Medical Device UDI Compliance

PDA Midwest – January 27, 2020

Today's Conversation

- What is a Medical Device?
- Intro to UDI
  - UDI Basics
  - Format
  - Timing
  - Solutions
- Use Cases
- Discussion

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Q&A – Pigeonhole

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PDAMW

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Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:

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

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and
- which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

Unique Device Identification System

- The US FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.
- The label of devices will include a **unique device identifier** (UDI) in human- and machine-readable form, which will ultimately improve
  - Patient safety
  - Device postmarket surveillance
  - Medical device innovation.

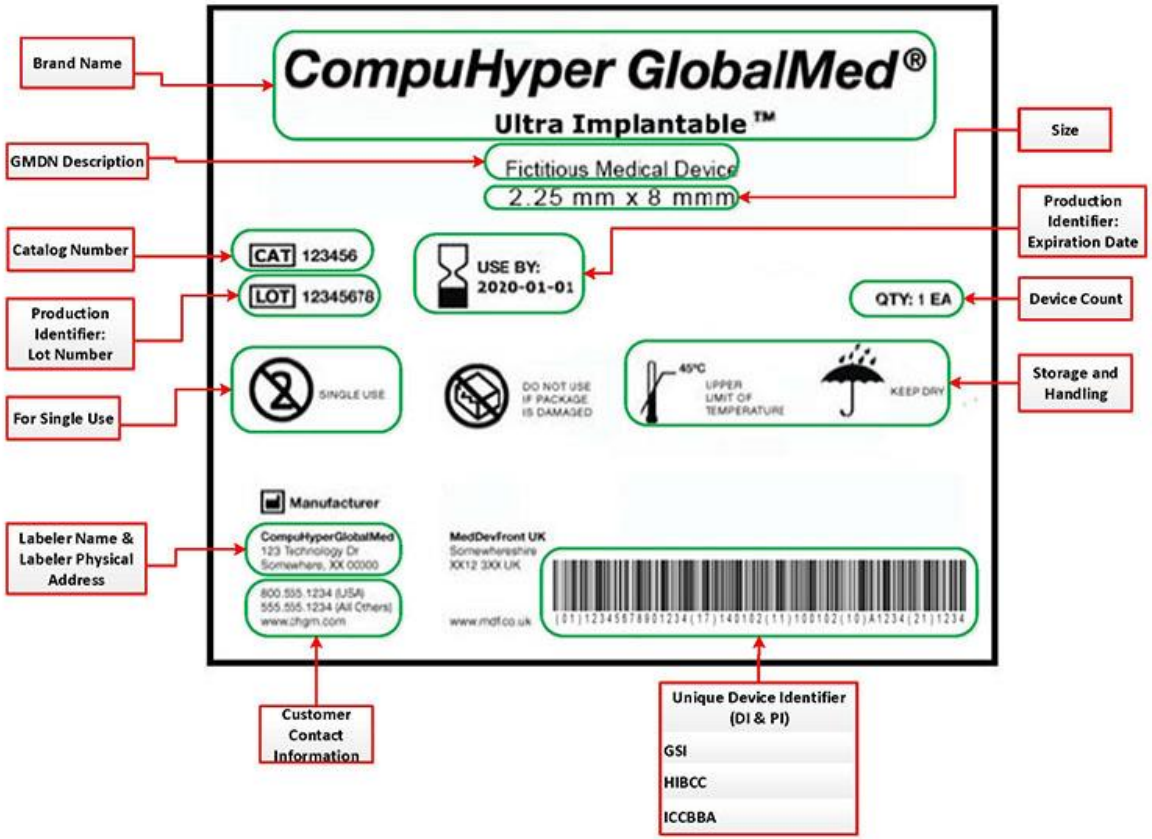
UDI Basics

- Include a unique device identifier (UDI), issued under an FDA-accredited issuing agency's UDI system, on device labels, device packages, and in some instances, directly on the device.
  - If a device is intended for *more than one use* and intended to be reprocessed before each use, the device labeler must also mark the UDI directly **on** the device.
- Submit device information to the Global Unique Device Identification Database (GUDID).

