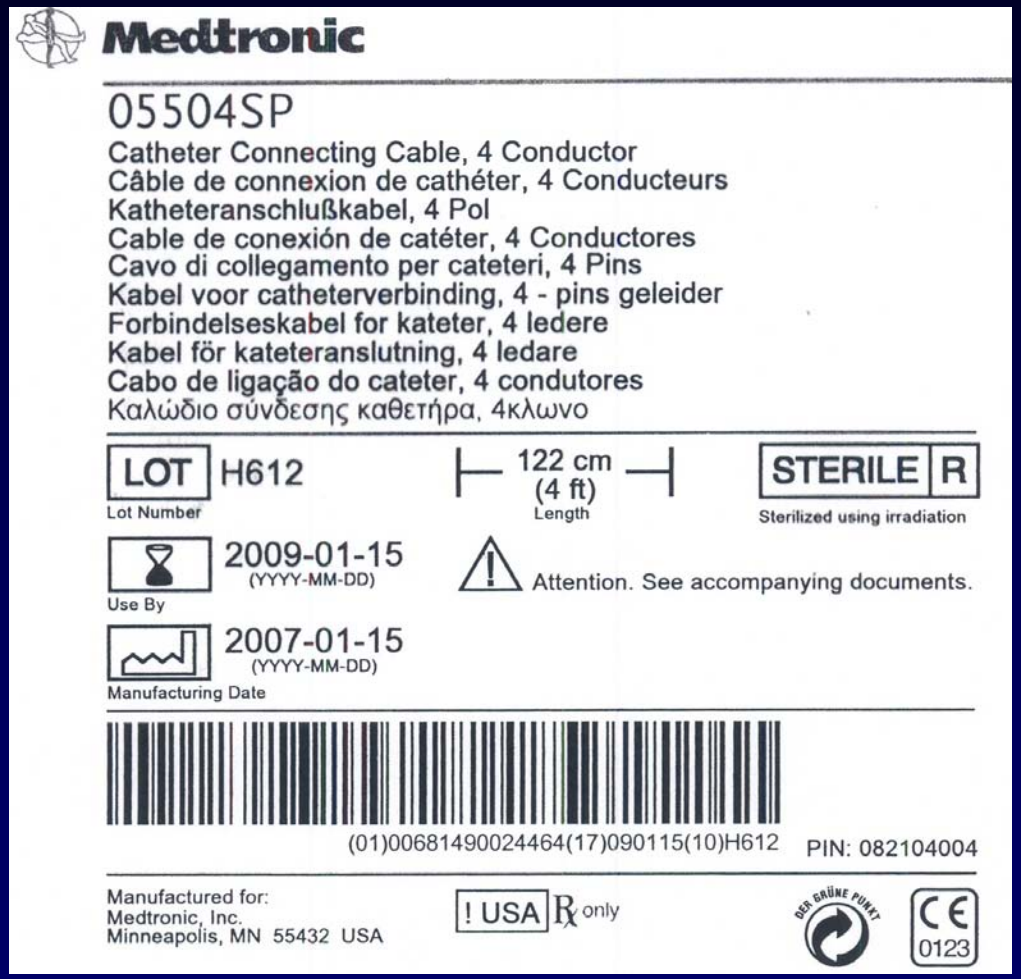
2nd – UDI Application

- Unique UDI applied to all levels of packaging, down to the lowest level (patient use/ unit of use)
- Human readable and/or encoded in a form of automatic identification technology
- Direct Part Marking (DPM) for some devices
- No specific technology would be identified (technology neutral)
- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)

