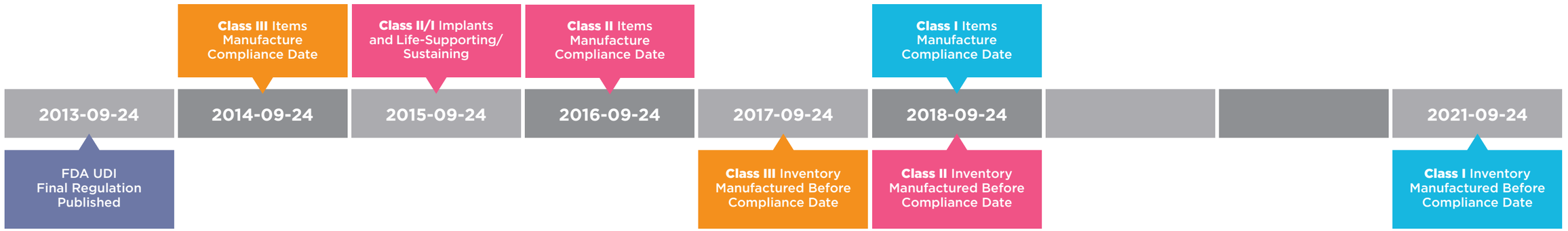
THE GLOBAL LANGUAGE OF BUSINESS

GS1 US FDA UDI RULE
QUICK GUIDE TO COMPLIANCE DATES

This poster is intended for use by hospital providers to anticipate total identification of medical devices and plan/budget for changes/upgrades to scanners, additional data fields, and functionality in material management and electronic health record systems for patient safety and supply chain efficiency.



U.S. FDA UDI

- The label* of EVERY medical device (including all In Vitro Diagnostics) must have a UDI
- EVERY device package (containing a fixed quantity of a version or model) must have a UDI
  - Any other approach is an exception or alternative from these requirements

*Section 201(k) "label" as a display of written, printed, or graphic matter upon the immediate container of any article.

WHAT IS A UDI?

- Identifier/code on device label and packaging (and, in some cases, on the device itself)
- **Two parts: UDI = DI + PI**
  - **Device Identifier** (DI) (static) specific to device version or model (GTIN®)
  - **Production Identifier(s)** (PI) (dynamic) one or more currently used control/production identifiers such as lot/batch number, serial number, manufacturing date, or expiration date (application identifiers)
    - If on the label, then needs to be included in the AIDC (Automatic Identification and Data Capture) technology
    - Does not require any changes to currently used PIs

COMPLIANCE DATES

Implementation (Compliance) Timeframes

- **2014:** Class III and devices licensed under Public Health Services Act
- **2015:** Class II/I implants and life-supporting/sustaining
- **2016:** Class II items
- **2018:** Class I and items that have not been assigned a class

For Direct Marking

- Compliance dates are extended by two years
- Except for Federal Drug and Administration Safety and Innovation Act (FDASIA) (Y2) devices—still 2015
- Direct marking only required for reusable devices that need to be "reprocessed" before reuse

Products & Inventories Existing Before Compliance Date

- Devices that are manufactured and labeled before their compliance date have an exception from the rule
  - The exception expires three years after the compliance date for that device
  - One year extension could be granted
  - Direct part marking compliance marks

WHY DO GTINS CHANGE?

The most common reasons for a GTIN to change are:

- Change in the specifications, performance, size, or composition of the device to an extent greater than the specified limits ***(this includes the package itself)***
- Change in quantity of a device package or addition of a new device package
- Change from a non-sterile package to a sterile package, or from a sterile package to a non-sterile package
- Re-labeling of the original labeler's device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark
- Change to outside package dimensions

NOTES & TOOLS

Information on U.S. FDA UDI Regulation

- www.fda.gov

Reference Tools

- *GS1 General Specifications*
- GS1 Healthcare GTIN Allocation Rules
- Healthcare Provider & Supplier GTIN Tool Kits
- www.gs1us.org/hcudi

Disclaimer

This document is intended to demonstrate the use of GS1 Standards for UDI. It does not provide any guidance or advice regarding regulatory compliance. Please consult your internal regulatory staff for compliance questions.

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