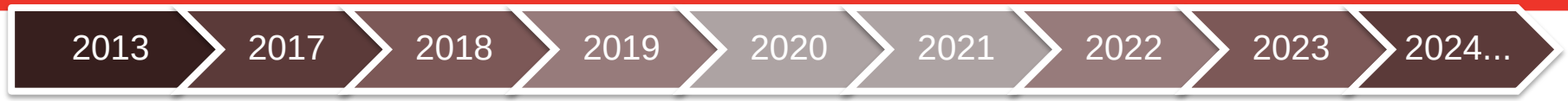
UDI Format

- **Device identifier (DI)**, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- **Production identifier (PI)**, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - Lot or batch number within which a device was manufactured
  - Serial number of a specific device
  - Expiration date of a specific device
  - Date a specific device was manufactured;
  - Distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Example Label



Global UDI Regulatory Landscape



US – 2013 Final FDA UDI Regulation

US – Sept 2019 Class II DM and Class I

EU – May 2020 MDR – EUDAMED go live

Ecuador - May 2021

S Korea – July 2021 Class 2

China – Jan 2021

India – 2022 Medical device regulation

Saudi Arabia - Feb 2022 Class B/C

EU – May 2023 MDR – Class II a/II b go live

Turkey follows EU MDR – May 2023 Class II a/II b go live

EU – May 2025 MDR – Class II a/II b Direct Marking

Turkey follows EU MDR – May 2025 Class II a/II b Direct Marking

Approved Legislation

Potential Legislation

Canada

Argentina

Australia - May 2023 Class II a and II b

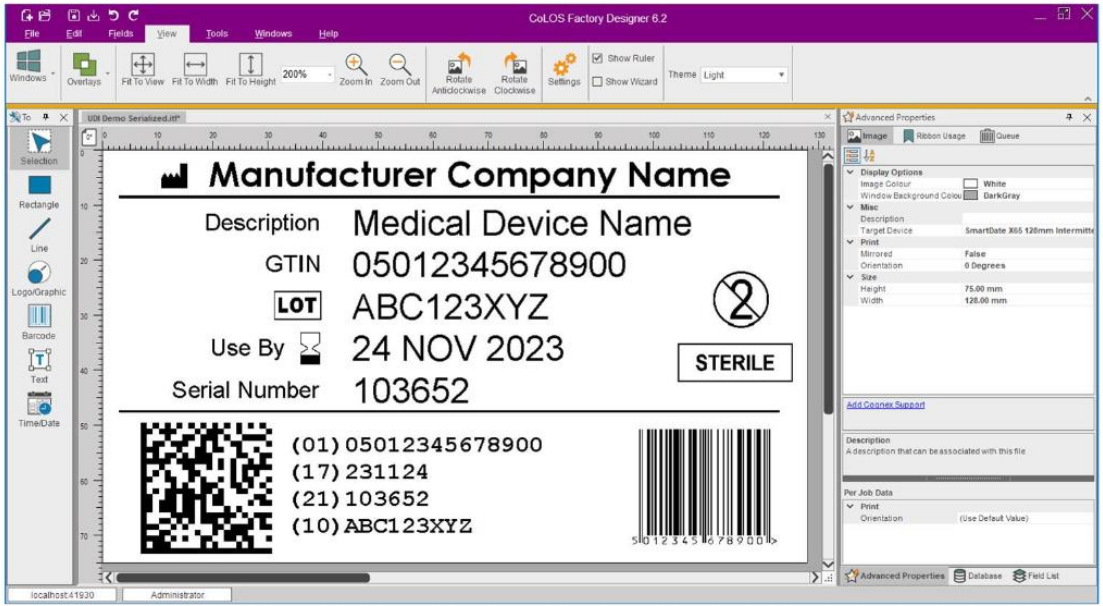
Taiwan – June 2023 Grade 2 medical devices

Colombia

Continuous monitoring of regulations is needed to ensure compliance for existing devices in the market and new devices that are launched.