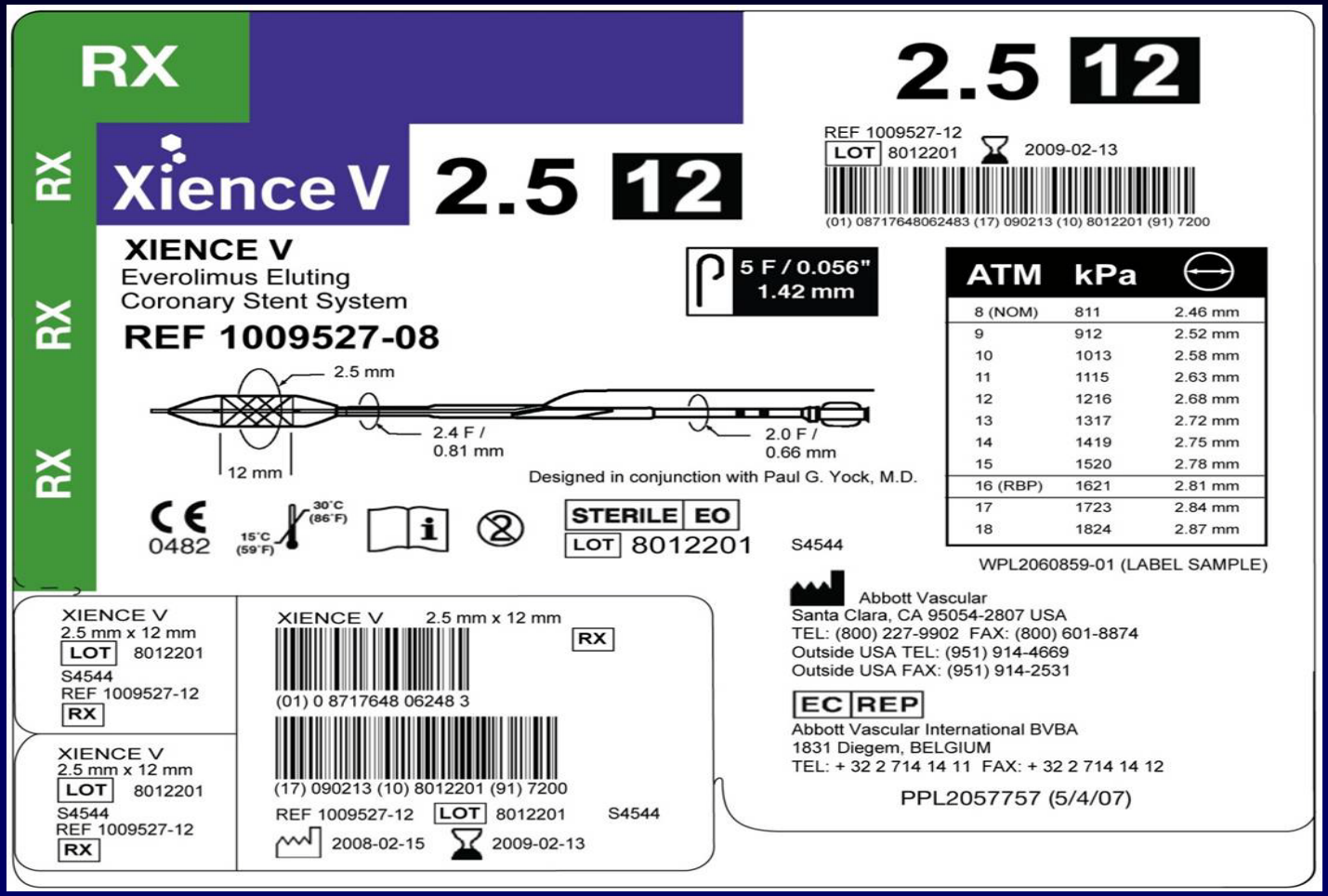
UDI Application Example



UDI Application Example



UDI Application Example



UDI Application - DPM

Where feasible – DPM required for:

- Reusable/re-sterilized devices
- Long-term implants
- Stand-alone software

Manufacturers can decide not technologically feasible.

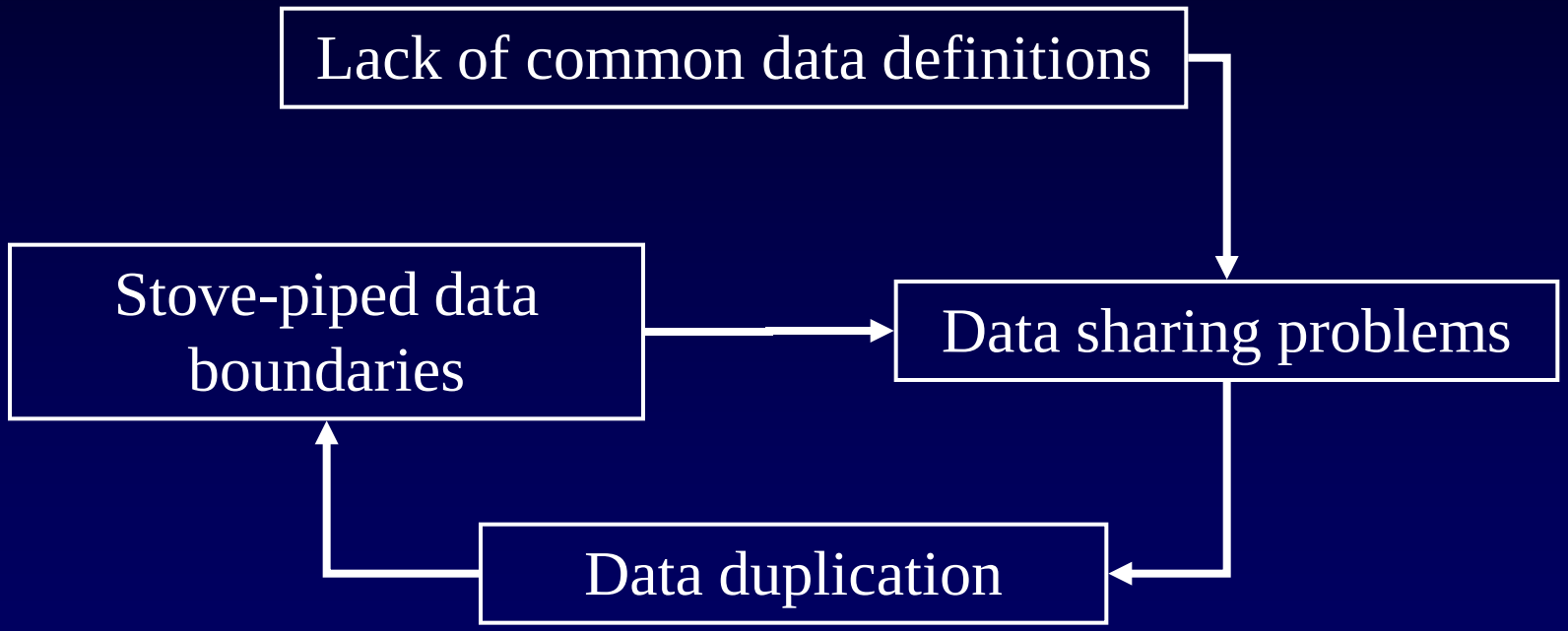
Combination Products and Kits

- Each combination product with device PMOA has its own UDI.
- Each kit (devices only) has its own UDI
- Each separable device constituent part of a combination product gets its own UDI.
- Each device in a kit gets its own UDI