COMPLY WITH UDI REGULATIONS

RELIABLE MARKING AND CODING TECHNOLOGIES TO ENSURE COMPLIANT PRODUCTS



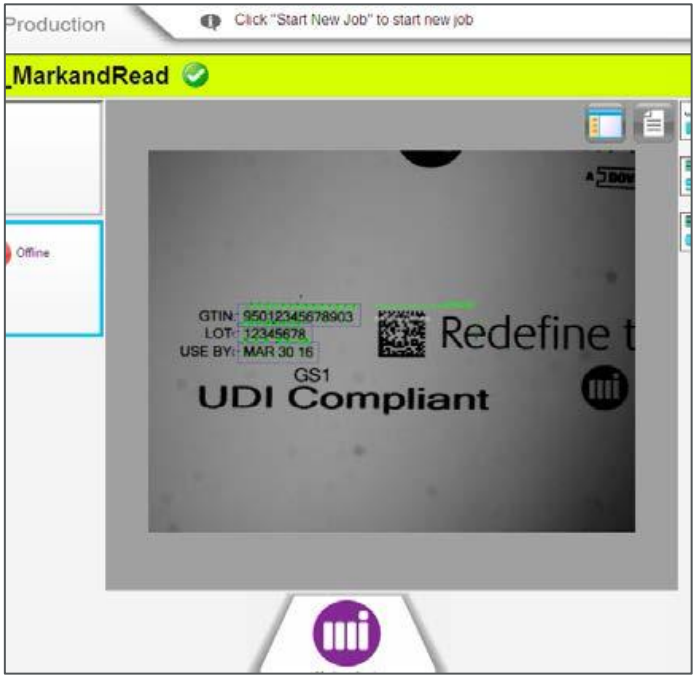
Systech design of a GS1 datamatrix UDI label

These regulations require manufacturers to print both unique ID and identifiers on their products or packaging in human readable and GS-1 barcode formats.

Whether it is directly on your product, bags, pouches, trays or cartons, we have the right technology to ensure your products comply.

PRINT SCANNABLE BARCODES

PRINT THE RIGHT MESSAGE ON THE RIGHT PACKAGE AT THE RIGHT TIME



OUR UDI SOLUTION SETS INCLUDE FULLY INTEGRATED PRINTER AND VISION SYSTEMS

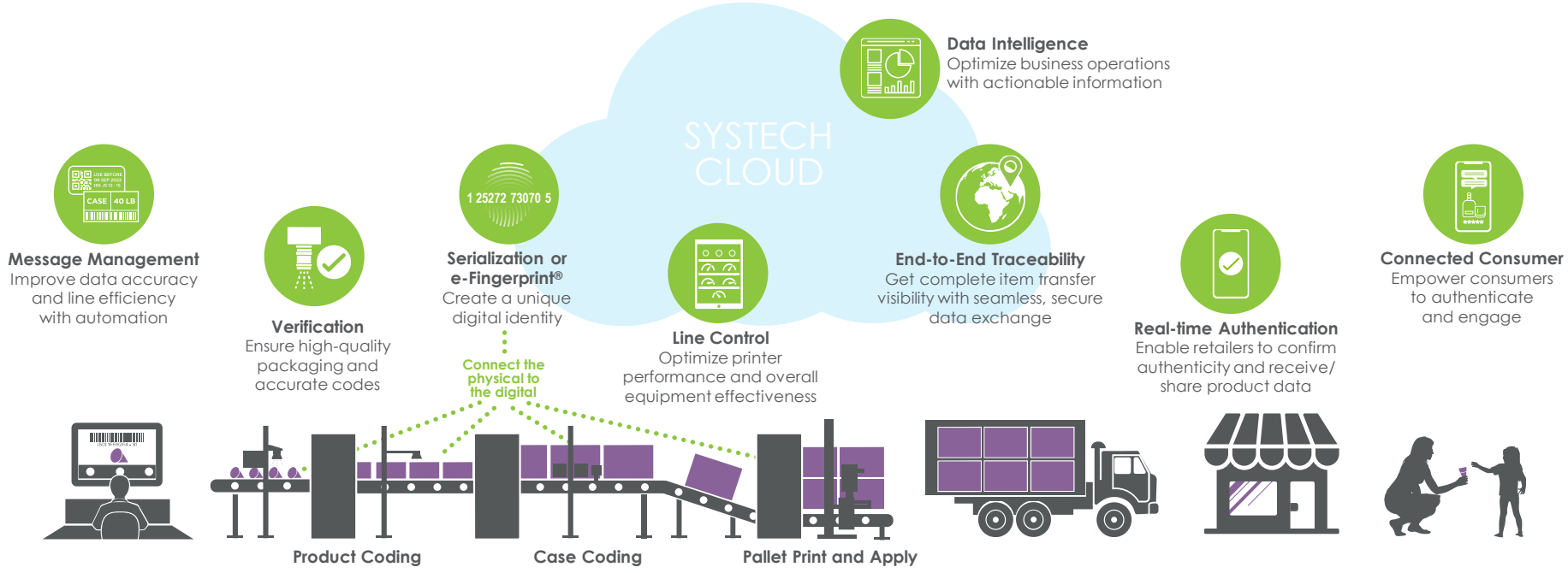
Our solutions include integrated scanner and vision systems to ensure that the right message gets on the right product, at the right time.

Both printer and vision configurations are stored on a single HMI- no need to manage separate pieces of equipment with multiple interfaces.

CONNECTED & SAFE Supply Chain

from packaging operations to the consumer's hands

SYSTECH
a solutions division of Markem-Imaje



Reduce Waste | Drive Efficiency | Achieve Compliance | Detect Threats | Engage Consumers | Gain Insight

Unique Device Identification
Case Studies

Lilly Devices in scope for UDI

HumatroPen

Luxura HD
and Luxura HD Sample

HumaPen Savvio

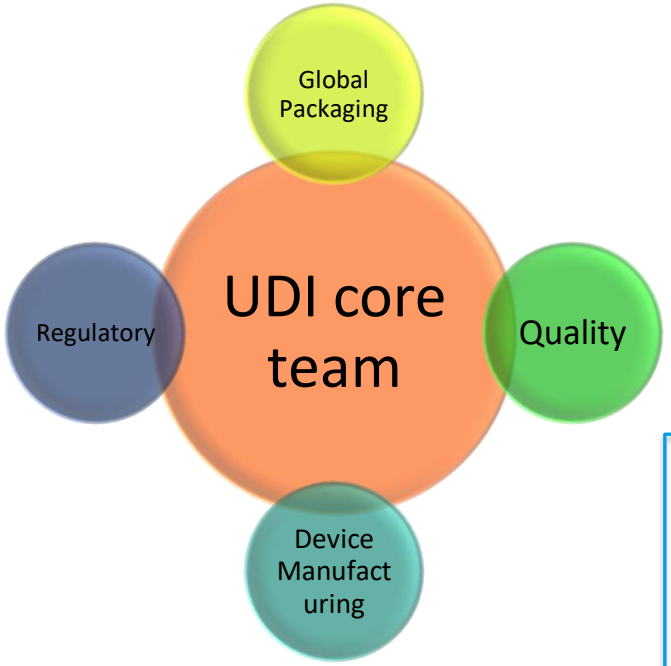
HumaPen Ergo II

Zyprexa Relprevv

Connected Care Device kits

Future launch

UDI Implementation



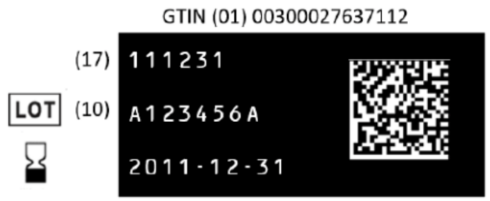
Implementation strategy

- Established a cross functional core team to analyze new regulations, interpret and document requirements and oversee the implementation.
- Perform technical impact analysis at the packaging site for each new regulation.
- Initiate artwork change – incorporate static information in the artwork such as Device Identifier (DI) portion of the UDI.
- Implement packaging line changes.
- Create UDI record in the national regulatory UDI database (GUDID, EUDAMED)

Lessons Learned

- UDI requirements are extremely cross functional. It involves regulatory, quality, packaging engineering, manufacturing, IT and supply chain organizations. Collaboration is key to success.
- Have global processes and procedures and governance structure. UDI is becoming a requirement in many countries.
- Benchmark to share learnings and best practices. Leverage external experts for complex device scenarios.

Examples for UDI on device packs



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Discussion