3rd - UDI Database Development

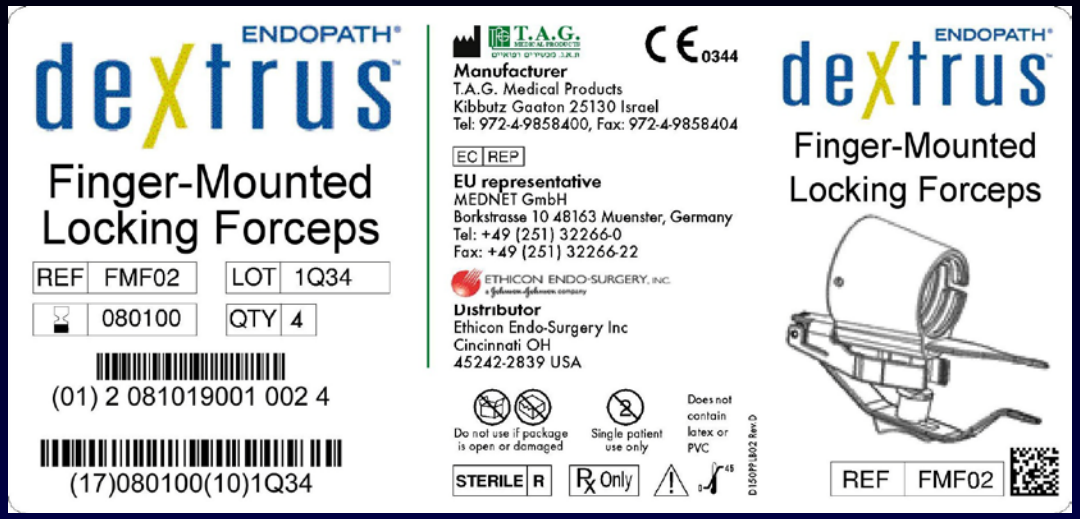
- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Size; Description
- Device model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility
- Contains known, labeled allergen (e.g., latex)
- FDA premarket authorization (510k, PMA)
- FDA Listing Number

Focus on Master Data



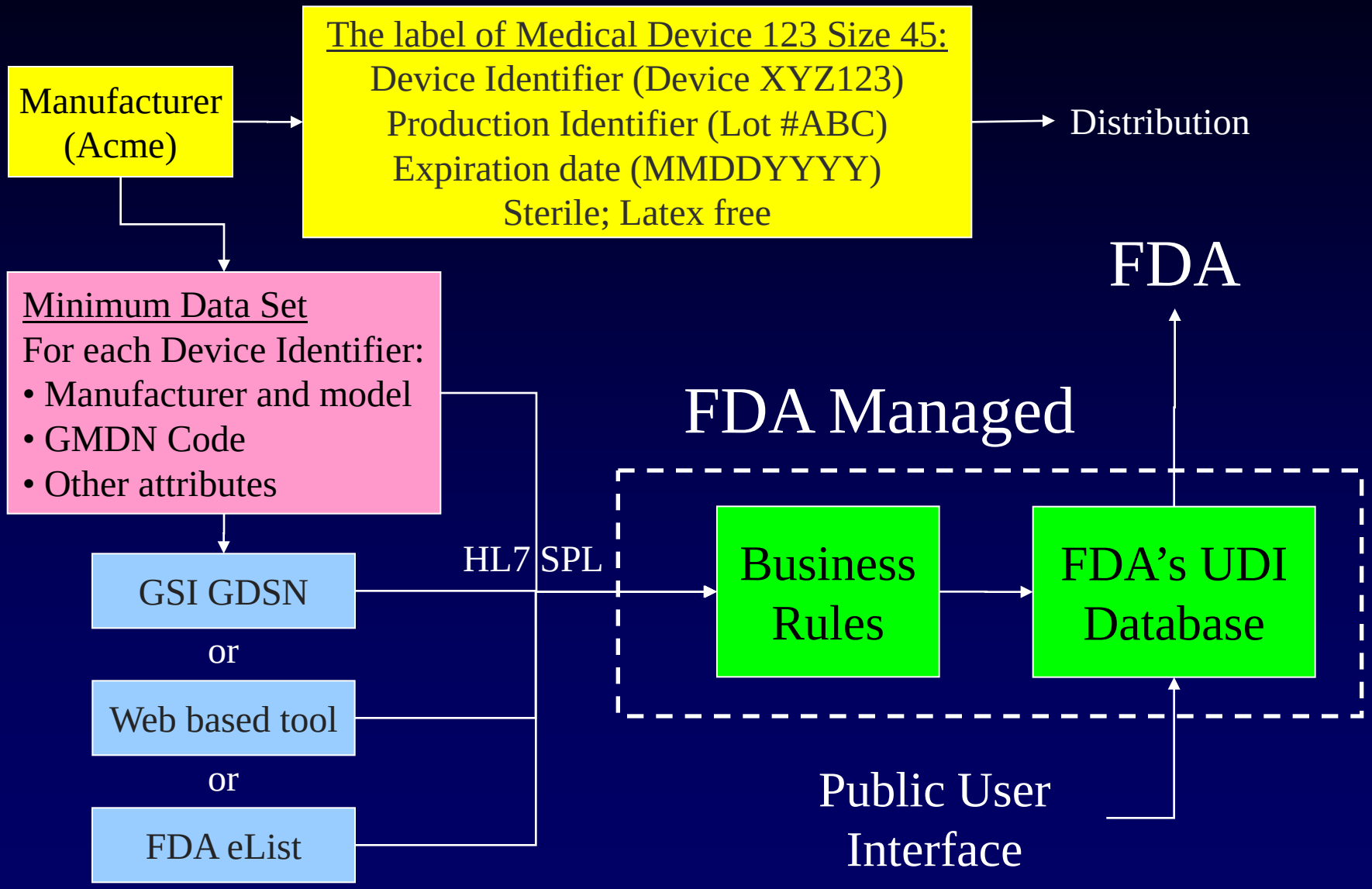
Focus on Master Data

- Agreed to, standard critical business data that can be shared across systems.
- Virtual or actual integration
- Policies and procedures for creation, access, update, and management of central resource.
- Emphasis on data quality, integration, single version of the truth, data stewardship.
- MDM is complementary to data warehousing and business intelligence



- Device Identifier: GS1 20810900100024
- Endopath Dextrus Finger Mounting Locking Forceps
- Ethicon Endo-Surgery Inc, Cincinnati, Ohio
- Jane Smith; 1-888-888-8888; JSmith@JNJ.com
- Controlled by Lot; Expiration Date
- Packaged sterile; Single Use; Prescription
- GMDN code: 12345; 510k: K982013
- Package of 1; Storage conditions: between 0-24º C
- Does not contain latex or PVC

FDA's UDI Database



Business Rules for UDID

- Identify base packaging
- Validate that all of the DIs are unique
- Validate that all required fields are appropriately complete
- Check that the listing number is valid
- If changes to any attribute, require new DI
- Check for appropriate groupings of higher-levels of packaging

Implementation

- Based on premarket risk class:
  - class III – 12 months after final rule
  - class II – 36 months after final rule
  - class I – 60 months after final rule
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process
- Expect manufacturers and groups of manufacturers to submit requests – results of which will posted.

HL7 SPL

- Working with HL7 SPL r5 Team to model UDI GHTF data elements
- Definitions
- Representation of Various Product combinations
- Identifying a Product without packaging
- Defining System requirements for UDID and internal FDA Product Information Database
- Accept , Store and Transmit HL7 SPL message

GMDN

- Development of global nomenclature to support regulatory and research activities.
- Preferred terms provide high degree of specificity
- Used for signal detection and device comparisons during data surveillance and analyses
- New governance model and activities in place
- Sustainable funding model under development
- Used with UDI/UDID to provide multiple levels of use (general → specific)

4th – Adoption and Implementation

- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EHRs – and use of EHRs for registries and other postmarket activities

Limitations of UDI and UDID

- UDI is a foundational element – it unambiguously identifies a specific device (at its unit of use).
- Benefits accrue only if used by all stakeholders.
- UDID contains only “static” identifying and product information.
- UDID does NOT contain production information, such as lot or serial numbers – and is NOT track/trace or other similar purposes requiring the full UDI.
- UDID provides link to product information- not a replacement for Recalls/Adverse Event Databases.

Unique Device Identification

www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
UniqueDeviceIdentifiers

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